PHD

An Investigation of Errors in the Preparation of Injectable Medicines in the Pharmacy Environment and On Hospital Wards

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Submitted to the University of Bath in accordance of the requirements of the degree of Doctor of Philosophy

Presented by

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Copyright declaration

Signed: Abdulaziz Mohammed Ibrahim Almatroudi March 2018

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Abstract

Introduction: The preparation of injectable medicines involves a sequence of several phases, and an error at any stage of the preparation process could cause potential or actual danger to the patient. Few investigative studies have collected data concerning the incidence, type, severity and contributory factors associated with errors in the preparation of injectable medicines in pharmacy aseptic units and on hospital wards.

Aims: To determine the incidence, types and severity of errors arising during the preparation of injectable medicines within the pharmacy environment and in clinical areas of hospital across the UK; to explore pharmacy staff and nurses' opinions of the factors contributing to preparation errors; and to propose strategies to reduce these errors.

Methods: A mixed methods approach was used, comprising three stages. Stage one: direct observation of the preparation of injectable medicine in three pharmacy aseptic units (two were licensed and one unlicensed) and four hospital wards. Data were then analysed using descriptive statistics (One-way ANOVA test) to compare the findings. Stage two: a self-completion questionnaire was distributed to a panel of two consultant physicians, two senior pharmacists and one senior nurse. Each respondent was provided with a description of the errors previously observed in stage one and asked to independently score the severity of each on a scale from 0 (no harm) to 10 (death). Mean severity scores were mapped to consequence descriptors as follows: mean severity scores of <0.5 = negligible; 0.5-3.5 = minor; 3.5-6.5 = moderate; 6.5-9.5 = major; and >9.5 = catastrophic. Each of these consequence descriptors was then associated with a consequence score ranging from 1 (negligible) to 5 (catastrophic). The error frequency data was mapped to the NPSA likelihood grades (1 to 5) using the NPSA timeframe descriptors of frequency. A risk score was calculated for each of the types of medication errors observed, and the consequence score multiplied by the likelihood score. Stage three: semi-structured interviews (Face to Face) were undertaken to explore the opinions of pharmacy staff and nurses concerning factors contributing to injectable medicines preparation errors in pharmacy aseptic units and hospital wards. A questionnaire survey was also distributed to nursing staff working on the four hospital wards to confirm their perceptions regarding the factors contributing to injectable medicines preparation errors. A thematic analysis was then applied to the qualitative data, employing the theoretical framework outlined in Reason's (1990) accident causation model.

Results: The overall error rate for internal errors for the three different pharmacy units was 4.6% and the external error was 0.09% in the large licensed unit (A). Wrong batch numbers for starting materials on the worksheets and wrong doses were the most common errors noted. Failure to record syringe volumes on the worksheet was also commonplace at the unlicensed unit (C). The majority of these errors were judged to have a minor to moderate severity. However, after taking likelihood into account and calculating the risk score, two types of errors were graded as extreme risk, and seven types of errors were graded as high risk. Lack of staff experience, lack of training, use of look-alike/sound-

alike medicines, loss of concentration and distractions/interruptions inside the units were the factors most likely to result in an error. Poor layout of storage areas was stated as factor at the large licensed unit (A). Poor design of pharmacy computer systems was specified as a factor at the small licensed unit (B), while the heavy workload and low number of staff were specified as factors at the unlicensed unit (C). The following strategies were recommended in order of priority to minimise injectable medicines preparation errors in the three different pharmacy aseptic units: (1) effective use of computer alert systems (unit (A) & (B)); (2) improving the systems supporting the management of safe medicines (unit A); and (3) additional training of pharmacy staff at the (unit C).

The overall rate of errors in the preparation of injectable medicines on the four wards was 32.4%. Disregard for a clean/uncluttered treatment room, breach of aseptic non-touch technique (ANTT), wrong addition/mixing of drug, unused gloves, and failing to double check the final product were the most common preparation errors at both hospitals. Faulty labelling and filter needles not being used as specified were common in one hospital (Wards (H) and (B)). Products being prepared in an unsuitable location (e.g. nursing station) was also common in one of these wards (Ward B). Disregard for a clean/uncluttered treatment room was specified as a factor at ward (S), while no double check for the final product was reported as factors at ward (C). The majority of the errors reported were ranked as of moderate to major severity for patients. However, after accounting for error frequency, twelve types of errors were graded as posing extreme risk. High workload with staff shortages, lack of knowledge or experience, lack of training, lack of concentration, forgetting to complete tasks, and distractions/ interruptions while in the IV treatment room were the most common contributory factors cited. Poor design/layout of the IV treatment room, lack of equipment and materials and lack of commitment or adherence to NHS Trust guidelines and policy processes were especially apparent on wards (H) and (B), while inadequate staff education were specified factors on wards (S) and (C). The following strategies were recommended in order of priority to minimise injectable medicines preparation errors in the four hospital wards: (1) improving training and education programmes (ward (S) and (C)); (2) preventing distractions/interruptions (ward (H) and (B)); (3) creating a commitment to guidelines and policies (ward (H) and (B)); (4) reporting and identifying errors (ward (H) and (B)); (5) systemising workflow (ward (C) and (B)); and (6) offering staff sufficient breaks during each shift (ward B).

Conclusion: This is one of the first empirical studies to explore preparation errors in injectable medicines at three different aseptic pharmacy units and four hospital wards. The aim and objectives of the research were achieved. The results confirm injectable medicines preparation errors are prevalent in pharmacy and hospital environments and may cause severe harm to patients. Future work is essential to implement the recommended strategies and evaluate their success in practice.

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List of Abbreviations

Medication Errors	MEs
National Health Service	NHS
World Health Service	WHO
Patient Safety	PS
Anesthesia Patient Safety Foundation	APSF
Institute of Medicine	IOM
Department of Health	DOH
National Patient Safety Agency	NPSA
Patient Safety Incident	PSI
National Reporting and Learning System	NRLS
NHS Commissioning Board	NHS CB
Canadian Patient Safety Institute	CPSI
National Patient Safety Foundation	NPSF
Institute for Health Improvement	IHI
Adverse Drug event	ADE
Adverse Drug Reaction’	ADR
Medication Incidents	MIs
Adverse Event	AE
Medication-Use Process	MUP
National Coordinating Council for Medication Error Reporting and Prevention	NCC MERP
Medicines Administration Errors	MAEs
Error-Producing Conditions	EPCs
Royal Collage of Nursing	RCN
Royal Pharmaceutical Society	RPS
Medicines Control Agency	MCA
Injectable preparation errors	IPEs
Medicines and Healthcare products Regulatory Agency	MHRA
Failure Mode and Effects Analysis	FNEA
Institute for Safe Medication Practices	ISMP
Total Parenteral Nutrition Preparation	TPN
Central IV Additive Services	CIVAS
Nursing and Midwifery Council	NMC

Chapter One

General Introduction

1.0 Introduction

1.1 Background

The detection and prevention of medication errors (MEs) has become important for all healthcare providers (Kohn et al., 1999). Based on the World Health Organization (WHO), the aim of healthcare is to improve quality of life while reducing and preventing MEs in pharmacy environments, hospital ward areas, and other departments (WHO, 2000). However, many errors arise in healthcare, both known and unknown (Santell, 2008). During patient management, the healthcare professionals must make sure that the needs of the treatment outweigh the risks (Bates, 2007). Risk has been described as:

> *"The probability or likelihood that harm may occur, coupled with the consequence of that harm"* (Burrows, 2004, p.10).

The concept of risk management was introduced into the National Health Service (NHS) in the early 1990s. Risk management is an overall process to determine, evaluate, and control error (Burrows, 2004). Clearly, errors are not easy to control or manage (Zhang et al, 2004). Furthermore, MEs have the potential to harm patients and may result in increased morbidity and mortality, and, in turn, higher hospital treatment costs (National Patient Safety Agency, 2015).

Patient safety (PS) is the basis for good quality patient care. This has been defined as:

> *"The prevention of errors and adverse effects to patients associated with health care"* (WHO, 2012, p. 1).
>
> And
>
> *"The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare"* (Vincent, 2010, p. 31).

Vincent (2010) reported that:

> *"**Patient safety** is the foundation of good patient care. The unnerving fact that healthcare can harm us as well as heal us is the reason for suggesting that patient safety is the heart of healthcare quality. Effectiveness, access to care, timeliness and the other dimensions of quality are all important. But when a member of your family goes into hospital or receives other healthcare then above all you want them to be safe. There is something horrifying about being harmed, or indeed causing harm, in an environment of care and trust. Both for patients and staff, safety is the emotional heart of healthcare quality. I also believe in terms of understanding, improvement and day-to-day running of healthcare that safety is a touchstone and guide to the care that is given to the patients; the clinician or the organization that keeps safety to the fore in the midst of the many other often competing priorities achieves something remarkable and provides the care that we would all want to receive"* (Vincent, 2010, p. ix).

Despite continuous improvements in health services, healthcare providers can represent a cause of harm to patients, mainly as an outcome of the latent risks associated with injectable drug preparation. In the past five decades, numerous studies have been published on healthcare-related harm. This has prompted further acknowledgement by governments and healthcare providers that PS in an issue that should be processed at both a national and global level.

1.2. Patient Safety and the provision of healthcare

1.2.1. Patient safety

The potential of medication to cause injury was established in 1930 when the term 'iatrogenic sickness' was first utilised, meaning 'illness caused by healthcare. In 1964, Schimmel published the first research on PS based on the incidence of complications arising at a single university medical service. The study sample was more than 1000 patients, and the results showed that 20% of patients had experienced at least one medical error, with 16 cases leading to fatality. In the pioneering Harvard Medical

Practice Study (Brennan et al, 1991) on PS, Brennan and colleagues found that errors in healthcare occurred in 4% of patients when they studied the records of over 30,100 patients admitted to 51 US hospitals in 1984. Of these, 28% of the errors were classified as having caused no harm, 3% of these mistakes led to significant harm (life threatening and serious injury), and around 14% led to patient death. In the following year, the Anesthesia Patient Safety Foundation (APSF) was established in the US with the specific focus of reducing the mortality and morbidity rate correlated with anaesthesia, given the common impression that anaesthesia itself caused significant mortality (APSF, 2010). A study by Wilson and colleagues (1995) analysed data from 14,179 patients at twenty-eight hospitals in Australia and reported that 16% (n = 2302/14,179) of patients had experienced errors in their care. However, 51% of these mistakes were assessed as having high preventability. Despite these studies, errors in healthcare were rarely considered within the field of therapeutic research until 1999, when the US Institute of Medicine (IOM) published the report 'To Err is Human: Building a Safer Health System' (Kohn et al., 2000). The report assessed the harm caused by mistakes in US healthcare and suggested strategies to increase PS (Kohn et al., 2000). The report also showed that between 44,000 and 98,000 people died annually in the US as an outcome of preventable mistakes in healthcare, and that these errors cost more than $27 billion (Kohn et al., 1999; Brennan et al., 1991; Thomas et al., 2000). PS has received increased attention since the publication of this significant report, (Knaus, 2002; Han et al., 2005; Crowley, 2006; Clancy, 2009; Ulrich & Kear, 2014; Ameer, 2015).

In 2000, the UK Department of Health (DOH) published the report An Organization with a Memory, which reflected the approach of 'To Err is Human'. The report summarised that errors in healthcare affected approximately 10% of patients, leading to approximately 400 deaths or incidents of major harm or 'life threatening, and serious

injury' every year. The report described how the capacity to learn from mistakes was inadequate in the UK healthcare system (DOH, 2000). The report encouraged investigators to assess errors in healthcare and classify the failures leading to patient harm (Fisher et al., 2015). Since the launch of the report, significant and necessary research has been undertaken to enhance PS across the NHS. The construction of a safer NHS for patients was initiated in 2001 by defining the responsibilities of healthcare staff and applying the recommendations in the DOH report (Carruthers and Philip, 2006). A significant suggestion was to support the development of local and national systems for monitoring and reporting errors in healthcare. This was to be developed and maintained by a separate independent agency, the National Patient Safety Agency (NPSA), which was established that same year (DOH, 2001).

PS is defined by the NPSA as:

> *"The identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimise harm to the patient"* (NPSA, 2004, p. 97).

A patient safety incident (PSI) is defined by the NPSA as:

> *"Any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving NHS-funded healthcare"* (NPSA, 2004.P.97*).*

The NPSA created a criteria categorisation system for PSI terminology depending on the type of errors and the severities occurred to the patient (Table 1.1).

Table 1.1: Patient Safety Incident classification terms (adapted from NPSA, 2004, p.97)

Previous terminology	New terminology and definition
Clinical risk	**Patient safety:** *"The identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimise harm to patients".*
Incident critical Incident medical error Clinical error medical Mistake sentinel event Adverse incident Adverse event clinical	**Patient safety incident:** *"Any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving NHS-funded healthcare".*
No harm event	**Patient safety incident (level of severity no harm):** **"***A patient safety incident that caused no harm but was not prevented ('impact not prevented') or a patient safety incident that was prevented".*
Near miss/close call	**Patient safety incident (prevented):** **"***Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to patients receiving healthcare".*

The objective of the NPSA was to improve health services and safeguard patients' health by identifying and evaluating errors (DOH, 2001), and publishing training programmes to prevent errors to patients (Smith, 2004). Central to the NPSA was the institution of a national system for collecting reports of patient safety incidents. Thus the National Reporting and Learning System (NRLS) database was established in England and Wales in 2003 and has been used to record PS incidents and identify specific areas where errors or near misses can occur (NPSA, 2003). The NPSA (2003) stated that a cultural change from blame to openness was essential to the effectiveness of error reporting. To further enhance PS, the NPSA developed a document entitled Seven Steps to Patient Safety to describe what NHS organisations should do to enhance patient safety. The key components (adapted from NPSA, 2003, p. 7) were as follows:

1. Building a culture of safety.

2. Guide and support all staff members.

3. Combine risk management activities.

4. Enhance reporting.

5. Engage and communicate with patients and the parents.

6. Study and share safety programmes.

7. Carry out solutions to avoid error.

In 2012, responsibility for PS was transferred from the NPSA to the NHS Commissioning Board (NHS CB, commonly known as NHS England) (NPSA, 2012). The NHS CB uses the NRLS database, considered the world's most comprehensive database of patient safety information, to classify and address important patient safety issues at their source (NPSA, 2012). Working across sectors, the NHS CB utilises PSI data to analyse risk, drive learning and improve patient safety (NPSA, 2012). Figure 1.1 shows data from a previous study on the 526,376 medication errors reported during 2005–2010, representing nearly 10% of all PSIs in that period (Cousins et al, 2012).

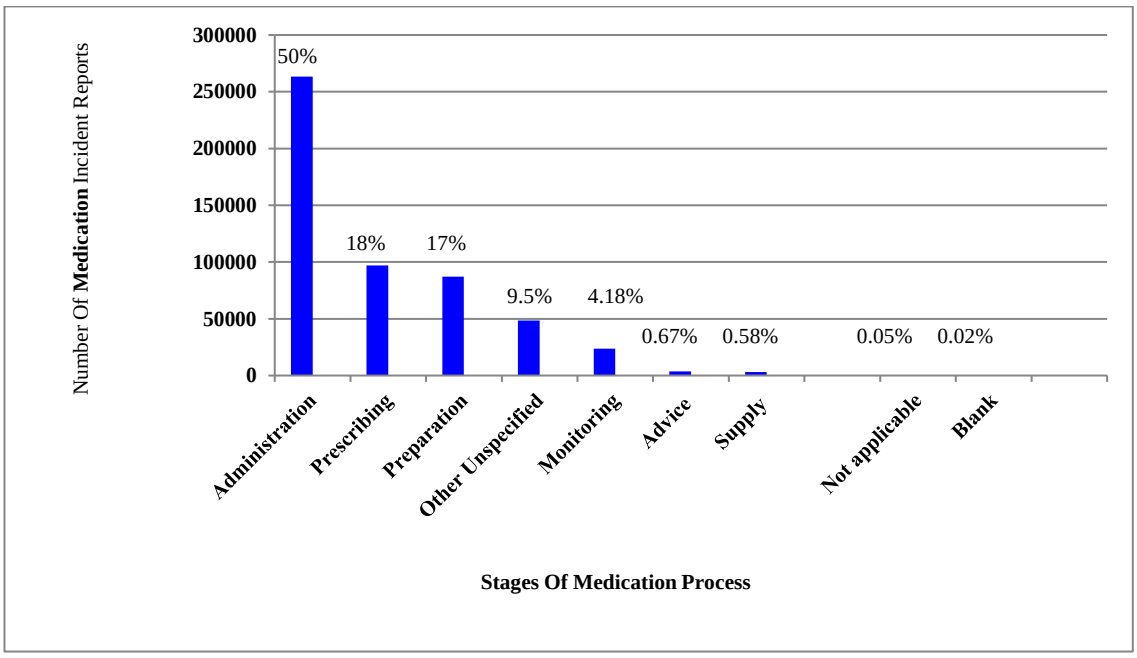


Figure 1.1: Medication incidents and the phases of the medication process between 1 Jan 2005 and 31 Dec 2010 (Cousins et al., 2012).

Healthcare organisations throughout the world now take PS very seriously, resulting in the establishment of special agencies for PS including the World Alliance for Patient Safety (WHO, 2009), the Canadian Patient Safety Institute (CPSI, 2015) and the National Patient Safety Foundation in the US (NPSF, 2015). The key purpose of these agencies is to minimise errors in the medical field by defining the contributing factors of such errors and then building strategies to prevent them from occurring again (WHO, 2009). These PS organisations have all contributed to the enhancement of PS. For example, the World Alliance for Patient Safety has published training programmes to improving PS in many countries focused on injectable medicines and guidance on the correct procedures for medication use (WHO, 2013). Terry and colleagues (2005) reported that, in the UK, the NPSA has contributed to improving PS by developing reporting systems to collect and analyse cases from staff and patients. The NPSA also has several resources and tools available to help NHS organisations make modifications to their working environments and safety procedures with the purpose of minimising errors in healthcare (NHS, 2009). Despite these interventions, latest reports show that PS remains a global problem, even in developed nations. In 2013, James showed that preventable PSIs were responsible for two million deaths globally and more than 200,000 cases of major harm per year in the United States (James, 2013). These numbers were depends on results from four studies using the Institute for Health Improvement (IHI) Global Trigger Tool for detecting patient safety incidents from hospital medical files (Griffin and Resar, 2009). A World Health Organization report on patient safety incidents among inpatients in the European Union (EU) found that more than 10% of admitted patients were influenced by patient safety incidents, and that 60% of these errors were preventable (WHO, 2013). Lastly, in the United Kingdom, a new report from the DOH and the Secretary of State for Health (2018)

reported that more than 237 million medication errors are made across the UK hospitals every year and caused the death of 22,000 patients. This research has stated that errors in healthcare are common and can be a significant factor leading to major harm to patients. Most healthcare errors are considered preventable. Clinical governance has been presented as a comprehensive strategy to process patient safety problems and develop the quality of healthcare at the individual and organisational levels (Scally and Donaldson, 1998).

1.2.2. Clinical governance

The concept of clinical governance is a framework for the NHS, which aims to enhance the quality of healthcare provided, and guarantee that a safe and appropriate expectation of care is delivered. Starey (2001) identified six components of clinical governance that can together provide high-quality healthcare (Figure 1.2).

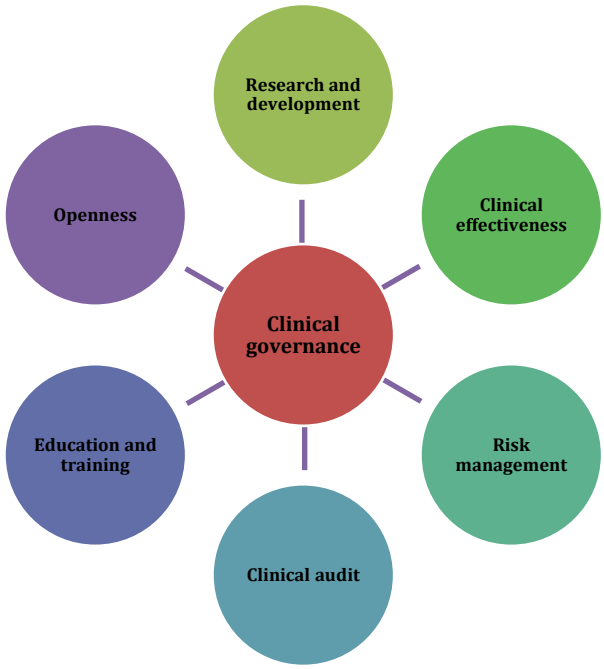


Figure 1.2. The components of clinical governance (Starey 2001, p. 2).

Dean (2000) stated that clinical governance is not a new idea; it integrates several quality factors that have been established for some time and increases the quality of healthcare provided to patients. In late 1997, the DOH published a report entitled "The new NHS: modern, dependable", which classified the basic procedures needed by organisations to ensure efficient clinical governance. These chief actions were as follows: procedures to ensure quality improvement, such as clinical audit, are in place; evaluation of risk management and implementation of risk reduction programmes; application of evidence-based practices; implementation of ongoing development programmes; development of leadership skills; and specified responsibilities at the level of clinical teams. The WHO and IOM have also suggested that risk management and ensuring safety are important factors in effective and high-quality healthcare (WHO, 1989; Institute for Safe Medication Practices, 2001). Hence, clinical risk management has been incorporated into healthcare to minimise the harm resulting from healthcare errors (Vincent and Moss, 1995).

1.3. Medication errors (MEs)

MEs alone, whether occurring inside or outside of the hospital or pharmacy environment, clearly cause death or severe harm to patients every year (Bateman & Donyai, 2010).

1.3.1. Differential terminology used for MEs

Diversity exists in the terminologies and definitions used to describe MEs (Allan & Barker, 1990; O'Shea, 1999; Crowley, 2006; Lisby et al. 2010; Kongkaew et al. 2013 Ameer, 2015). For instance, 'adverse drug event' (ADEs), 'adverse drug reaction' (ADRs), 'potential adverse drug events', 'medication incidents' (MIs) and 'medication

errors' (MEs) are all used to define issues associated with drug use (Australian Council for Safety and Quality in Health Care, 2002). Yu and colleagues (2005) reviewed more than 150 PS reports and identified over 23 different terms related to medication incidents and more than 117 different definitions. The term adverse event (AE) was the most commonly defined term, with twenty-one definitions, followed by error (thirteen definitions).

This variance in definitions is believed to be a key factor leading to the non-reporting of medication errors (Armitage & Knapman, 2003; Crowley, 2006; Ghaleb et al, 2010, Ameer, 2015). In addition, variable classifications and rates of errors make the evaluation of data between studies challenging or unacceptable (Bates, 1996; Caldwell et al., 2001; Ghaleb et al., 2010; Kongkaew et al., 2013). Furthermore, to develop effective strategies to reduce the incidence of medication errors and thus to mitigate their effects requires a method for reliable comparison of medication errors, which cannot be succeeded without a clear and agreed definition of medication error and associated terms (Yu et al. 2005; Ferner, 2009; Aronson, 2009).

1.3.2. Definition of medication errors (MEs)

In simple terms, a medication error is a mistake that happens at any point during the medicine process (Gandhi et al., 2000). In 1996, Bates reported that some definitions of medication error concentrated on the medication use process (MUP) and ignored errors in the prescribing stage (Bates, 1996). The author believes that this definition of medication errors was insufficient as prescribing errors are an important factor that can lead to serious injury or death. Crowley (2006) reported that most of the definitions of medication error concentrated on administration errors without including preparation

errors, and argued that this may lead to a lack of improvement in the healthcare provided to the patient. Several definitions of ME are used by organisations concerned with medication safety. Based on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), an ME is defined as:

> *"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care product, procedure, and system, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring and use"* (NCC MERP, 1998, p. 6).

In 2006, Ferner and colleague suggested a comprehensive definition of ME as

> *"A failure in the treatment process that leads to, or has the potential to lead to, harm to the patient"* (Ferner & Aronson, 2006, p. 1013).

Ferner and colleague described the management procedure as the procedure that starts after the decision to begin management and involves prescription, the assembly of starting materials, preparation, dispensing, administration, and monitoring, which is the last phase of management (Ferner & Aronson, 2006). This definition was found to be the most robust when examined against different scenarios of MEs (Yu et al., 2005). The NPSA definition of medication errors, which encompasses the whole medication procedure, is:

> *"Any incident where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicines advice, regardless of whether any harm occurred or was possible"* (NPSA, 2009, p. 6).

Table 1.2 shows other examples of ME definitions that include all MUPs, most of which use the phrase 'error' and relate MEs to the possibility of error prevention. Table 1.3 illustrates examples of ME definitions that focus on the differences between prescribed and prepared drugs.

Table 1.2: Definitions of MEs that covered all medication use processes, and used the term 'error' or 'errors'

Study	Definition
US Pharmacopeia (1995)	*"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the drug is in the control of the health care professional, patient or consumer"*
Bates and colleagues (1995)	*"Errors occurring at any stage in the process of ordering or delivering a medication, regardless of whether an injury occurred or the potential for injury were present. They include the entire range of severity, from trivial errors to life-threatening errors"*
Kohn and colleagues (2000)	*"An error occurring at any stage in the process of delivering a medication. They include the entire range of severity, from trivial errors, such as orders that necessitated clarification or missing doses, to life-threatening errors, (such as a patient receiving a ten-fold overdose of a toxic agent "*
Australian Council For Safety And Quality In Health Care (2002)	*"Failure in the (drug) treatment process that leads to or has the potential to lead to, harm to the patient and includes an act of omission or commission "*
Lisby and colleagues (2005)	*"Errors in the medication process: ordering, transcription, dispensing, administration and discharge summaries"*
Kopp and colleagues (2006)	*"An error occurring during the medication use process, regardless of whether an injury occurred or the potential for injury was present"*
World Health Organization (WHO, 2009)	*"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer"*
Lisby and colleagues (2012)	*"An error in the stages of the medication process − ordering, dispensing, and administering and monitoring the effect − causing harm or implying a risk of harming the patient"*
Kongkaew and colleagues (2013)	*"Any error in the prescribing, dispensing, or administration of a drug, irrespective of whether such errors lead to adverse consequences or not"*

Table 1.3: Examples of ME definitions that highlight the differences between prescribed and prepared medicines.

Study	Definition
Allan and Barker (1990)	*"Deviation from the physician's medication order as written on the patients chart"*
Dean and colleagues (1995)	*"A dose prepared (or omitted) that deviated from the most recently written medication order for that patient "*
Cooper (1995)	*"A dose of medication that deviates from the physician's medication order on the patients chart"*
Dean and Barber (2001)	*"Any discrepancies between the medication prescribed and that prepared"*
Barker colleagues (2002)	*"Any discrepancy between the prescriber's interpretable medication order and what was prepared to a patient "*

1.3.3. The correlation between ADEs, potential ADEs and MEs

The definitions that follow relate to the principal terms, their meaning and their relationship. Some of these definitions agree with NPSA defined terminologies, while others have been chosen by leading healthcare professionals. It is vital to clarify the correlation between ADEs, ADRs, potential ADEs (Near miss) and MEs when studying approaches to increase safety in medicine use (Bates et al., 1995; Morimoto et al., 2004).

ADEs are typically defined as 'preventable ADE', which includes MEs resulting in patient injury during any phase of the medicines management for example: hypothermia due to overdose of analgesic and opiates, and 'non-preventable ADE', which include harm arising from the use of a medicine which is not the result of any mistake (i.e., an ADR) (Von Laue et al., 2003; Otero & Schmitt, 2005).

Adverse Drug event (ADE)

> *"Injuries resulting from medical interventions related to a drug"* (Bates et al., 1995, p. 199).
>
> And later shortened to
>
> *"An injury due to medication"* (Morimoto et al., 2004, p. 307).

Adverse drug reaction (ADRs) (non-preventable ADE)

> *"Injury from medication not involving any error"* (Von Laue et al. 2003.P. 409).

ADEs have been divided into different categories, (Morimoto and colleagues, 2004, p. 307):

Potential ADE (Near miss):

> *"… A medication error with the potential to cause an injury but which does not actually cause an injury, either because of specific circumstances or because the error is intercepted and corrected"*

In simple expression "*Medication errors that do not result in patient harm or errors with potential for harm but detected before they reach the patient*" (DOH, 2004, p.22)

For example,

I. Wrong volume of diluent: Picked 100ml Sodium Chloride 0.9% instead of 50 ml Sodium Chloride 0.9%.

II. Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume, but corrected before given to patient.

Preventable ADE (reached the patient):

"…An injury that is the result of an error at any stage in the medication use"

Figure 1.3 shows the correlation between MEs, ADEs, and ADRs. The red ring exemplifies preventable drug events (all MEs, all potential ADEs, and preventable ADEs). Only a few types of medication errors are preventable ADEs or potential ADEs. Furthermore, all potential ADEs (near miss) are medication errors and, that only limited types of preventable ADEs are also medication errors.

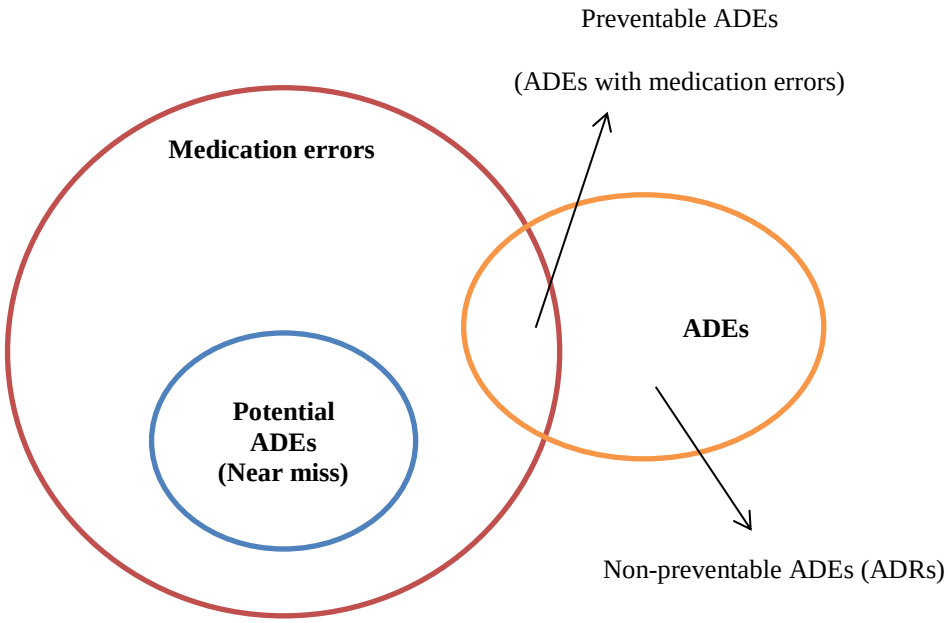


Figure 1.3. The correlation between PS incidents involving medicines (from Morimoto et al., 2004, p. 307)

1.3.4 Prevalence and preventability of medication errors in hospitals

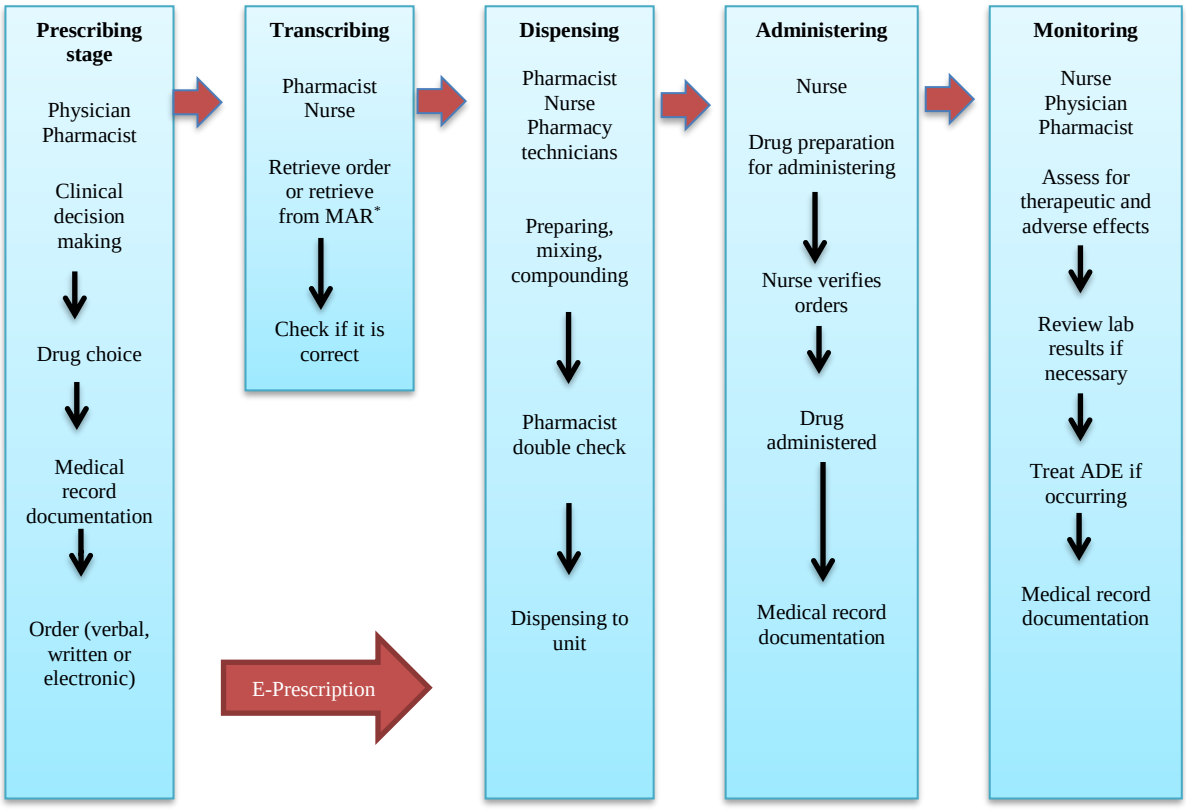
There have been numerous studies reporting MEs in hospitals throughout the world. In 1994, Leape reported that 20% of patients in US hospitals had experienced MEs and were also considered a key factor of resulting harms (Leape, 1994). Bates and colleagues (1995) examined data from more than 4,000 patients at eleven medical and surgical wards in two hospitals. The authors recognised 247 definite ADEs and 194 potential ADEs. The ADEs were considered preventable in 28% of all cases, and represented a major harm in 42% of cases. Furthermore, in 1995, the Quality in Australian Health Care Study examined the medical records of 14,100 patients at 28 hospitals in Australia and reported that 11% of all errors among admitted patients were MEs. The study showed that more than 40% of MEs were considered preventable, around 16% were identified as causing major harm and more than 5% led to death (Wilson et al., 1995). In another investigation of General Practice in Australia, 51% of reported errors were stated to be medication errors and more than 70% of which were preventable (Runciman et al., 2003). A systematic review by Von Laue and colleagues (2003) examined the occurrence and preventability of ADEs in hospital settings globally and found that ADEs affected between 0.5% and 7% of admitted patients, with up to 57% of these ADEs being preventable. In 2006, Otero-Lopez and colleagues recognised more than 190 ADEs with 2,643 hospitalised patients 7% (n= 191/2643), 20% (n=38/191) of which were preventable. Williams (2007) has identified that medication errors influence between 1.8% and 13.6% of patients admitted to hospitals. Nuckols et al (2007) studied more than 3,800 error reports from three voluntary reporting systems in two US hospitals. They stated that medication errors accounted for 28.2% (n=1094/3875) of all reported errors, and that about 92.9 %(n= 1017/1094) of these MEs were preventable. Furthermore, preventable medication errors found to be

around 45% (1017/2246) of all preventable errors analysed in the research, an observation which reveals the increased preventability of medication errors compared with other types of errors (Nuckols et al., 2007). An investigation of medication errors in an NHS hospital reviewed incident reports and discharge records, as well as direct observation of drug prescriptions by pharmacists, and found that ADEs composed 50% of total AEs identified, with 10% affecting patients (Olsen et al., 2007). A study in Japan specified 1,010 [1.7% (incidence=17/1000 patient per day)] ADEs and 514 [0.87% (incidence=8.7/ 1000 patient per day)] MEs at three hospitals over a 6-month period. Among all ADEs, 33% caused severe harm, 14% were preventable, 4.9% life threating, and 1.6% caused death (Morimoto et al., 2010). Another study examined 1,000 deaths in ten acute hospitals in England in 2009 and found that 5% of adult deaths had a 50% or more chance of being prevented. Twenty-one percent of these preventable adult deaths were because of the wrong medicine or incorrect fluid treatment (Hogan et al. 2012).

In summary, medication errors are common, and account for a large percentage (10% n=526,167) of reported incidents. Between 2005 and 2010, medication errors were the second most common type of error stated by the NRLS in England and Wales, after patient accidents (Cousins et al., 2012). The report showed that MEs represented 10% of all PSI. The percentage of MEs increased from 10% to 11% between 2005 and 2010, and to 11.4% and 11.1% in 2011 and 2012, respectively. In 2013, MEs was the third most commonly reported class, acting 11% of all stated errors (NPSA 2013).

1.4. Medication use process (MUP) (Prescribing/dispensing/administration/monitoring errors/review)

MUP describes the phases through which drugs pass before being delivered to the patient, and are illustrated in Figure 1.4. In pharmacy or hospital environments, these stages include (A) prescribing; (B) transcribing; (C) preparing, usually by registered nurses; (D) dispensing; (E) administration; and (F) monitoring of treatment effects and possible adverse events (IOM, 2007). These phases form a complex system that contains approximately twenty steps, meaning that there are twenty chances for MEs to happen.



[1]**MAR** = medication administration record

Figure 1.4. MUP in hospital environments (adapted from IOM, 2007, p. 68)

Several investigative studies (e.g. from observational research) on the incidence of medication errors in UK hospitals have been reported, with most medication errors reported in hospitals shown to arise during drug prescribing (usually including transcribing) and administration, followed by preparing/dispensing and monitoring (Ashcroft & Cooke, 2006; NPSA, 2009). Comparable findings to the IOM (2007) on medication error categories within each medication use process step have been recognised in an analysis of medication errors at a UK hospital (Ameer, 2015). These mistakes can happen during any phase of prescribing, transcribing, preparation and dispensing or administration. However, it should be noted that sufficient monitoring of treatment effects and adverse events is not performed continuously (Vogenberg & Benjamin, 2011). The wrong patient, time, medicine, dose and administration route have all been identified typical types of MEs and have been labelled the 'five wrongs' (Ghaleb et al., 2010; Ameer, 2015).

In previous studies, investigators have used different definitions to describe MUP stages (Tully, 2012), that vary between countries, meaning that MUP comparisons between hospitals in the UK and in Europe or the US are somewhat unreliable due to the variances in the procedure.

Table 1.4, adapted from James (2009), shows the differences in MUP between these countries. As is apparent from Table 1.4, the main difference is the number of types of healthcare professionals (i.e. physician; pharmacist and nurses) involved in the different stages of MUP in the UK compared to the hospital environments in other countries in Europe and the US. For example, in the UK, hospital prescriptions are handwritten, or computer generated by physicians, pharmacist prescribers, and nurse prescribers;

however, in European and US hospitals they are handwritten or computer generated by physicians only. Furthermore, the most notable differentiation between the UK, Europe and US hospitals is the use of unit dose systems for drug dispensing and distribution. In the US hospital setting, the unit-doses for each prescribed medicine are dispensed for individual patients in a pharmacy and stored in a computerised cabinet on the ward until use. In the UK, wards hold stocks of common medicines which can be used for any patient, whilst whole boxes of unusual medicines are supplied for individual patients when needed.

Table 1.4. A summary of MUPs in hospital environments in the UK, Europe and the US (adapted from James, 2009, pp. 36)

MUP	UK hospital environments	European hospital environments	US hospital environments
Prescribing	Prescriptions are handwritten or computer generated by doctors, nurses' prescribers, and pharmacist prescribers. Prescription types include medication charts and discharge and outpatient prescriptions.	Prescriptions are handwritten or computer generated by doctors. Prescription types include medication charts and discharge and outpatient prescriptions.	Prescriptions are handwritten or generated using computerised physician order entry systems by doctors. Prescription types include medication charts and outpatient prescriptions.
Transcription	Medication orders may be transcribed from a prescription to a pharmacy requisition by nurses, pharmacists, and pharmacy technicians.	Nurses transcribe details from a prescription to a pharmacy requisition.	Nurses transcribe details from a handwritten prescription to pharmacy requisition or medication administration record. Computerised physician order entry generated prescriptions are accessed directly by pharmacy via the computer system.
Dispensing	Pharmacists review patient's drug chart, prescription and pharmacy requisition on the ward to identify prescribing and transcribing errors (clinical checks). Centralised pharmacy departments assemble medications. Patients are supplied with an original manufactures' packed labelled with patient name, date of dispensing, drug name, strength, form, directions for administration and warning/cautionary advice. Some pharmacies will dispense discharge prescriptions at ward level using patients' own drugs or previously supplied medications. All total parenteral nutrition and parenteral cytoxic medications are prepared by pharmacy. Some pharmacies prepare a limited number of intravenous medications.	Pharmacists and pharmacy staff work solely from the centralised pharmacy departments. Medication charts, discharged and outpatient prescriptions are checked by pharmacists for accuracy and appropriateness of prescribing and transcribing. Pharmacy supplies patients with manufactures' original packs of medicine without a dispensing label giving details of drug or directions.	Pharmacy staff review medication orders for safety from a decentralised pharmacy unit at ward level. Unit doses of each drug ordered for a patient are assembled by the decentralised pharmacy. All intravenous medications for patients are prepared and supplied by the decentralised pharmacy department.
Administration	Medication is stored in a locked drug trolley or individual patient locker. Nurses administer medications to patients and document supply on the medication chart which is both a prescription and a record of medication administration.	Medication is stored in locked cupboards on the wards. Nurses document administration of medications to patients on a medication administration chart.	Medication is stored in computerised drug cabinets. Nurses document administration of medications to patients on a medication administration chart.

1.4.1 Cost of medication errors

Addition to the injury that may outcome from MEs, their financial implications and costs may be important. In 1997, Bates and colleagues assessed the costs associated with 190 ADEs, of which 60 were preventable, in patients admitted to hospital in the US. They reported that ADEs increased the period of hospitalisation by three days, with an estimated cost after the event of $2,570. In preventable ADEs, the length of hospitalisation increased by five days, with costs after the event of $4,695. The IOM (2007) report assessed the additional cost of managing each preventable ADE that arises in hospital to be almost $8,755, and with the statement that 400,000 preventable ADEs happen every year, the overall additional cost of all MEs on the US healthcare system was estimated at $3.7 billion per year.

Roughead and colleague (2009) proposed that more than 185,000 patient admissions happen each year in Australia because of MEs, accounting for 2-3% of admissions to Australian hospitals and costing about $660 million. Furthermore, around 50% of these incidents were potentially preventable.

In the UK, the DOH (2004) has stated that 10-20% of all MEs were estimated to cost the NHS £200–400 million, which with legal action costs added was almost £750 million (Smith, 2004). The NPSA (2007) report rated the cost of preventable injury resulting from medication errors and showed that preventable medication errors cost the UK NHS more than £700 million each year. This included the cost of preventable inpatient injury, £411 million; the cost of preventable admissions due to harm caused by drugs, £359 million, and the cost of legal action, £4 million. In addition, Cousins and colleagues documented that the cost of MEs was almost £985 million in 2008 and

more than £2 billion in 2012 (Cousins et al., 2012). From 2012 to 2014, medication costs in hospitals increased by 17% to £5.8 billion (Health and Social Care Information Centre, 2014).

1.5 Review of studies reporting MEs

Over the last two decades there has been a rapid development of ME indication in worldwide. But, a small number of comprehensive studies were conducted. Bates et al. (1995) studied the incidence and preventability of ADEs in two US hospitals by reviewing charts and self-reported events by nurses and pharmacists. They reported that 48.4% (n = 128) of 264 preventable ADEs happened during the prescribing phase and that 11.3% (n = 30) occurred during transcribing. They acknowledged that a limitation of their study was that it was carried out in teaching hospitals, meaning that findings might not be generalisable.

Leape and colleagues examined patient profiles in two hospitals and reported that 38.9% (n = 130) of 334 errors happened during the prescribing phase, and 38% (n = 126) in the administration phase. The most common types of medicines administration errors (MAEs) were wrong dosage (27%; n = 34), wrong administration technique (14%; n = 18), wrong drug (12%; n = 15), and omissions (8%; n = 10) (Leape et al., 1995).

Kaushal et al. (2001) analysed medication errors in children's clinics at two US teaching hospitals. They reported that most medication errors happened during the prescribing phase, representing 73.7% (n= 454/616) of errors reported, and 10.06%

(n=62/616) arose in the transcribing phase. The most common type of error was wrong dosing, at 34%.

Dean and colleagues examined the incidence and clinical significance of prescribing mistakes at a UK hospital. The analysis included more than 36,100 written drug prescriptions over 4 weeks, and detected a prescribing error in 1.4% (n = 538/36,200) of the prescriptions. The majority of errors 60.9% (n= 328/538) happened during the prescription writing process, while errors that happened during the prescribing decision process represented 39% (n = 210/538) of the total. The most common types of errors were dosing errors (53.7%; n = 289/538), errors in selecting the demand for drug treatment (17.8%; n = 96/538) and errors when writing instructions on how to give the medicine (12.8%; n = 69/538). Furthermore, the authors stated that most of the severe errors (about 58%) happened during the prescription writing procedure, and that the transcribing error rate was less than 1%. Overall, (26.3%; n=142/538) of errors were potentially severe, of which 58% happened during the prescribing decision process (Dean et al., 2002).

An analysis of 24 hospitals and 12 nursing homes in the US approved by Joint Commission on Accreditation of Healthcare Organizations identified that the proportion of medication errors was 18.8% (n=605/3216) of all administered medicines (Barker et al., 2002). In spite of the fact that the rate was lower in hospital settings, (16.4%) compared with nursing homes (21.7%) but this variance was not significant. The most common types of mistakes were administering the wrong dose, timing, administering an unauthorised medicine, and omission.

Observational investigations of medication errors in intensive care units reported that error rats started from 7% to 56% of observed medicines administrations (Tissot et al., 1999; Van den Bemt et al., 2002).

Tissot and colleagues observed medicines administration errors in medical and surgical wards at a teaching hospital in France and found that medicines administration errors rates ranged from 15% for all detected medicines (Tissot et al., 2003).

Winterstein and colleagues (2004) examined the nature of ME reports in a single teaching hospital and reported that 73% (n = 174/240) of analysed MEs happened in the prescribing phase and 6% (n = 15/240) in the transcribing phase.

A study examined dispensing errors recognised in a NHS hospital pharmacy showed that 2% of 4,849 dispensed medicines had more than one dispensing error (Beso et al., 2005). One clear weakness in the study analysis, which was based on self-reporting, was that errors may have been under reported, particularly those identified outside of the department, in order to avoid blame. The different types of mistakes reported in each MUP phase support this observation. Errors identified outside of the department were less likely to be labelling errors (66% n=21/32) and more likely to be content errors (34% n=11/32) (e.g. missing doses or incorrect drug); this may reflect the fact that content errors are easier to identify, or that they are noticed as more significant and thus reported.

In the UK, the rate of administration errors was significantly higher than that of other phases of the medications use process and started from 47% to 84% (Ashcroft & Cooke, 2006; Maidment & Thorn, 2005). In 2006, Ashcroft and colleague examined medication error reports in an online reporting system over twenty six-months in a large

university hospital in the UK (One thousands beds). The authors found that 46.4% (n=230/495) of the 495 presented errors were associated with the administration phase, compared with 38.7% (n=190/495) in the prescribing phase and 14.7% (n=73/495) in the dispensing phase (Ashcroft and Cooke, 2006). In the same year, an observational study in the US examined dispensing errors at one hospital. The results identified 5,075 dispensing errors, a rate of 3.6% (n = 140,755 doses), and that 79% of these errors were discovered during double checks with 21% of observed errors undiscovered. Among the undiscovered errors, 24% were potentially harmful, of which 0.8% were life threatening (Cina et al., 2006).

A systematic review of the incidence of medication errors in children wards was managed by Ghaleb and colleagues (2006) and included 8 observational investigations from 5 various countries, involving the UK hospitals. The authors reported that the observed medicines administration errors rate was 0.6% and was 10.3% when intravenous medicine were excluded, and that higher rates of 18–27% were found when intravenous medicine were included. The most common errors were omission errors, wrong administration route and wrong frequency of administration.

Kopp and colleagues (2006) reported that Intensive Care Unit errors in a US teaching hospital from 27% during the administration phase. The most common types of errors were omissions 47.6% (n = 20/42) and wrong dose 14.2% (n = 6/42).

An investigation carried out in New Zealand presented that 61% (n = 224) of errors happened at the prescribing phase compared with 45% (n=164) during the administration phase, 15% (n=55) during the monitoring phase, and 9% (n=34) at the dispensing phase (Kunac & Reith, 2008).

Lewis and colleagues carried out a systematic review of the prevalence, incidence and types of mistakes correlated with the prescribing phase in adult or paediatric hospital settings. The review, which involved 65 studies (25 from the US and 22 from the UK), reported that 7% of medicine orders involved errors and found that the most common mistake was prescribing the incorrect dose (Lewis et al., 2009). In the same year, the NPSA stated that 53% (n=34,137) of medication errors reported at hospitals in England and Wales in 2009 happened during the administration of medicines, compared with 18% (n=11,180) during the prescribing phase and 11% (n=7,436) during the medicine preparation phase. In the same year, a Malaysian observational study examined the incidence of MAEs and found an error rate of 11.3% (n=127) in 1,118 observed doses. In total, 10% of errors were potentially life-threatening. The most common errors were incorrect administration time (25%; n=34), wrong administration technique (16%; n=22), and unauthorised medicine errors (14%; n= 19). The authors identified that IV doses were more likely to be linked with errors, compared with non-IV doses (21% vs. 7.9%; $P < 0.001$) (Chua et al., 2009).

Valentin and colleagues (2009) observed data from 113 ICUs in 27 countries, including 16 centres in the UK, to investigate MAEs associated with parenteral medicines. The authors reported that MAEs happened in 7.3% (n = 861\11,725) of administrations and influenced 33% of patients. The authors also reported 75 errors per 100 patient days. The most common types of errors were wrong time (44.8%; n = 259), omissions (30.1%; n = 386) and wrong dose (13.7%; n = 118).

In 2009, James and colleagues presented a review of global studies on the incidence and type of dispensing errors. The analysis included 18 studies of hospital pharmacy errors from the UK and 18 from the US, and determined the rate of both prevented (i.e.

errors detected in the pharmacy) and unprevented (i.e. errors detected after the drug has left the pharmacy) dispensing errors. In UK hospitals, eight studies showed that the rate of prevented dispensing errors ranged from 0.10% to 2.6%, and nine studies found that the rate of unprevented errors ranged from 0.008% to 0.02%. Higher percentages were reported in US hospitals, where prevented dispensing errors rates ranged from 0.05% to 17% (16 studies), although only one research stated the rate of unprevented dispensing errors (0.76%). The most common types of unprevented errors were dispensing of the incorrect dose, incorrect quantity, incorrect drug strength and incorrect drug. Dispensing of the incorrect drug or strength and faulty labelling were the most common types of prevented dispensing errors in both manual and automated systems (James et al, 2009). Nevertheless, other studies from the UK have shown that automation systems significantly decrease drug content mistakes (e.g. incorrect drug, incorrect form, incorrect quantity and incorrect strength) (Fitzpatrick et al., 2005; Franklin et al., 2008).

A Japanese analysis assessed the incidence of ADEs and found an error rate of 67% (n = 319) at the prescribing stage compared with 17.4% (n = 83) at the monitoring phase, 14.2% (n = 68) at the administration stage, and 1.8% (n = 8) during the dispensing phase (Morimoto et al., 2010).

Ghaleb et al. (2010) reported that 13.2% (n = 391/2,955) of medicine orders were related with prescribing errors at five NHS hospitals in London. The most common types of prescribing errors were incomplete prescriptions (41%; n = 161), use of abbreviations (24%; n = 94), and dosing mistakes (11%; n = 44).

Poon and colleagues observed 6,732 medicine administrations in medical, surgical, and Intensive Care units at a 735-bed teaching hospital in the US and found an overall error

rate of 11.5% (n=776/6,732). The most common mistakes were wrong administration route (37.2%; n=289/776), incorrect documentation (24.7%; n=192/776) and dosing errors (21%; n=163/776). Generally, 1.8% (n=123/6,732) of observed administrations were categorised as potentially clinically significant, 1.3% (n = 88/6,732) caused serious injury and 0.029% (n = 2/6.732) were life-threatening (Poon et al., 2010).

Ghaleb and colleagues studied one hundred sixty one nurses preparing and administering medicines and found an error rate of 19% (n=429/ administration errors/2,249 opportunities for error) (Ghaleb et al., 2010).

Kelly and colleagues (2011) reported that, out of 2,129 observed drug administrations, 11% involved errors. The rate of errors increased more than 30% when timing errors were added. The most commonly observed errors were incorrect time (71%), wrong preparation (8%), omissions (5%), wrong form (5%) and wrong dose (3%).

A large investigation by James and colleagues (2011) examined the rate and description of prevented and unprevented dispensing incidents reported in 5 Welsh NHS hospital pharmacies. Among 221,670 dispensing events, a significant difference was observed between prevented incidents (0.13% n=131/100,000) and unprevented incidents (0.01% n= 16/100,000). The investigation also reported significant differences in the ratio of incidents involving a faulty on the label or incorrect directions ($p = 0.02$), dispensing the wrong strength ($p = 0.02$), wrong medicine information on the label ($p = 0.01$), and incorrect expiry dates ($p = 0.002$) between prevented and unprevented incidents.

Rodriguez and colleagues (2012) reported that (23%; n=509/2,314) of administered medicines at 2 medical centres in Spain that used automated prescribing and dispensing

systems were linked with errors. They found that 86.6% (n = 441/509) of errors happened at the administration phase and 13.3% (n=68/509) happened during the preparation phase. The most commonly detected mistakes were the use of wrong administration procedures (14%; n =321); wrong preparation (i.e. wrong dilution [2%; n=40]); omission (1%; n =32), and wrong route (1%; n=27). In total, 96% of errors did not cause harm at all, whereas 2% needed monitoring and 0.5% were linked with short-term harm.

Keers et al. (2013) performed an international systematic review of 91 observational studies to analyse the prevalence and type of MAEs and found a median error rate among adult and paediatric studies of 20%, involving timing mistakes and 8% without timing mistakes. The most common mistakes reported were wrong dosage, unauthorised medicines, timing errors and omissions. However, another systematic review of MAEs in hospitals found that the median error rate was 10.5% of the overall opportunity for error (TOE), from 34 studies. The median error rate in a further fifteen studies was 6.9% of the TOE (Berdot et al., 2013). In the same year, a systematic review of UK observational MAE research (n = 16) reported a total error rate of 6% for non-IV doses and 36% for IV doses. The study presented that MAEs for IV doses were five times higher than for non-IV doses (McLeod et al., 2013).

A two-year research of 20 hospitals in the UK compared the proportion of prescribing errors made by junior physicians with those made by senior physicians and other prescribers. Throughout the research phase, pharmacists checked medicine orders for prescribing errors. The authors found that among 124,260 checked medication orders, 11,235 prescribing mistakes were recognised in 10,986 orders, giving a mean error rate of 9% for all medicine prescribers. The findings stated a significantly higher rate of

errors among physicians in training compared with consultants. The error rate in prescriptions written by physicians in training was 8.6% for foundation year 1 physicians and 10% for foundation year 2 physicians, compared with an error rate of 5% for consultants. The most common types of errors detected in the research were the omission of drugs needed at admission (29%) followed by under-dosage (11%) and over-dosage (8%) (Ashcroft et al., 2015).

All of the studies above are large-scale, and well recognised. Despite the different settings, methodologies, and ME rates stated in these studies, they all show that MEs are a common problem that affect both adult and paediatric inpatients worldwide. They also show the high preventability of MEs. Some of the research reviewed above investigated MEs only on weekdays (Van den Bemt et al., 2002; Tissot et al., 2003). Other studies did not explore MEs during night shifts (Greengold et al., 2003, Tissot et al., 2003). Moreover, a number of studies did not identify the observation times (morning, evening, or night), and whether the observations were presented during weekdays or weekends (Ridge et al., 1995). Previous studies were very varied in the number of observation sites. For instance, Barker et al. (2002) employed a large sample size (n=3,216 doses) across 36 organisations to classify the prevalence of MEs. A large sample such as this may provide more representative results (Barker et al., 2002). Table 1.5 presents more details about other large-scale investigations of MEs. It includes the essential information relating to each research, and a summary of the main results. As can be noted, the research can be categorised into two groups: prospective observational research, and retrospective research to investigate MEs.

Table 1.5. A summary of the research investigating medication errors

Study	Location	Study settings	Method /Design	Error rate	Errors type & rate	Comment
Dean et al (1995)	UK & US	Two large University hospitals UK: 2756 opportunities for error US: 919 opportunities for error	Observational studies	MAEs: UK 3% US 6.9%	**UK:** Omission (58% 49 n=) Incorrect dose (14% n= 12) Incorrect formulation (10% n= 8) Incorrect medicine (7% n=6) **USA:** Omission (22% n=14) Wrong dose (30% n=19) Unordered medicine (25% n= 16)	N/A
Lesar et al, 1997	**US**	A teaching hospital. 9-year study period were assessed. **Size of sample**: 3,903,433 prescriptions.	Prospective study; pharmacists used any available information sources, including the pharmacy computer system which had automated checking functions, to evaluate prescriptions prior to dispensing.	Prescription errors PEs 0.29% (n=11,186/3,903,433)	In total 35.7% (n=3,997) related to antibiotics.	N/A
Ho et al (1997)	UK	One elderly care ward 2,170 opportunities for error and 119 MAEs	Observational studies	MAEs = 5.4% (119/2170)	Omissions (50.4%) Incorrect dose (16%, 19) Incorrect preparation technique (13%) Unauthorised dose (10.9%, 13).	MAE rate was significantly higher on weekdays (6%) than weekends (4%). MAE rate was higher during pharmacy opening hours (8%) than during the closing hours (5%).

Continued Table 1.5

Study	Location	Study settings	Method /Design	Error rate	Errors type & rate	Comment
Barker et al (2002)	**US**	36 hospitals opportunities for error = 3216	Observational studies	MAEs with timing mistakes 18.8% (605/3216) MAEs without timing mistakes 10.8%	Timing mistakes (43%) Omission (30%) Wrong dose administration (17%) Unauthorized medicine (4%)	7% of errors were assessed as potential ADEs. The significant potential risk factors: Morning/evening shift, and IV administration.
Greengold et al (2003)	UK	2 University hospitals 9,453 opportunities for error and 1,457 errors	Observational studies	MAEs: General nurses:[4] 14.9% (545) MAEs Medication nurses:[5] 15.7% (912)	Wrong administration technique (6.4%) Incorrect dose preparation (1.4%) Omissions (0.9%) Wrong dosage (0.8%) Wrong route (0.6%) Wrong Intravenous rate (0.2%)	N/A
Lisby et al (2005)	Denmark	One medical and one surgical ward 2467 opportunities for error in all stages and 1065 errors	Observational studies	Ordering (39% n= 167), Transcribing (56% n= 310), Dispensing (4% n=17), Administration (41% n=166).	Lack of identity control (36,4%, 150), Incorrect time (4.4%, 18) Incorrect delivery (2.9%, 12) Incorrect administration technique (1.9%, 8)	**Severity of MAEs:** Fatal (1% n=2) Major injury (20% n=33) Significant (32% n=53) Non-significant (46% n= 77)
Prot et al, (2005)	France	A paediatric teaching hospital. 1-year period were observed. **Size of sample:** 336 patients, 485 nurse-observation periods.	Prospective study; 12, 5th year pharmacy students accompanied nurses giving medicines (undisguised) and observed the preparation and administration of medicines to find discrepancies between physicians' orders and actual medicine administration	AEs 31.3% (n= 538/171) opportunities for error.	19.7% related to Anti-infective which were the 3rd highest drug class associated with errors (OR=2.57, 95%CI: 1.01%–6.57%) [6].	N/A

[4]Who did not join the programme, offered comprehensive care, involving medicine delivery, for six patients each. [5]After getting a brief review programme on safe medicine use, were responsible especially for medication delivery for up to eighteen patients each. [6]OR: Odds Ratio; CI: Confidence Interval.

Continued Table 1.5

Study	Location	Study settings	Method /Design	Error rate	Errors type & rate	Comment
Jayawardena et al, 2007	**US**	One community teaching hospital. Computerised prescription order entry system. **Study** for 1 year. **Size of sample**: 466,311 prescriptions.	Retrospective study. Pharmacist reviewed prescriptions placed before the medicine was released to the nursing staff. If there was any hesitation about a specific order, the pharmacist would directly identify the prescription with the staff.	[7]PEs 0.71% n=3,321	53.9% (n=1,790) related to antibiotics.	
Bertsche et al, 2008	**Germany**	One teaching hospital. One monitor visited each ward in the busy morning hours from 7 to 10 for 10 days. **Size of sample:** 87 nurses observed.	Prospective study; three-trained pharmacy students monitored drug handling (storage, preparation and administration) and assessed the occurrence of 20 detected errors.	60.5% n=833 handling errors	Preparation. (68.5 n=571%) Administration (30.5 n=254%) Storage (1% n=30)	In total, (29.5% n=246) related to antibiotics which was the medicine class most linked with errors.
Lewis et al, 2009	**UK**	Published between 1985 and 2007 that stated on the finding and rate of PEs in prescriptions handwritten for hospital environment were reviewed. **Size of sample**: 65 studies (including 25 from the US and 22 from the UK).	Systematic review to identify appropriate studies.	PEs was 32%.	N/A	N/A
Valentin et al, 2009	**Worldwide**	113 ICU in 27 countries (involving 17 from the UK). Drug administrations to all adult patients staying in the units, involving those admitted or discharged during a 24-hour period. **Size of sample:** 1,328 patients (including 200 from the UK) who received 11,725 drug administrations.	Prospective study; All nurses and physicians were asked to fill in a single multi-entry questionnaire (self-reporting) available at the bedside of each patient that ask if, and at what time, a mistake in IV medication had happened.	861 MAEs affected 441 patients MEs= 33.2% (n=441/1328)	Of these, MAEs, 20.7% (n=179/861) associated to antimicrobials which was the 2nd most commonly related with errors 9.4% n=1905 Of all antimicrobial administrations.	N/A

[7] PEs: Prescribing errors

Continued Table 1.5

Study	Location	Study settings	Method /Design	Error rate	Errors type & rate	Comment
Dornan et al, 2009	**UK**	19 teaching hospitals. All new prescriptions made on seven monthly- separated weekdays were examined. **Size of sample**: 124,260 prescriptions.	Prospective study pharmacists reported errors in prescriptions as part of their routine job.	PEs 8.9% n=11077 / 124,260	16% (n=1,790/11077) related to antibiotics.	N/A
Rodriguez-Gonzalez et al, 2012	**Spain**	One teaching hospital. 2-gastroenterology ward, all drug administrations during all shifts over a 1-week period were observed. Size of sample: 73 patients who received 213 drugs.	Prospective study, six pharmacists and five nurses disguisedly observed drug administrations and assessed the MEs rate.	60.5% n=833 handling errors	MEs 21.9%n=509/2314	12.8% n=297/2314 related to antibiotics which was the drug class most linked with mistakes. There was a significant relationship between MEs and antibiotics incidence (OR=3.1, 95%CI: 1.98–4.85)
Berdot et al, 2012	**France**	One teaching hospital. 4 adult wards, drug administrations to all patients during the three medicine rounds on each of 6 days per ward were observed. **Size of sample**: 28 nurses caring for 108 patients.	Disguisedly observational study. MEs while accompanying nurses and observing the preparation and administration of drugs. Directly after the round, the pharmacist compared the drug administrations to the physician order.	MEs was 28% n=415/1501	55 (13%) MEs occurred in 50 anti-infective (12%) opportunities for error (33% of all 150 anti-infectives opportunities for error.	N/A
Seden et al, 2013	**UK**	Nine hospitals (3 teaching; 3 district; 3 specialist). Every hospital was asked to check a minimum of 400 prescriptions. All types of medication orders were checked. **Size of sample:** 4,238 prescriptions.	Prospective study. Clinical pharmacists prospectively reported PEs at the phase of clinically checking admission or discharge prescriptions.	3,011 PEs were detected in 1,857 prescriptions (44% of all prescriptions assessed).	423 (23%) contained antibiotics. These involved 130 (31%) antibiotic-related PEs (18% of all 724 antibiotic prescriptions).	N/A
Keers et al (2013)	**UK**	Published between 1985 and May 2012 that stated on the rate of MEs resulting only from direct observation at long-term care or hospital settings were reviewed. **Size of sample:** 91 studies (including 25 from the US and 22 from the UK).	Systematic review; to classify qualified studies.	ME rate: [8]IQR=19.6% 8.6-28.3% US 19% 4.9-23.5% UK 22% 6.4-35.9%.	Out of 10 studies specified the medications most commonly related with errors, 4 reported that antimicrobials was most common error	N/A

[8] IQR: interquartile range.

1.6 Injectable Medications Errors

Injectable medicines are an important aspect of healthcare and are given to nearly all inpatients. Furthermore, injectable medicines are not always used effectively with errors occurring all too often (WHO, 2013). MEs occurring in the hospital or pharmacy environment have been shown to cause death or major harm to patients every year (Crowley, 2006; Cousins et al., 2012; Ameer, 2015). The highest-risk medicines are typically those administered by injection. Injectable drugs must be carefully prepared and administered, and patients receiving injectable drugs should be monitored closely. Injectable drugs are classified by the NPSA as high-risk medications (NPSA, 2007), and defined as follows:

> *"Medicines intended for administration by bolus injection, perfusion or infusion by any of the following routes: intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intradermal, intraventricular, epidural, intravascular, intravitreal, intrapleural and intraocular"* (NPSA, 2007, p. 9).

The UK NRLS received 9,000 reports on medication safety incidents related to injectable drugs in 2006. Moreover, these incidents accounted for 53% of patient deaths or major harm to patients (NPSA, 2006). As a result, the UK NPSA published Patient Safety Alert 20, 'Promoting the Safer Use of Injectable Medicines' (NPSA, 2007). Its recommendations are summarised below (adapted from NPSA, 2007, p. 2):

1. Start a risk assessment of injectable drug procedures and products in all hospital wards to classify high risks, and develop an action plan to reduce them.
2. Ensure that there are up-to-date policies and protocol/procedures for prescribing, preparing and administering injectable drugs in all hospital wards.

3. Ensure basic technical information on injectable drugs is available and accessible to healthcare staff in hospital wards at the point of use.
4. Implement a purchasing for safety policy to encourage purchase of injectable drugs with inherent safety features.
5. Afford training for, and supervision of, all healthcare staff involved in prescribing, administering and monitoring injectable drugs.
6. As part of the annual drugs management audit programme, healthcare organisations should include an audit of medicine practice with injectable drugs.

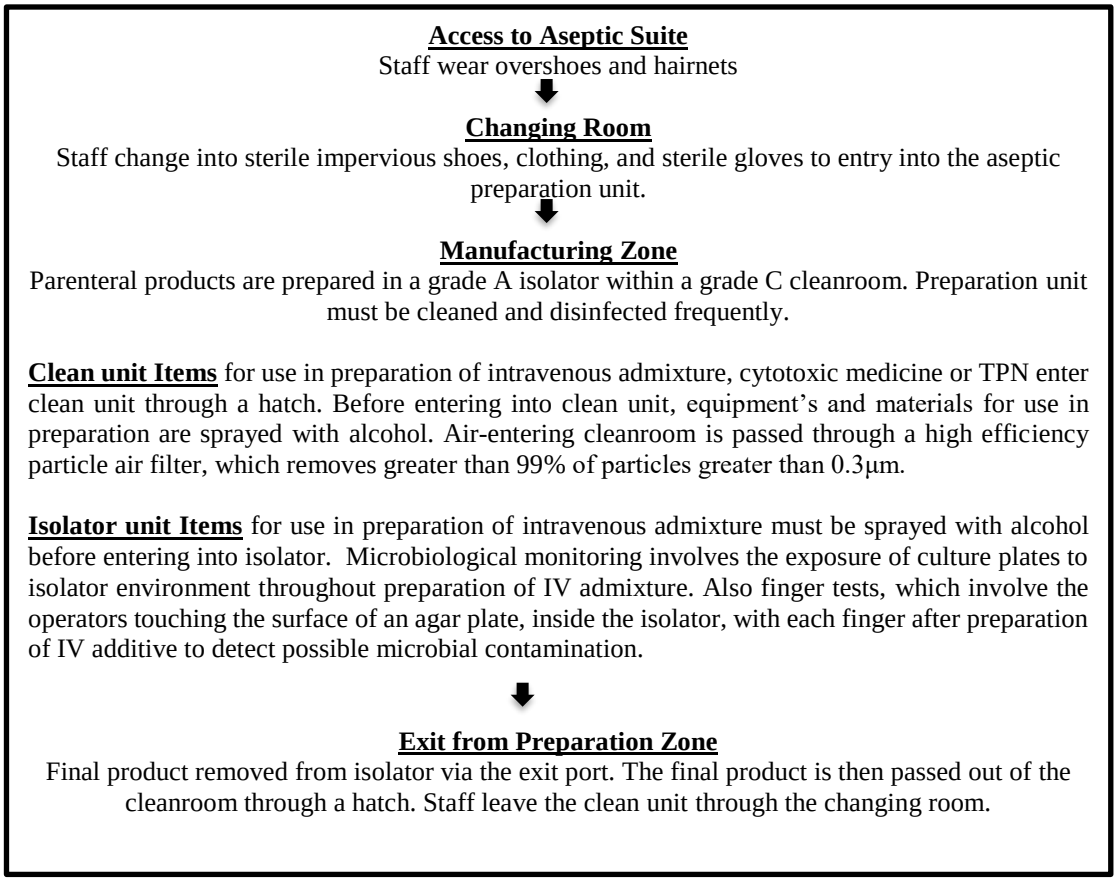
A preparation error is defined as

> *"The preparation of an injectable medication that deviates from the prescription, manufacturer's guidelines, nationally or locally agreed-upon policy, procedure or guidance, or generic standards for clean or aseptic preparation"* (Crowley, 2006, p. 136).

Concerns about the safety of injectable medicines were reported in the late 1970s due to the severity of errors associated with these therapies (O'Hara et al., 1995). The Breckenridge report (1976) noted the risks related with the preparation of injectable products in hospital wards. It recommended that injectable drug preparations should be under the control of a specialised pharmacist in an adequate workplace (Breckenridge, 1976). It stated that IV medicines should be prepared in pharmacy-run facilities but where this was not possible, pharmacists should be available in hospital wards to advice about IV additions and be heavily included in medical and nurse training. Aseptic pharmaceutical preparation facilities are now commonplace within the NHS and in private hospital pharmacies (Medicines and Healthcare Products Regulatory Agency, 2014).

In the UK, pharmacy aseptic preparation units are licenced differently by the Medicines and Healthcare Products Regulatory Agency (MHRA), which licenses units that have a policy for preparing drugs without the need for marketing authorisation (i.e. for preparing batches of products). Other unlicensed units can prepare drugs only for a named patient (e.g. hospital prescriptions) (MHRA, 2012). Figure 1.5 shows the specialised environmental conditions required for preparing injectable medicines in a pharmacy aseptic unit, adopted by many pharmacy aseptic production units in the UK.

Figure 1.5. Typical environment conditions used to prepare injectable drugs in a pharmacy aseptic unit (adapted an observed aseptic unit in the UK large unit, 2014).



1.7 Injectable Preparation Errors (IPEs)

Clearly, there are many stages from the prescription of an injectable medicine to its administration, and injectable errors can be introduced during any of these stages (Fraind et al., 2002). Although ideally all injectable medicines prepared in pharmacy and significant proportion made in hospital wards. Cousins et al, 2012 reported that there were a total of 526 376-medication errors reports during (2005-2010), which represents preparation errors 3rd most important injectable medicines errors.

There are two types of IPEs:

Internal errors (near misses):

Errors in the preparation of an injectable medicine that are discovered during the work process before the medication has been delivered to the bedside for patient use.

External errors (errors):

Errors in the preparation of an injectable medicine that are discovered and recorded after the medication has left the pharmacy unit or IV room in the hospital ward and which may or may not lead to patient harm.

1.7.1 Review of studies reporting IPEs in aseptic pharmacy settings

Some studies on the type, incidence, and causes of injectable MEs in pharmacy settings are summarised in Table 1.6. In 1996, Escoms and colleagues examined the incidence of self-reported anti-neoplastic drug preparation errors in a Spanish hospital between 1993 and 1994 (Table 1.6). They found an overall low incidence of errors (6.6%; n = 314 errors/4,734 preparations) and attempted to classify these by error type. The most frequent type of preparation errors centred on product labelling (3.1%; n=150

errors/4734 preparation) (e.g. incorrect expiry date on label and wrong type of diluent) (Escoms et al., 1996).

An observational study by Flynn and colleagues in 1997 examined error rates in five US hospital pharmacies during the preparation (i.e. compounding) of intravenous (IV) admixtures. Using comprehensive methodology, the authors provided a detailed description of the pharmacy procedures at each of the study sites and a clear description of the role of the observer, especially concerning inclusion/exclusion criteria when classifying errors. Using disguised, direct observation, a reasonably high error rate (8.6%; n = 145 errors/1,679 doses) was noted and the specific types of errors observed and drugs associated with these errors were described. However, no effect of daily workload on error rates was identified. The authors also highlighted error-related issues associated with automated compounding machines (see Table 1.6) (Flynn et al., 1997).

Limat and colleagues studied the frequency, type and associated risk factors of preparation errors in a single centralised cytotoxic preparation unit in France. They used a retrospective study design based on the self-reporting of errors by pharmacy technicians to show the types of minor and major errors reported. Errors occurred in approximately 0.45% of preparations. They also found that major risk factors contributing to errors included unsuitable drug product presentation and the number of bottles used in the preparation. Specifically, they found that increased workload increased the incidence of error. Specifically, a daily workload of 60 or more preparations per day was associated with a higher incidence of errors (see Table 1.6) (Limat et al., 2001).

In 2008, Parshuram and colleagues examined errors in the preparation of IV medications in a Canadian hospital using a direct observation methodology in a nonclinical environment (i.e. they set up various 'work trial' tasks outside of working hours (Table 1.6). Participants included a range of personnel (including nurses and pharmacy technicians) involved in the preparation of IV medicines. They also examined the relationships between a range of individual characteristics and other factors (e.g. stress, fatigue) and observed errors. They identified mistakes in 1.5–4.9% of infusion-preparation tasks and a greater magnitude of infusion errors among fatigued personnel (Parshuram et al., 2008).

The following year, Sacks et al. examined the frequency, type and severity of MEs associated to the parenteral nutrition process in a US hospital. The authors state in their method that this was an observational study, but clearly it was not. Instead, it is an evaluation of data from the hospital's internal error reporting system. An error rate of 1.6% was identified in parenteral nutrition prescriptions, and the types of transcription and preparation errors were documented. Twenty-four percent of observed errors occurred during preparation. The authors showed the distribution of harm for the errors observed but did not classify these results according to phase, meaning that it is impossible to determine the level of harm specific to preparation errors. However, the percentage of preparation errors was much higher than that associated with the use of high-risk drugs, both within their hospital setting and within partner hospitals using similar error reporting procedures (Sacks et al., 2009) (see Table 1.6).

Bateman and Donyai analysed self-reported errors from the National Aseptic Error Reporting Scheme from 2004 to 2007, which occurred throughout the aseptic

preparation process. They found an overall low incidence of preparation errors (0.5%; n= 4,691 error reports/958,532 preparations) (see Table 1.6). The authors acknowledged that the majority of reported errors were identified before the product left the pharmacy, so the data mainly represent near misses. Furthermore, the study details the personnel involved in making errors, those involved in recognising them, a full breakdown of the different types of errors and phases of the system in which they occurred, and various other factors shown by the data to be associated with particular errors (categorised by the process involved). The authors acknowledged the weaknesses of their study, namely that it was based on self-reported data and that the focus was on near misses rather than errors that caused harm (Bateman & Donyai, 2010).

In 2010, Serrano-Fabia and colleagues studied the efficacy of a multi-disciplinary approach to minimising errors in antineoplastic chemotherapy and identifying them before they reached the patient. Over the course of 2 years, they identified errors including those during preparation in a centralised pharmacy compounding unit. They found an overall low incidence of preparation errors (0.35%; n = 58 errors/16,473) and reported that, within a multi-disciplinary team, the pharmacist identified the most MEs (see Table 1.6) (Serrano-Fabia et al., 2010).

In 2011, Ranchon and colleagues examined MEs in the use of antineoplastic drugs and their associated costs in a centralised cytotoxic preparation unit in a hospital setting in France (Table 1.6). They described the process from prescribing to dispensing, and detected errors using self-reporting and double-checking of the preparation process. The low error rate identified for preparation errors (0.12%; n = 26 errors/22,138 preparations) suggested that errors may have been under-reported due to a fear of blame

and a bureaucratic and time-consuming process for reporting incidents (see Table 5) (Ranchon et al., 2011).

An observational study conducted in a university hospital in Germany examined drug preparations made in a central pharmacy and compared them with those made on the ward. They found more errors on ward-prepared solutions but found a significant error rate in those made in the pharmacy too. They break down the error rate according to the three infusion solutions prepared: amiodarone, noradrenaline, & hydrocortisone (Dehmel et al, 2011) (see Table 1.6).

Some of the studies outlined in the literature review above have reported the error rate as a function of the number of injectable preparations. Several different techniques have been used to classify and investigate IPEs in pharmacy settings. These can be divided into prospective observational studies, and retrospective review studies. An observation study of the injectable preparation practice is carried out in either a disguised or an undisguised manner. Retrospective review studies identified IPEs by reviewing medication errors specific reports, and analysing serious incident reports and medication charts. Using a direct observation method will provide great vision into the culture of injectable medication safety within the pharmacy environment (Flynn et al., 2002; Parshuraman et al., 2008).

In total, the studies reported that the observed IPEs rate ranged from 0.12% to 8.6% (Escoms et al., 1996; Flynn et al., 1997; Limat et al., 2001; Sacks et al., 2009; Bateman & Donyai, 2010; Serrano-Fabia et al., 2010; Ranchon et al., 2011). The majority of errors observed were incorrect dose, faulty labeling, and incorrect type of diluent. There

is increasing concern about the number of patients harmed by IPEs in pharmacy aseptic departments in the UK; the number of studies published on this subject is increasing rapidly. A limited numbers of studies are available on IPEs as shown in this review, the majority have been focused on administration and prescribing mistakes. Although IPEs can also result in significant patient harm, there has been relatively little investigation in this area.

Given the increasing attention on the role of guidelines and procedure for injectable preparations in pharmacy aseptic units, it is important to understand the frequency, types, and causes of the IPEs that currently occur, to help identify strategies to prevent IPEs from occurring in the future.

Table 1.6. A summary of the research investigating the types, incidences of injectable medications errors and methods used in Pharmacy Environments

Study	Location	Medical domain	Method / Design	Error type	Error rate	Comment
Escoms et al (1996)	Spain	Antineoplastic preparations	Analysis of an internal "paper control" based error detection process relying on self-report/detection of errors Longitudinal (1 year)	Preparation errors	314 errors / 4734 preparations (6.6%) 314 errors / 94680 error opportunities (0.3%)	No association between number of daily preparations (i.e. workload) and error rate
				Faulty labelling	150 errors / 4734 preparations (3.1%)	
				Incorrect expiry date	47 errors / 4734 preparations (1%)	
				Wrong type of diluent	24 errors / 4734 preparations (0.5%)	
Flynn et al (1997)	USA	Patient-specific IV admixtures (e.g. antineoplastic, parenteral nutrients)	Direct, disguised observation Cross-sectional (5 days)	Preparation errors	145 errors / 1679 doses (8.6%)	Associations between types of materials and solutions and error rates No observed association between workload and error rate
				Clinically important preparation errors	30 errors/1679 doses (2%)	
				Unauthorised drug	7% of errors	
				Wrong dose	69% of errors	
				Wrong base solution	16% of errors	
				Omission	3% of errors	
				Wrong preparation technique	5% of errors	

Continued Table 1.6

Study	Location	Medical domain	Method / Design	Error type	Error rate	Comment
Limat et al (2001)	France	Cytotoxic preparations	Self-detection by technicians during preparation or at time of control Longitudinal (1.5 years)	Preparation errors	140 errors / 30819 preparations (0.45%).	A strong association between drug produce presentation (e.g. no. vials) and preparation errors
				Major errors	0.19%	
				Wrong dose	39/140 errors (27.9%)	An association between workload and errors (i.e. >=60 preparations a day was a significant risk factor for errors)
				Labelling	11/140 errors (7.9%)	
				Unauthorised drug	4/140 errors (2.9%)	
				Incompatible diluent or set/bag	5/140 errors (3.6%)	
				Minor errors	0.26%	
				Wrong infusion set	31/140 errors (22.1%)	
				Final volume	22/140 errors (15.7%)	
				Wrong diluent	21/140 errors (15%)	
				Final presentation	6/140 errors (4.3%)	
Parshuraman et al (2008)	Canada	Morphine infusions	Direct observation hospital staff involved in preparing IV infusions[1] Performing infusion preparation tasks in a non-clinical setting. Infusions were tested objectively later Cross-sectional	Drug volume calculations	58 errors / 1180 drug volume calculations (4.9%)	Factors positively associated with concentration errors were fewer infusions per week, increased years professional experience, use of more concentrated stock solutions and preparation of smaller dose volumes.
				Rounding calculations	30 errors / 1180 rounding calculations (2.5%)	
				Volume measurements	29 errors / 1767 syringe-volume measurements (1.6%)	
				Infusion mixing	7 errors / 451 infusions (1.6%)	
				Objective analysis of morphine infusions	160 errors / 464 infusions (34.5%)	

[1] 14% of the sample were pharmacists/pharmacy technicians (referred to from here on as pharmacists). The rest were nurses and anaesthesiologists. However, pharmacists were for the most part significantly represented among those participants who made at least one error: drug volume calculation errors (35% were made by pharmacists), rounding errors (6% were made by pharmacists), volumetric errors (24% were made by pharmacists), infusion concentrations outside of limit (81% were pharmacists).

Continued Table 1.6

Study	Location	Medical domain	Method / Design	Error type	Error rate	Comment
Sacks et al (2009)	USA	Parenteral Nutrition preparations	Analysis of a self-report error reporting system Longitudinal (1.5 years)	Preparation errors including: Wrong selection of electrolyte salt Incorrect medicine dose Non-prescribed medicine used	18 preparation errors / 4730 preparations (0.4%)	Preparation errors were associated with specific PN components: electrolytes (65%), drugs (29%), Macro-nutrients (6%)
Bateman & Donyai (2010)	UK	Aseptic preparation units	Analysis of UK National Aseptic Error Reporting Scheme reports Longitudinal (4 years)	Preparation errors Transcription Calculation Medicine Diluent Final volume Label Expiry Container Other	4691 error reports / 958 532 items made (0.5%) 11.1% 5.5% 4.2% 4.3% 6.5% 34.2% 7.5% 2.3% 19.3%	Most error reports related to cytotoxic products (40%), IV additives (27%), adult parenteral nutrition (15%), and other prefilled syringes (7%) Technicians were most likely to be associated with making errors (51.2%) followed by ATO`s (25.5%) and pharmacists (15.2%) Other factors perceived to have contributed to errors include individual staff error (78.1%), distraction/interruption (4.3%), inadequate training (3.7%), and excessive workload (3.1%)

Continued Table 1.6

Study	Location	Medical domain	Method / Design	Error type	Error rate	Comment
Serrano-Fabia et al (2010)	Spain	Antineoplastic preparations	Self-report and cross validation of the pharmo-therapeutic process Longitudinal (2 years)	Preparation errors	58 errors / 16473 preparations made (0.35%) were preparation errors	Within a multi-disciplinary team, the pharmacist identified the most medication errors
Ranchon et al (2011)	France	Antineoplastic preparations	Self-report and double checking of fabrication process Longitudinal (1 year)	Preparation errors[2]	26 errors / 22138 preparations made (0.12%)	Strange interaction between overall errors and month of the year
Dehmel et al (2011)	Germany	Pharmacy-based automated production	Objective analysis of prepared solutions Cross-sectional	Drug concentration deviates from intended concentration by: >=5% >10%	 16 / 100 solutions (16%) 5 / 100 solutions (5%)	N/A

[2] Inadequately defined in paper

1.7.2 Review of studies reporting IPEs in ward settings

Several studies on the type, incidence, and causes of injectable errors in ward settings are summarised in Table 1.7. O'Hare et al. (1995), who used a disguised observation method in one UK hospital, stated that 291 mistakes were identified in 168 of the observed doses, of which 237 errors were made by senior house officers (non-consultant hospital doctors). Of the 132 doses given by senior house officers, 97.7% (129 errors/132 doses) had at least one error, compared with 83% (39 errors/47 doses) of those given by nurses. The majority of errors were: incorrect administration time, incorrect rate of administration, incorrect volume of diluent, omitted dose, and incorrect diluent. The authors stated that no major or serious errors were detected. They also showed that mistakes in IV administration of medicines were statistically more likely amongst busy junior medical staff than amongst nurses, who have formal training and operate a double-checking system. O' Hara and colleagues also reported that a reduced workload and improved quality of care may minimise errors in the future (see Table 1.7).

Hartley and Dhillon (1998) carried out research to establish the incidence, type, and causes of prescribing and administration IV drug mistakes occurring on two surgical and one medical ward in one UK hospital. The errors were categorised in regard to their potential to harm the patient and the implications for the system of supply, preparation and administration. Most of the drugs were administered via IV (47%, 72 IV drugs/154 patients). The authors reported that 14% (25/178) of prescription IV drugs from both medical and surgical wards did not follow the local policy on prescribing, and 11% (20/178) were stated to be clinically inappropriate. Over 39 days the authors observed 42% (320/772) of all preparation and administration IV doses. The majority of errors

were: wrong time of doses (53%, 168/320), omissions (13%, 40/320), and incorrect preparation technique (7%, 23/320). The authors assessed the severity of errors observed, and identified that 78% (198/254) were classed as representing a minor risk to the patient, 17% (44/254) were classed as representing moderate risk, and 5% (12/254) represented a major risk to the patient. While the majority of errors observed had a minor effect on the patient, the study suggested that using knowledge of the causes observed to change or support the existing system of IV drug supply, preparation and administration, could minimise the IV drug error rate (see Table 1.7).

Bruce and Wong (2001), in a direct disguised observation research in one UK hospital, reported an error rate lower than other previous studies; this may be because of the different methodologies, small sample size, or more effective nursing training and operating procedures. The authors identified 27 errors, which produced an error rate of 25%, including incorrect time errors. Excluding wrong time errors, the most frequently occurring type of error, reduced this error rate to 10.3% (see Table 1.7).

Wirtz and colleagues (2003) observed IV MEs in the UK and Germany. This study is useful because it identifies the different practices in British and German hospitals and analyses the occurrence of different error types within these different settings. The authors used a disguised observation methodology and convenience sampling, and found that one of the higher preparation error rates in IV dosing from 31%. The authors provided a breakdown of the different preparation error types and severities across the different settings. They also noted deviations from aseptic techniques but did not specifically identify these deviations as errors. The study also referenced useful medical error classification schemes, error severity schemes, and descriptions of error types, as well as listing the types of drugs most commonly associated with the different error types (see Table 1.7).

Taxis and Barber (2003), in an observational investigation in two UK hospitals, reported that 49% of 430 observed injectable doses correlated with more than one error. The authors reported a preparation errors rate of 7.4% (n = 32/430) and administration error rate of 36% (n = 155/430). The findings showed that the most common errors observed were rapid administration of an IV bolus dose (30%), wrong diluent (8%), wrong dose (3%), and omission (3%). Furthermore, errors were evaluated according to Reason's classification system (i.e. slips, lapses, mistakes, violations, and active/latent failures). The authors employed an observational approach by a subject expert and follow-up interviews with staff involved in errors. They ranked the severity of the errors and discussed factors associated with different errors by staff (see Table 1.7).

Cousins et al. (2005) examined errors associated to IV drug preparation and administration in hospital wards in England, France and Germany. This study included some useful information relevant to the design of the present study, and identified labelling errors, diluent errors and errors in aseptic methods. However, the focus of this study was limited to nurses preparing injectable treatments in ward areas. Several violations in aseptic technique were observed, and the UK aseptic clean room scenario (with its associated stringent training) was presented as a model of how aseptic errors could be eliminated. The authors found that the observed preparation error rates were 69% (n = 185/273) in the UK, 52% (n = 262/425) in Germany, and 34% (n = 34/100) in France (see Table 1.7). The following year, Crowley (2006) investigated the incidence and type of injectable preparation errors using a direct observation approach in hospital wards that were employed from an acute university hospital NHS Trust located over four sites, providing a wide range of secondary and tertiary specialties with more than 1,500 inpatient beds. Using direct observation, a reasonably high error rate (39.7%; n = 27 errors/68 doses) was noted (for 6 doses more than 1 mistake was

detected), and the specific types of errors observed and drugs associated with these errors were described. However, no assessment of error severity was carried out (see Table 1.7) (Crowley, 2006).

Fahimi and colleagues examined errors in the preparation of injectable medications by nurses at the ward level in a university hospital in Iran (Table 1.7). They identified a low rate of preparation errors (127 errors/4,040 opportunities for error [3%]) (Fahimi et al., 2008). Narula et al. (2011) examined reported errors (using an internal hospital error self-reporting scheme) in the entire paediatric parenteral nutrition process (Table 6). They divided the process into different sections, including transcription, preparation and dispensing. The results revealed errors in other stages but not in the preparation stage. The authors suggested that this was because the process is tightly controlled, and suggested that, based on other evidence, that self-reporting did not necessarily lead to an underestimation of errors in that particular hospital for various organisational reasons (Narula et al., 2011) (see Table 1.7).

Ong et al. (2013) used direct observation to examine preparation and administration errors for IV drugs prepared at the ward level in a hospital setting in Malaysia. The authors identified an overall preparation error rate of 32.8% (n = 112/349). Interestingly, they classified errors as occurring pre-preparation, during preparation, and during labelling, and described in detail many of the errors found within these phases and the drugs they were associated with (see Table 1.7). They also used a chi-square test to examine the factors associated with errors and identified factors including administration time (pre-preparation errors) and amount of IV drug to be given (preparation and labelling errors).

The majority of UK studies on preparation errors have investigated both the preparation and administration of injectable drugs by nurses in clinical areas (O'Hare et al., 1995; Hartley & Dhillon, 1998; Bruce & Wong, 2001; Taxis & Barber, 2003, 2004; Wirtz et al., 2003; Cousins et al., 2005). However, two studies focused solely on nurse preparation errors (Taxis &Barber, 3004; Crowley, 2006). All research used direct observation of nurses to detect preparation errors. Higher error rates were observed in injectable preparation in hospital clinical areas, with the observed error rate ranging from 7.4% to 39.7% (Taxis & Barber 2003; Crowley, 2006; Ong et al., 2013).

In total, the rate of errors during injectable preparation and administration ranged from 42% in two studies from Germany and the UK (Writz et al., 2003; Taxis & Barber, 2004) to 69% in one UK-based study (Cousins et al., 2005). Factors contributing to nurse preparation errors were classified as: inadequate training, staff shortages, complex calculations, lack of workspace, and interruptions (Crowley, 2006). A limited number of studies focused on injectable preparation errors, while most studies investigated injectable administration. Injectable drug preparation is an important step before the drug is administered to the patient, and incidents at this phase are less likely to be detected before administration, resulting in more opportunities for error. This review suggests that more studies investigating injectable drug preparation errors are required. The results of such studies should enhance the safety of injectable medicine preparation, by minimising the number of incidents and consequently the harm that might result from these. Identifying the mistakes, understanding the causes, and ultimately building strategies to minimise the risk of injectable errors from occurring in the future are essential to achieving such an aim.

Table 1.7. A summary of the research investigating the types, incidences of injectable medications errors and methods used in Hospital Environments

Study	Location	Study settings	Method / Design	Error rate	Errors type & rate	Comment
O'Hare et al (1995)	UK	**One paediatric hospital**	Disguised observation IV medicine administration errors; type, rate, potential sever Number of IV doses observed 179	Overall preparation and administration error rate 168 doses with 291 errors. 93.9% doses	Incorrect time of administration (78%, 140/179) Incorrect rate of administration (64%, 114/179) Incorrect volume of diluent (13%, 24/179)	No potential sever errors
Hartley & Dhillon, (1998)	UK	One hospital: three wards, district general hospital, drug rounds observed	Disguised observation IV medicine prescribing and administration errors (rate, type, cause, potential harm) Implication to MUP Number of IV doses observed 323	Overall preparation and administration error rate 79.3% morphine PCA, insulin & heparin infusions were excluded	Wrong time of doses (53%, 168/320), Omissions (13%, 40/320) Wrong preparation technique (7%, 23/320)	Potentially severe errors (5%, n=12), Potentially moderate errors (17%, n=44) Potentially minor errors (78%, n=198)
Bruce & Wong, (2001)		One hospital: admissions ward, continual daytime	Disguised observation Error rate during preparation and administration of IV medicines. Number of IV doses 107	Overall preparation and administration error rate (25%, 27/107)	Wrong time (16%, 17/107), Wrong preparation technique (6%, 6/107) Incomplete labeling error (2%,2/107)	Good hand washing and used gloves is the single most important procedure for the prevention of nosocomial infections; hands have been shown to be an important route of transmission of infection.

Continued Table 1.7

Study	Location	Study settings	Method / Design	Error rate	Errors type & rate	Comment
Taxis and Barber (2003)	UK	**1** university hospital and 1 **non-**university general hospital (**10** wards)	Disguised observation. Data were collected on **6-10** consecutive days on each ward involving weekends and covered all times of medicine rounds.	**Error rate** (49%, 212/430) **Preparation errors** (7.4%, 32/430) **Administration errors** (36%, 155/430) **Both types of errors** (6%, 25/430).	Errors in multiple step preparations (14%, 50/345), Bolus dose injection (73%, 172/235), Intermittent infusion (9%, 15/163) **Preparation errors:** errors in solvent/diluents (8%, 36/430), incorrect dose (3%, 12/430), and omission (3%, 12/430) **Administration errors:** fast bolus dose (peripheral line) (30%, 127/430), fast bolus dose (central line) (8%, 36/430), Incompatibilities (3%, 12/430).	Potentially severe errors (1%, n=3), Potentially moderate errors (29%, n=126) Potentially minor errors (19%, n=83)
Wirtz et al. (2003)	UK & Germany	3 large teaching hospitals	Disguised, direct observation of 3 different ways of dealing with IV medications[1] **Total** of 615 observed doses**:** 337 preparations and 278 Administrations **Participants** Nurses and junior doctors	**(TBP): Preparation errors:** 22%, **Administration errors**: 27% **(TGP): Preparation errors:** 23% **Administration errors** 49% **(GSP): Preparation errors:** 31% A**dministration errors** 22%	**Types of preparation errors** **TBP:** wrong dose 3%, wrong dosage form 7%, omissions 10%, and wrong preparation technique 3% **TGP:** wrong dose 21%, omissions 1%, and wrong preparation technique 1% **GSP:** wrong dose 5%, wrong dosage form 2%, omissions 20%, wrong preparation technique 1% **Types administration errors** **TBP:** wrong rate 27%. **TGP:** wrong rate 37%, and compatibility errors 17% **GSP:** wrong rate 20%, and compatibility errors 2%	**Potential minor errors** 27% **Moderate to severe errors** 74%

[3]The traditional British ward pharmacy service (TBP), the German method involving large stocks of commonly prescribed medicines on wards (TGP) or another German method where a satellite pharmacy service is used (GSP)

Continued Table 1.

Study	Location	Study settings	Method / Design	Error rate	Errors type & rate	Comment
Taxis and Barber (2004)	Germany	1 surgical ward and 1 surgical ICU.	22 nurses were observed. 34% of all prescribed doses were observed	**Overall rate** (48%, 58/122) **Preparation errors** (19%, 23/122) **Administration errors** (23%, 28/122) **Both types of errors** (6%, 7/122).	**Preparation errors:** Errors in solvent/ diluents (20%, 24/122), wrong dose (2%, 3/122), Omission (1%, 1/122), unauthorised medicine (2%, 2/122) **Administration errors:** Fast bolus dose (2%, 3/122), incompatibilities (25%, 31/122).	**Potentially minor errors** (13% n=16) **Potentially moderate** (31% n=38) **Potentially severe errors** (3% n=4)
Cousins et al. (2005)	UK & Germany & France	**UK:** Medical and surgical wards in four hospitals **Germany:** 2 surgical ICUs and 1 general surgical ward **France:** 1 Immunology department	**Direct observation** **Participants** Nurses Total of 824 preparations and 798 administrations were observed.	Preparation and administration error rates excluding faulty labelling and omissions: **UK** (69%, 185/273) **Germany** (52%, 262/425) **France** (34%, 34/100)	**UK:** faulty labelling (43%), incorrect diluents (1%), incorrect rout (1%), wrong rate (48%), wrong time (18%), incorrect dose or infusion volume (0.5%). **Germany:** faulty labelling (99%), incorrect diluents (49%), incorrect rate (21%), incorrect time (2%), incorrect dose or infusion volume (2%). **France:** faulty labelling (20%), incorrect diluents (18%), incorrect rate (5%), incorrect time (4%), incorrect dose or infusion volume (5%)	**N/A**
Crowley (2006)	UK	Medical, surgical wards, paediatric ward and critical care in acute teaching hospital NHS Trust	**Direct observation** **Participants** Nurses Total of 68 preparations were observed	**Preparation errors** (39.7%, 27/68)	Wrong addition / mixing (23.5%, 16/68) Faulty labelling (13.2%, 9/68) Unacceptable clean technique; re-use of single dose container (2.9%, 2/68) Expired / degraded or unknown expiry (2.9%, 2/68) Wrong medicine (2.9%, 2/68) Diluent error (2.9%, 2/68)	**N/A**

Continued Table 1.7

Study	Location	Study settings	Method / Design	Error rate	Errors type & rate	Comment
Fahimi et al (2008)	Iran	**One** hospital (446 beds)	**Direct observation** **Participants** Nurses	**Frequency of preparation errors** (3%) 127 errors / 4040 opportunities for error	Wrong dose (17%) Diluent calculation (17%) Inappropriate diluent (9%) Inappropriate storage of drug before dilution (1%)	**N/A**
Narula et al (2011)	UK	**One hospital** **Participants** All hospital staff	Analysis of a self-report error reporting database	**Preparation / compounding errors:** No errors	N/A	N/A
Ong et al (2013)	Malaysia	**Participants** **Nurses** **One hospital (34 wards)**	**Direct observation of IV preparation**	**Pre-preparation errors** 311/349 samples (91.2%) **Preparation errors** 112/349 samples (32.8%)	Wrong drug (0.3%) Cleaning (9.3%) Sterilisation (26%) Concentration (54.5%) Mixing (6.3%) Wrong dose (4.6%) Expiration (2.6%)	N/A

1.8 Significance of the research

The preparation of injectable drugs is a high-risk, complex procedure, yet very little is known about preparation errors in UK hospitals. There is a need for investigations that can expand the current understanding of factors influencing injectable drug preparation in UK hospitals and how incidents that threaten patient safety arise. In 2006, the UK National Reporting and Learning System (NRLS) received 9,000 reports of medicine safety incidents related to injectable drugs. That year, injectable drugs accounted for 53% of patient mortality or harm due to medication errors (NPSA, 2006). In response, the UK NPSA published a report called 'Patient Safety Alert 20: Promoting the Safer Use of Injectable Medicines' (NPSA, 2007). In this thesis, an injectable preparation error is defined as "the preparation of an injectable medication that deviates from the prescription, manufacturer's guidelines, nationally or locally agreed-upon policy, procedure, or guidance, or generic standards for clean or aseptic preparation" (Crowley, 2006). This study adopted this definition to enable a direct comparison of injectable drug preparation errors. By using Crowley's study in particular, this protocol can take advantage of that study's links with Patient Safety Alert 20 (Crowley, 2006).

An in-depth assessment of errors can help to recognise strategies to avoid similar mistakes occurring in the future and thus improve PS. Injectable medicines are considered hazardous mainly because of the immediate onset of the systemic effects that they can trigger, the low therapeutic index of many injectable medicines, and the difficulty of reversing pharmacologic effects after injectable administration (MEDMARX database 2002–2006, 2008). Mistakes in the preparation of injectable drugs within the pharmacy environment occur are rate of 0.12%-8.6% (see literature

review 1.7.1), and the consequences of such errors can be catastrophic (NPSA, 2007). For example, in 2006 at Guy's and St Thomas' Hospital in London, a baby died following the administration of an overdose of glucose after the wrong dose was calculated in a pharmacy aseptic production unit (R v. Guy's and St Thomas' NHS Trust, 2008). In another case, at Guy's and St Thomas' Hospital in London (2007) a child needed extra supportive treatment after having a ten-fold overdose of vinorelbine. In an incident that occurred in June 2014, a baby died from septicaemia as an outcome of being administered Total Parental Nutrition (TPN) prepared from a raw ingredient contaminated with *Bacillus cereus* (NRLS, 2015). Studies on the inherent risk of harm related to drugs has shown that errors are reported for a large percentage of PSIs occurring in hospitals (Thomas et al., 2002; Nuckols et al., 2007; Morimoto et al., 2010; NPSA, 2015). ME reports from the UK have detected that the majority of incidents linked with patient harm and deaths happened during the preparation phase (NPSA, 2015). In response, this PhD project employed direct observation to investigate injectable drug preparation errors recorded in pharmacy aseptic units and hospital wards. This research focused on internal errors, or near misses that occurred during the preparation of an injectable drug. These were discovered during the work process before the medication had been delivered to the hospital bedside for patient use. The investigation will be guided by Reason's (1990) model of human error, and Vincent et al.'s (1998) framework for healthcare organisation accidents.

This study will explore the incidence and type of injectable medicines preparation errors. Furthermore, it will review and identify the most effective interventions to improve the injectable preparation of high-risk medicines. The preparation process of such injectable medicines, as well as the causes of errors and suggestions of how to avoid these errors, will also be investigated. Such research is needed in order to increase

the understanding of the processes, incidences, types and causes of injectable preparation errors, so that effective risk-reduction strategies can be developed and implemented to safeguard PS.

1.9 Aims & Objectives

The overall aim of this project is to investigate the incidences, types, severity and causes of errors in the preparation of injectable medicines within the pharmacy environment and hospital ward areas, with the goal of identifying strategies for reducing the risk of injectable preparation errors in both environments.

1.10 Research Objectives

Detailed research objectives for this thesis are summarised in Table 1.8.

Table 1.8. Research Objectives

Research Objectives	Determine the incidence of injectable medicine preparation errors in the pharmacy environment and hospital ward areas.
	Identify the types of injectable medicine preparation error in the pharmacy environment and hospital ward areas.
	Compare the incidence and types of injectable medicine preparation errors occurring in an unlicensed pharmacy unit, and in small and large licensed pharmacy units Compare the incidences and types of injectable medicine preparation errors occurring on four wards at two participating hospitals Determine the drugs involved in injectable medicine preparation errors in the pharmacy environment and hospital ward areas.
	Establish the causes of injectable medicine preparation errors in the pharmacy environment and hospital ward areas.
	Rank the severity of injectable drug preparation errors observed in pharmacy aseptic units and on hospital wards on a scale of 0-10. Identify strategies for reducing the risk of injectable medicine preparation errors in the pharmacy environment and hospital ward areas.

In the present study, the aim of the investigation is to identify strategies to minimise IPEs in pharmacy environment and hospital wards as illustrated in Figure 1.6. This data is collected using a number of methods: (1) observe injectable medicine preparation practice on three different pharmacy aseptic units and on four hospital wards, (2) explore the incidence and types of errors in different pharmacy aseptic units and on hospital wards (3) rank the severity of IPEs observed in pharmacy aseptic units and on hospital wards on a scale of 0-10, (4) characterise IPE contributory factors and interventions as stated by healthcare professionals in interviews and questionnaires using Reason's (1990) organisational accidents model, and (5) suggest strategies to minimise IPEs based on the interviewees perception and on the previous studies.

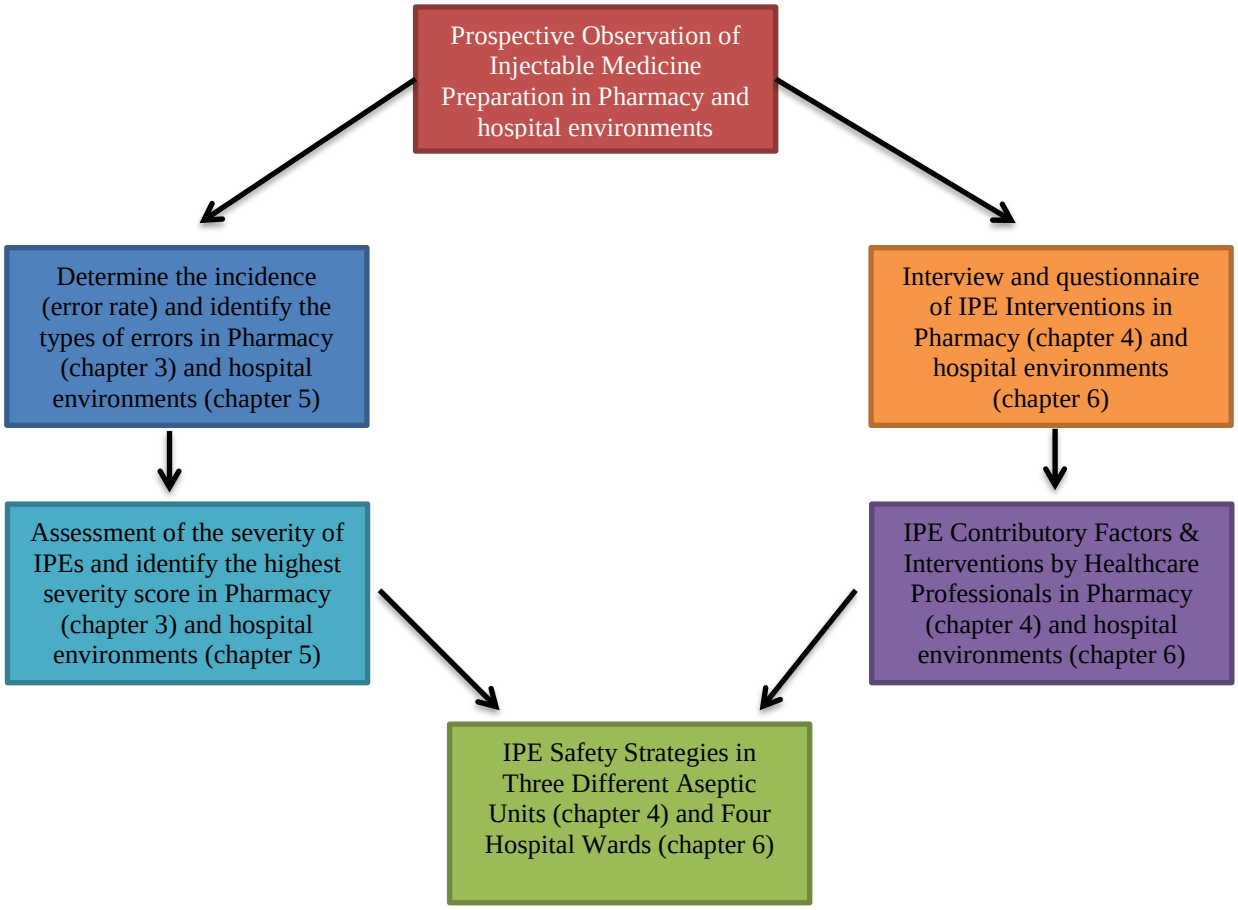


Figure 1.6: Overview of thesis content and associated chapters

Chapter Two

Research Methodology

2.0 Research methodology

2.1 Introduction

Investigation of medication errors (MEs) is essential for quality development owing to the unique relationships between ME contributory factors (Vincent, 2010; National Coordinating Council for Medication Error Reporting and Prevention, 2015; Ameer, 2015). Figure 2.1 illustrates that many MEs go unidentified and that most identified errors are not reported (Smith, 2004). Identifying MEs is the first step in reporting errors followed by use of information in error reports to build strategies for a safer treatment system and prevent errors from occurring again. Reports and alerts on MEs are significant for raising the understanding of the risks of these errors and to motivate healthcare organisations to develop their performance (Vincent et al., 2006). Several national healthcare systems and regulatory agencies, for example the Australian Patient Safety Foundation (APSF), NPSA, European Medicines Agency (EMEA), MHRA, Food and Drug Administration (FDA), United States Pharmacopeia (USP) and Joint Commission on the Accreditation of Healthcare Organisations (JCAHO) establish and release these warnings and reports (Crowley, 2006; Montesi & Lechi, 2009; Ameer, 2015)

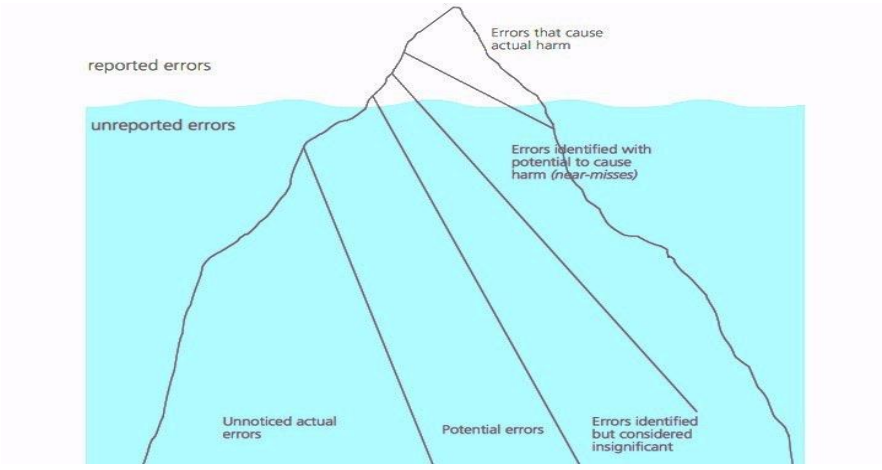


Figure 2.1: The medication error iceberg (adopted from Smith, 2004, p.22)

Several methods have been used to assess and investigate MEs in healthcare systems. The validity and reliability of the approaches used are significant, not just to study MEs however also to assess the efficiency of the strategies applied to minimise the rate of errors. Common methods for detecting MEs include direct observation, chart review and incident reports, interviewing staff providers, and managing medical rounds (Allan & Barker, 1990; Flynn et al., 2002; Thomas & Petersen, 2003; Tully & Franklin, 2015). A less commonly used technique involves urinalysis to examine for the absence of drugs, of the detection of omission errors using returned doses recorded in drug charts (Allan & Barker, 1990; Barker et al., 2002).

2.2 Medication error (ME) detection methods

Incident reports, chart review, and direct observation are the most common techniques used for detecting medication errors (Allan & Barker, 1990). Table 2.1 summarises the ME detection methods described in the literature and documents the advantages and disadvantages of each (adapted from Thomas and Petersen, 2003, p.62 and James, 2009, p.13).

2.2.1 Incident reports

Incident report deliver data from all hospital areas over a long time, in contrast with the observational technique, which offers data from a certain time period and from exclusive areas. However, the incident report technique may be insufficient for the identification of medication errors (Allan & Barker, 1990; Flynn et al., 2002; Thomas & Petersen, 2003, James, 2009). For example, in 2002, Flynn et al. reported that incident reports were less efficient than chart review and direct observation in exploring administration errors. Olsen et al. (2007) conducted a UK study on three different

approaches to explore adverse events (AEs) in the same group of patients. Out of two hundred and eighty eight patient discharges, real-time chart review identified sixty-seven MEs; pharmacy control "active control of admitted patient prescriptions and medicine management" identified thirteen MEs; and incident reporting identified eleven MEs. Three MEs were detected through both pharmacy control and chart review, and one ME was detected by both incident reporting and chart review. This suggests that incidence report were the least effective of those tested and that use of more than one ME detection method increases the validity of the results, as each approach identifies different errors.

2.2.2 Chart review

Chart review is known as a retrospective approach which depends on sources, for example administrative records, prescription data and drug charts, and has been reported to be less effective than direct observation for investigating error rates (Allan & Barker, 1990; Flynn et al., 2002; Montesi & Lechi, 2009, Ameer, 2015). Although it is used to detect prescribing errors, a limitation of chart review is that the documentation in the drug chart may be incomplete. Some errors might not be recorded on charts and may therefore be lost (Thomas & Petersen, 2003). Bates and colleagues described a further factor with respect to the reliability of data in the chart review approach whereby reports in some serious areas, for example Intensive Care Units (ICUs) may include more information than those on other wards, resulting in detection bias. Many studies, which have used chart review, have also employed other data collection approaches. These extra approaches involved requested reports from pharmacy department, optional reports from nurses, analyses of medicine sheets by a trained researcher and incident reports (Bates et al., 1993; Bates, 1995; Morimoto et al., 2010).

2.2.3 Direct observation

Observation has been shown to be the most accurate method for detecting MEs, especially preparation errors, but it is also the most expensive. A study by Flynn and colleagues (2002) in 36 US healthcare facilities investigated three methods of detecting MEs among 2,556 doses. The direct observation technique identified three hundred medication errors (12%; n=300/2556), whereas record review identified seventeen (0.6%; n=17/2556) and incident report analysis stated only one (0.03%; n=1/2556). The mean cost of error identified was much higher for direct observation ($4.8 per dose) compared with chart review ($0.6 per dose). Barker and colleagues stated that the comments collected by the observer were one of the advantages of observational techniques, and could be helpful in classifying the causes related to errors (Barker et al., 2002). A key concern with direct observation is the effect caused by the observer's presence. This is recognised as the reactive effect or the 'Hawthorne effect' (Smith, 2002). The Hawthorne effect advocates that:

> *The presence of the researcher, and the knowledge that the study is taking place, may influence the behaviours of the individuals being observed* (Smith, 2002, p. 168).

This effect has the potential to influence the validity of the research. According to Bowling (2002) and Smith (2002), several strategies can be used to reduce this effect. For example, they suggested that the observer should communicate with participants in the research area before data collection. In addition, to control behavioural changes, the observer needs to collect as much data and present for as long as possible (Bowling, 2002; Smith, 2002). To minimise the impact of the observation on the action of the observed individual, Alan and Barker (1990) also recommend conducting the disguised

observation method developed by Barker and McConnell (1962). Dean and Barber (2001) examined the validity of direct observation in investigating medicine administration errors and investigated the potential impact of observation on medicines administration errors rate by comparing the proportion of omissions documented on non-observation and observation days. The authors reported no change in the proportion of documented omissions between these days, and decided that observing staff during medicine administration at a UK hospital did not significantly impact the percentage of medicine administration errors.

An additional limitation of observational methods is that data gathered are specified to the observed shifts and periods and furthermore even during the observation shift, observation does not normally cover all medications. Most studies describe how more than one participant prepares medications at the same time, while only one or two observers may be present. Hence, some preparations may go undetected. Moreover, in these studies specific wards or units are investigated and therefore may not be representative of all wards or units in all hospitals (Allan & Barker, 1990; Barker et al., 2002). Another issue that has been considered is observer bias, described as:

> *"A system difference between a true situation and that observed owing to variation in perceptions" (i.e. interpretation)* (Bowling, 2002; p.362).

Observer bias can be controlled by good observer training, such as realisation to reporting what really occurred rather than what was supposed to have happened (Bowling, 2002).

Table 2.1: Summary of methods for detecting medication errors (adapted from Thomas and Petersen, 2003, p. 62 and James, 2009, p.13)

Method	Data collection	Incident type	Strengths	Weaknesses
Computerised monitoring	Computer systems screen administrative data and clinical database using pre-programmed criteria. Case note review is undertaken for identified incidents	ADEs and potential ADEs	1. Sensitive 2. Large amount of data obtained for identified incidents 3. Automatic	1. Requires advanced information systems (e.g. electronic patient records) and programming 2. Number of identified incidents depends on the information system links 3. Limited information on potential ADEs
Chart review	Trained reviewers screen patient's chart using pre- defined criteria to identify incidents.	[1]ADEs, [2]ADRs and Medication errors (Mainly [3]PEs and [4]MAEs	1. Large amount of information obtained	1. Costly 2. Time consuming 3. Relies on documentation of incidents in patient's chart 4. Dependent on reviewers' experience and ability to conduct an adequate review 5. Limited information on administration and preparation errors
Voluntary reporting (Incident reports and anonymous reports)	Details of incident reported by staff on standardised forms or in interviews	ADE, potential ADEs, ADRs and medication errors.	1. An ongoing reporting mechanism 2. Anonymity eliminates fear of disciplinary action 3. Inexpensive	1. Reporting requires an awareness of incident occurrence 2. Under-reporting due to fear of disciplinary action 3. Incidents may not be reported if considered harmless or advised against reporting by peer
Critical incident technique	Observation or interviews of staff to identify casual factors	ADEs, potential ADEs and medication errors	1. Detailed information on case incidents	1. Difficult analysis of data 2. Difficult interpretation of data 3. Multiple sources of bias
Litigation claims data	Review of litigation claims	ADEs and medication errors	1. Inexpensive	1. Less sensitive data 2. Limited data

[1]ADE: adverse drug event.[2]ADR: adverse drug reaction[3]PEs: preparation errors [4]MAEs: medicines administration errors

Continued Table 2.1

Method	Data collection	Incident type	Strengths	Weaknesses
Focus group	Multi-disciplinary discussion used to identify major incidents	ADEs, potential ADEs and medication errors	1. Target major issues 2. Rapid identification of Issues in need of addressing 3. Inexpensive	1. Does not address daily events or trends
Pharmacist intervention	Documentation of errors or issues identified and rectified by pharmacists during review of medication charts/case notes	Potential ADEs, ADRs and Medication errors	1. Large amount of information 2. Practical 3. Inexpensive	1. Depends on knowledge and experience of pharmacist 2. Limited information on administrative errors
Patient surveys	Postal surveys, telephone or direct interviews with patients to identify adverse events experienced following period of hospitalisation or outpatients appointment	ADEs, potential ADEs and medication errors	1. Can be used for outpatients 2. Detects incidents not documented in case note	1. Relies on patients awareness of incidence 2. Highly subjective, relying on patient recall 3. Resource intensive
Morbidity and mortality conferences and autopsy	Details of incident reported by healthcare professionals	ADE, potential ADEs, ADRs and medication errors.	1. Can recommend latent failure 2. Familiar to healthcare providers and required by accrediting groups	1. Hindsight bias 2. Reporting bias 3. Focused on diagnostic errors 4. Infrequently and non-randomly utilised
Direct observation	Investigators observe member of staff and document any incidents witnessed	Potential ADEs and medication errors (Mainly preparation and administration)	1. Highly sensitive 2. Large amount of data obtained in a short time 3. Does not rely on awareness of incidents or willingness of staff to report 4. Casual links can be identified	1. Requires trained observer 2. Expensive 3. Time-consuming 4. Presence of observer may influence staff (Hawthorne effect) 5. Observer may misinterpret observation 6. Limited information on prescribing errors

Despite its disadvantages, direct observation is considered the most thorough approach as it is the only method which does not rely on either staff being aware that they have made an error or the error having a consequence which is detectable in some other way. Staff are not usually aware an error has been made, as they intend to carry out procedures correctly, and many errors do not have a consequence that is detectable. Therefore, direct observation was chosen for this study.

2.3 Classification of errors

Numerous approaches of categorisation have been used to categorise medication related errors. For example they have been classified according to the phase of the medication use process (MUP) during which they occur (prescribing, transcribing, dispensing, preparation, administration or monitoring), the type of error (e.g. incorrect drug, incorrect diluent, wrong dose or incorrect expiry date). Alternatively errors can be categorised on the basis of a psychological classification of human errors that focus on the psychological mechanism of the incident rather than its type (i.e. incidents are identified according to whether they are errors, slips, lapses, or violations) (Ferner & Aronson, 2006). The psychological categorisation of Ferner and Aronson is based on Reason's (1990) human error theory and allows for a better understanding of the errors, which helps in developing strategies to prevent them. For example, improving clinicians' knowledge can reduce knowledge-based mistakes and introducing computerised decision support (CDS) tools can reduce rule-based mistakes. Training can help in preventing slips and checklists and computerised systems can help to reduce

lapses. Table 2.2 shows examples of each psychological class of ME, with potential preventive strategies.

Morimoto and colleagues used several standards to identify medication errors and adverse drug events (ADEs). Figure 2.2 shows the authors' categorisation of these errors according to phase (prescribing, transcribing, dispensing, preparation, administration, or monitoring), preventability (preventable or non-preventable MEs) (see Section 1.3.3), severity, individual responsible (e.g., pharmacist or nurse), and ameliorability (ameliorable or non-ameliorable ADE). The authors defined an ameliorable adverse drug events as harm where the severity can be minimised if a treatment is started, while a non-ameliorable adverse drug events is harm where the severity cannot be managed (Morimoto et al., 2004).

In the present study errors classified according types; incidence; severity and underlining causes were addressed.

Table 2.2: Examples of plans/strategies for minimising the incidence of different psychological classes of medication errors (adapted from Ferner and Aronson, 2006, p. 8–9)

Strategy for preventing error	Phase of management (Treatment) procedure	Examples	Strategy
Lapses- Memory-based errors	Agreeing to treat the patient Start to writing the prescription Dispensing the drug Preparing the drug Giving the drug Monitoring the management Modifying or stopping management	Forgetting that the patient is allergic to drug namely (penicillin) Omitting a date on which to stop giving drug Leaving a tablets or bottle on the counter when preparing Forgetting to wipe the rubber septum of a medicine vial Forgetting to check the allergy patient wristband Forgetting to organise a blood clinic appointment	Increased and improved skills training
Slips-Action-based errors	Agreeing to treat the patient Start to writing the prescription Dispensing the drug Preparing the drug Giving the drug Monitoring the management Modifying or stopping management	Absently writing chlorpropamide for chlorpromazine Dispensing 10mg vials of vincristine rather than 1mg vial Mixing up dopamine, not doxapram Injecting into an IVs a drug should to be administered by SC Making a blood clinic appointment for 6 months, not 6 weeks Stopping blood treatment after 6 months for recurrent deep vein thrombosis	1. Improved checking systems to identify slips 2. Improved 'triangulation' when drug, patient and condition are stated 3. Better use of barcodes
Technical slips	Agreeing to treat the patient Start to writing the prescription Dispensing the drug Preparing the drug Giving the drug Monitoring the management Modifying or stopping management	-- Writing illegibly, so that 'Daonil®' (glibenclamide) is dispensed for amoxicillin Dispensing the wrong drug or wrong strength Failing to mix infusion to which potassium was added Giving intravenous injection extravascular Failing to measure blood pressure properly Failing to STOP an intravenous giving set	1. Checklists 2. Computerised reminders 3.'Fail-safe' systems

Continue Table 2.2

Strategy for preventing error	Stage of treatment process	Examples	Strategy
Knowledge-based errors	Agreeing to treat the patient Start to writing the prescription Dispensing the drug Preparing the drug Giving the drug Monitoring the management Modifying or stopping management	Unaware of value of sodium bicarbonate in amitriptyline poisoning Unaware of the interaction between Factor VIII and warfarin Failing to know that chloroform and chloroform water are different Not knowing that Factor VIII dissolve with water Being unaware of the course of the major nerve Taking blood for lithium concentration into a heparin tube, unaware that it contains lithium heparin Continuing after 3 weeks to give amiodarone at the higher dose	1. Improved training 2. Computerised decision-support systems
Rule-based errors: misapplying a good rule	Agreeing to treat the patient Start to writing the prescription Dispensing the drug Preparing the drug Giving the drug Monitoring the management Modifying or stopping management	Starting cardiac massage in a patient who has fainted Prescribing oral treatment in a patient with difficult swallowing Holding needed management while checks are complete - Giving an intramuscular injection of diclofenac into the thigh Taking a blood sample at the time of trough lithium concentration Starting a short course of antivirus management	1. Improved training 2. Computerised decision-support systems
Rule-based errors: applying a bad rule or failing to apply a good rule	Agreeing to treat the patient Start to writing the prescription Dispensing the drug Preparing the drug Giving the drug Monitoring the management Modifying or stopping management	Prescribing Augmentin for sore throats Printing drugs chart without check the allergies Dispensing Augmentin and Amoxicillin together Preparing multi dose vials Not taking Augmentin tablets with water Monitoring for urine level when giving Augmentin Extending antibacterial treatment unnecessarily	Systematic examination of and improvement to rules

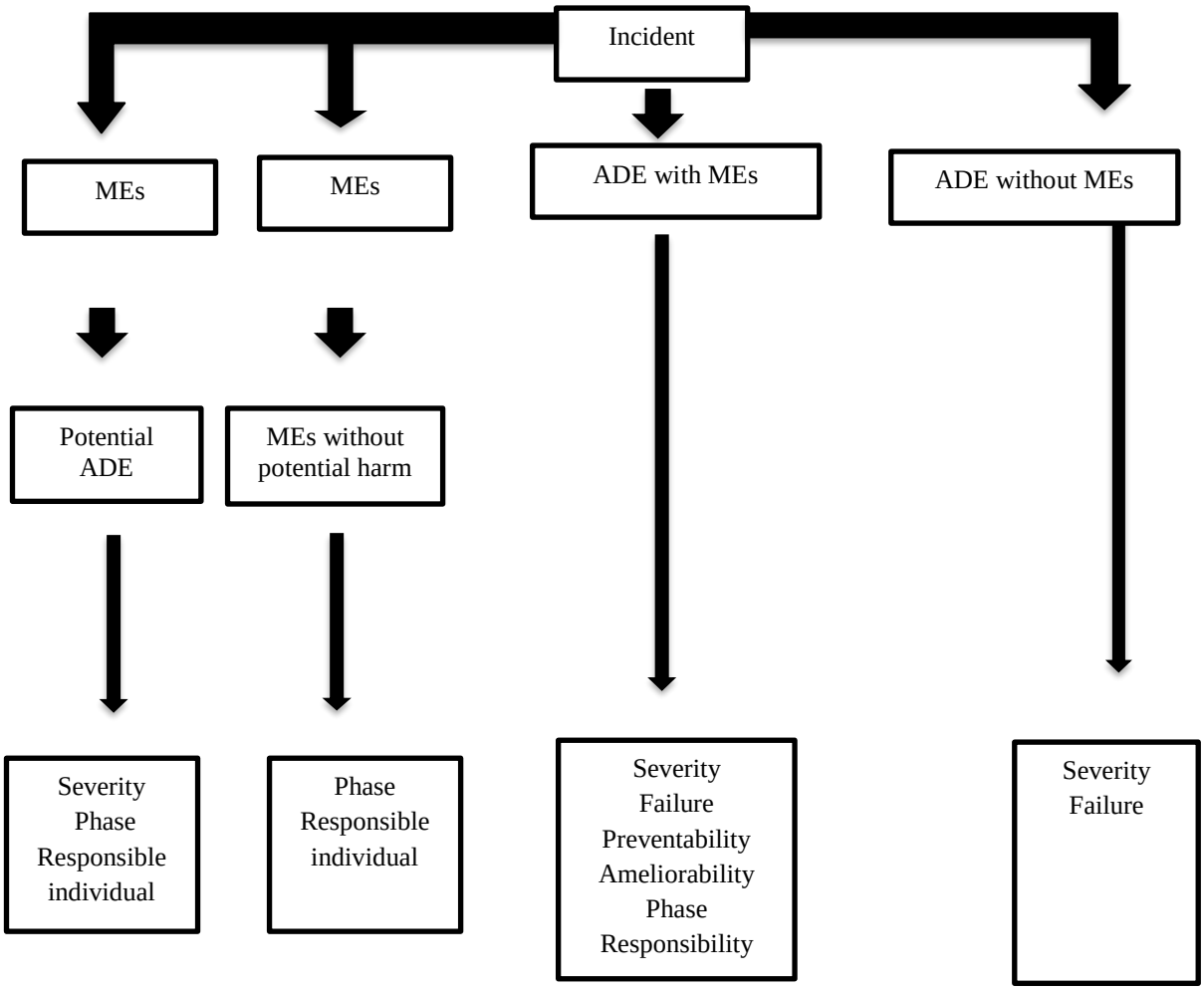


Figure 2.2. A diagram categorising the occurrence of adverse drug events and medication errors (from Morimoto et al., 2004, p. 312)

2.4 Identification of harm

Generally, patient safety incidents (PSIs) are categorised based on their potential clinical significance (harm caused) to patients, however the clinical effect of errors is individual and is according to the knowledge and experience of the researcher (NPSA, 2004). Numerous scales have been established and used to classify the severity of medication safety incidents. In 1999, Dean and Barber developed a validated scale to measure the severity of MEs employing a linear rating scale from zero (no harm) to 10 (death). This scale does not need the investigator to identify the patient outcome and is not influenced

by the healthcare profession of the evaluators (Dean & Barber, 1999). In 2001, the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) established an index of nine classes to grade the severity of medication errors to confirm the reliability of medication error recording (Figure 2.3) (NCC MERP, 2001).

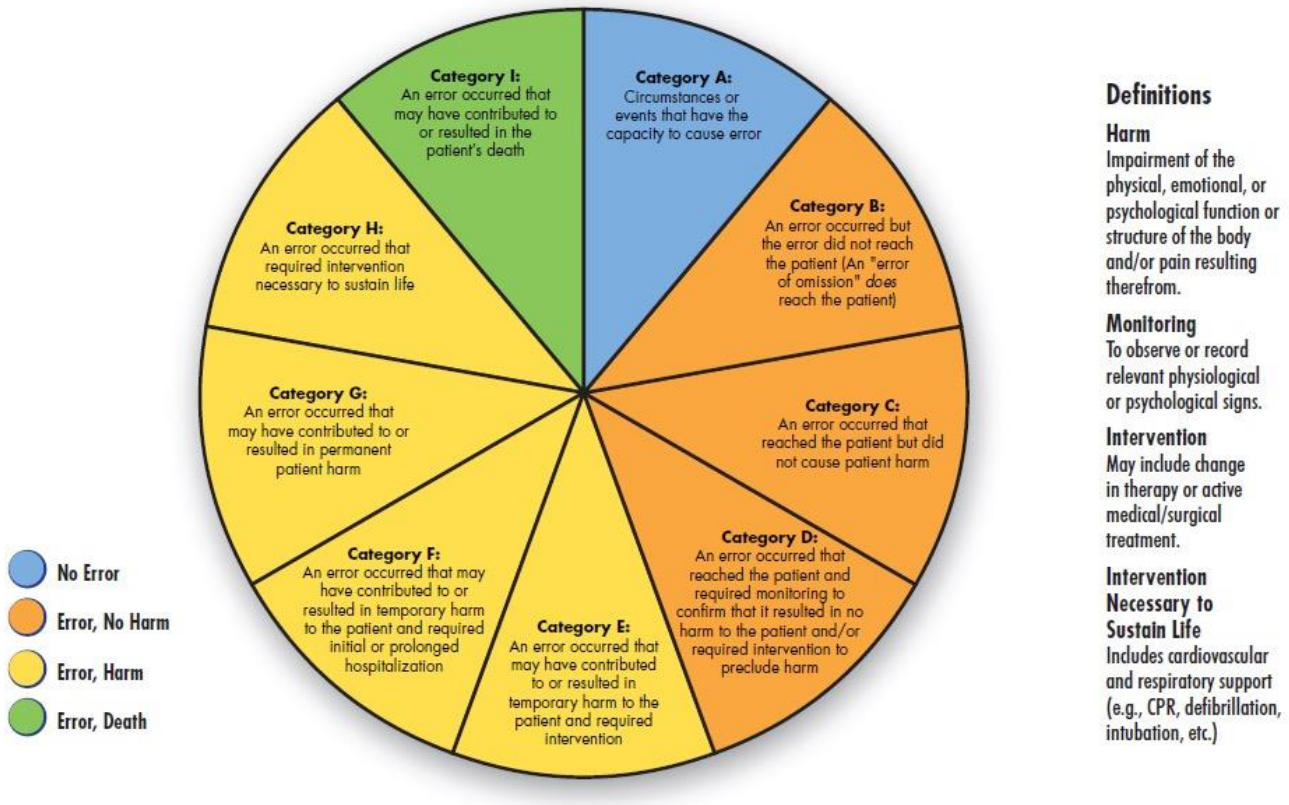


Figure 2.3: Index for classifying medication errors (adapted from NCC MERP, 2001, p.1)

When patient safety incidents are recorded in the National Reporting and Learning System (NRLS), real patient harm is recorded based on the National Patient Safety Agency (NPSA) categorisation of level of harm (NPSA, 2007). Table 2.3 illustrates the National Patient Safety Agency domains and definitions used for categorising the severity of real patient harm.

Table 2.3: National Patient Safety Agency domains and definitions for categorising the severity of patient harm (adapted from NPSA, 2007, p 54).

Domains	NPSA definition
Negligible (No harm)	*"Impact prevented: any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to the person(s) receiving NHS-funded care"* *"Impact not prevented: any patient safety incident that ran to completion but no harm occurred to the person(s) receiving NHS-funded care"*
Minor	*"Any patient safety incident that required extra observation or minor treatment, and caused minimal harm to the person(s) receiving NHS-funded care"*
Moderate	*"Any patient safety incident that resulted in a moderate increase in treatment, and which caused significant but not permanent harm to the person(s) receiving NHS-funded care"*
Major	*"Any patient safety incident that resulted in permanent harm to the person(s) receiving NHS-funded care"*
Death	*"Any patient safety incident that directly resulted in the death of the person(s) receiving NHS-funded care"*

2.4.1 NPSA risk scoring

In 2008, the NPSA established a risk matrix to help evaluate risk in a consistent manner (NPSA, 2008). Errors are studied by merging ratings of consequence (i.e. severity of patient harm) and likelihood (frequency) of recurrence to ascertain the magnitude of a given risk. The examples shown in Table 2.4 describe the consequence of a given severity and assign a value between 1 and 5 to the descriptors.

Table 2.4: Assessment of the severity of the consequence of an identified risk: domains, consequence scores and examples of the score descriptors (adapted from NPSA, 2008, p.7)

Consequence score (severity levels) and examples of descriptors					
	1	**2**	**3**	**4**	**5**
Domains	**Negligible (No harm**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Impact on the safety of patients, staff or public (physical / psychological harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days RIDDOR/agency reportable incident An event which impacts on a small number of patients	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients
Additional examples	Incorrect medication dispensed but not taken Incident resulting in a bruise/graze Delay in routine transport for patient	Wrong drug or dosage administered, with no adverse effects	Wrong drug or dosage administered with potential adverse effects	Wrong drug or dosage administered with adverse effects	Unexpected death

The frequency of each type of error was used to calculate an observed error rate and predict the number of errors likely to occur in one year.

$$\textbf{Observed error rate} = \frac{\text{Number of times a type of error occurred each in unit/ward}}{\text{Total observations in unit/ward}}$$

$$\textbf{Predicted number of errors in one year} = \frac{(\text{Observed error rate} \times \text{Total items prepared in unit/ward}) \times \text{Numbers of working days/year}}{\text{Number of days of observation}}$$

Values obtained for the predicted number of errors in numbers of working days/year (365 in hospital ward and minus weekends and bank holidays =252 for pharmacy units) for each hospital ward and pharmacy unit were mapped on to NPSA frequency descriptors to obtain a likelihood score of 1–5, as presented in Table 2.5.

Table 2.5: Mapping of error frequency into NPSA time frequency description to obtain likelihood score.

NPSA frequency	NPSA descriptor	NPSA likelihood score
Not expected to occur for years	Rare	1
Expected to occur at least annually	Unlikely	2
Expected to occur at least monthly	Possible	3
Expected to occur at least weekly	Likely	4
Expected to occur at least daily	Almost certain	5

The assessment of 'likelihood' means that the probability of a risk happening is ranked from 1 to 5, and the higher the number means the more likely it is that the consequence will occur. Consequence and likelihood scores were multiplied together to calculate a risk score (1-25). This then enabled the risk level of the different types of error to be

determined. Table 2.6 shows the risk matrix as both numerical scoring and colour bandings. A risk management strategy must be used to classify the level at which the risk will be run by the hospital's organisation, gives main concern for corrective action, and determines whether risks are to be accepted on the basis of the colour bandings and/or risk score (NPSA, 2008). According to the clinical consequence of the incident and the likelihood of recurrence, incidents are scored from 1 to 25, where higher scores mean higher incident risk (NPSA, 2008). The advantages of the model risk matrix are presented in Table 2.7.

Table 2.6: Grading risk score by multiplying consequence score and likelihood score (NPSA, 2008).

Risk score	Assigned grades
1-3	Minor risk
4-6	Moderate risk
8-12	High risk
15-25	Extreme risk

Table 2.7: Advantages of the risk matrix (from NPSA, 2008, p. 11).

	Advantage
Risk matrix	It is simple and flexible
	NHS Trusts are familiar with the matrix.
	It is depends on simple mathematical formulae and is easy for use in extra notes.
	If the risk classification is altered, NHS Trusts will still be able to compare scores to monitor risks and confirm they are measured in a comparable condition.
	Four colour bandings for classifying risk that may be useful for some NHS Trusts.

In the present study the validated Dean and Barber (1999) was applied and used to calculate consequence score. This combined with error frequency data to calculate a risk score analogues to that used by NPSA (2008).

2.5 Methodology and study design

2.5.1 Methodology

This research will meet the requirements of Patient Safety Alert 20 promoting the safer use of injectable medicines by undertaking a study of the risks associated with injectable medicine preparation (NPSA, 2007). The researcher (AA) has used direct observation to detect and record injectable drug preparation errors (IPEs) made by staff in pharmacy aseptic units and on hospital wards. A mixed methods approach has been used employing quantitative and qualitative techniques. Quantitative methods measure a phenomenon and produce numerical data, which can be statistically analysed. Qualitative methods assess the meaning of people's experiences. Quantitative data will be analysed to identify the incidence and types of injectable medicine preparation errors. Qualitative research will focus on those who have made errors in order to further explore the causes of injectable medicine preparation errors (Spradley, 1979; Flynn et al. 1997; Limat et al. 2001; Wirtz et al. 2003; Parshuram et al. 2008). Health sciences research has used qualitative methods since 1990. Furthermore, highly respected medical journals such as the British Medical Journal have begun including qualitative studies, which are important for assessing the quality of research (Reynolds et al, 2011). Neergaard and colleagues noted that qualitative description is not meant to be a theory development or the expository meaning of an experience however is:

> *"A rich, straight description of an experience or an event"* (Neergaard et al., 2009; p.2).

Furthermore, whereas quantitative research is useful for identifying types and incidents of errors, qualitative research methods can

> *"Explore the complexity of human behaviour and generate deeper understanding"* (Johnson & Waterfield, 2004; p.121).

2.5.2 Study design

A mixed-methods approach offers several advantages for this project. A quantitative method is useful for identifying the incidence and types of errors made in the preparation of injectable medicines (Flynn et al., 1997; Wirtz et al., 2003; Parshuram et al., 2008). In the Health Sciences, SPSS is the software most commonly used for statistical data analysis and was chosen for this study. SPSS makes it easy to generate frequency tables, bar charts and a variety of other quantitative representations of data that can clarify the frequency of the data and associations between different types of data (Neergaard et al., 2009). A qualitative method allows exploration of the causes of errors in the preparation of injectable products (Flynn et al., 1997; Limat et al., 2001; Wirtz et al., 2003; Parshuram et al. 2008).

A summary of the advantages and disadvantages of the mixed-methods approach is shown in Table 2.8 (Creswell, 2009). Qualitative data will be analysed according to the human error theory, and Reason's model of accident causation.

Table 2.8: A summary of the advantages and disadvantages of the mixed-methods approach (Creswell, J., 2009).

	Advantage	Disadvantage
Mixed- methods Approach	Can account for a broad range of variables, questions, and hypotheses.	Time consuming and expensive.
	Can expand a set of results.	Must have experience in both quantitative and qualitative research.
	Can identify additional research opportunities.	More time spent on analysis.
	Can detect data that may have been missed using only one design.	May be difficult to combine or interpret data.
	Can corroborate previously established results.	Must experiment to achieve the correct mix.

In this investigation, case study methodology has been adopted (Yin, 2009). Yin, defines the case study research method as

> *"An empirical inquiry that investigates a contemporary phenomenon within its real-life context; when the boundaries between phenomenon and context are not clearly evident"* (Yin, 2009.p.18)

Case study design is flexible and is useful for identifying the types, incidents and causes of errors in the preparation of injectable medicines (Creswell, 2009). However, case studies have several weaknesses. For example, obtaining access to an organisation can be difficult (Collis & Hussey, 2009). There can also be difficulty analysing the data because of the huge amount of data collected (Hodkinson, P. & Hodkinson, H., 2001). The advantages of the case study design are that they often produce unexpected results and can produce in-depth understanding of the theoretical framework of this research (Hodkinson, P., & Hodkinson, H., 2001).

2.5.3 Ethical approval

Ethical approval for this investigation was obtained according to the University of Bath's Research Ethics policy (Appendix1). Details of ethical approval obtained for this study are documented in chapter three and five.

2.5.4 Data Storage

Data collection forms were stored in a locked filing cabinet at the University of Bath and according to the rules of the National Data Guardian for Health and Care in the UK (2016); the results will be kept for five years. These data do not contain any personal information and will be kept strictly confidential.

2.6 Quantitative study

2.6.1 Direct observation (overview)

Direct observation was used to identify the types and incidence of internal and external errors occurring during the preparation of injectable drugs. Observation is the gold standard method for identifying medication errors (Allan & Barker. 1990; Flynn et al. 1997; Smith. 2002; Parshuram et al. 2008). Observational approaches have been used previously in healthcare sites and in regard to medication preparation (Carthey, 2003) (see section 2.2.3). This study used an observation schedule to guide the data collection from directly observed staff in the preparation of injectable drugs. In a quantitative observation at study:

> *"The researcher observes and records activities and/or interactions to provide numeric frequencies of these different activities, often possibly with the intention of investigating relationships between them and/or generalising the findings to a wider population" (*Smith, 2002; p.l61).

Direct observation is a valuable tool, which enables investigators to record actual events, instead of trusting reports that might not accurately represent what has been happening (Allen & Barker, 1990; Dean & Barber, 2001; Bowling, 2002; Smith, 2002; Carthey, 2003; Bryman, 2004), as has been the method previously (Hoppe–Tichy et al., 2002; Crowley, 2006). The study participants might feel under pressure, or uncomfortable about being observed when preparing injectable medicines. However, study participants who felt uncomfortable or stressed are unlikely to consent to participate in research. Throughout the data collection process, and with participants' consent, the investigator watched, but did not interrupt, nursing staff as they prepared injectable drugs (see section 2.2.3).

There are several other methods used to detect errors during the preparation of injectable medicines, which are not presented in this project because it doesn't fit the research objectives (Table 2.9). Moreover, the weaknesses of these methods justified, why they were not chosen (Flynn & Barker, 2007).

Table 2.9: Quantitative Methods for detecting medication errors (from Flynn & Barker, 2007).

Method	Strengths	Weaknesses
Telephone survey	1. Suitable for low literacy groups. 2. Findings can be getting quickly	1. Needs list of phone numbers. 2. Response rates often low. 3. Questionnaire needs to be brief.
Postal survey (Self-completion)	1. Can reach large numbers. 2. Questionnaires can be fairly long and detailed. 3. Inexpensive	1. Not appropriate for non-English speakers except if translation service available. 2. Needs expertise in use of statistical package for analysis. 3. Time-consuming.
Critical incident technique By Participant observation	1. Helpful to determine cause of mistakes. 2. Useful aiming of main problems	1. Very large sample required. 2. Data interpretation difficult.
Chart review	1. Best detection often used in the studies of Adverse Drug Events. 3. Clinical significance of injectable medication errors.	1. Expensive method. 2. Time consuming.
Computerised surveillance	1. Inexpensive. 2. Reasonably sensitive.	1. Dependent upon technology in use. 2. Needs an electronic prescribing and electronic patient data system to be available.

In order to identify risk reduction strategies, it is important to have a complete understanding of the types of errors occurring in a health care setting. Therefore, this project used the direct observation method, as it enables the researcher to record real events rather than trusting reports that might not completely and accurately represent all errors (Allen & Barker, 1990; Dean & Barber, 2001; Bowling, 2002; Smith, 2002; Carthey, 2003; Bryman, 2004). The advantages and disadvantages of using non-participant direct observation are summarised in Table 2.10.

Table 2.10: A summary of the advantages and disadvantages of using direct observation (Allen & Barker, 1990; Dean & Barber, 2001; Bowling, 2002; Smith, 2002; Carthey, 2003; Bryman, 2004).

	Advantage	Disadvantage
Direct observation	Enables capture of events as they occur.	Expensive and fatiguing; need to maintain attention for long periods.
	More reliable and valid than self- reporting.	Assigning skills and transferring knowledge from the staff to the observer can be challenging.
	Independent of willingness to report incidents.	Observer should be existing where can observe all needed data.
	High response rate with single observer.	Participant may change his/her behaviour if the research topic is sensitive.
	Does not rely on memory.	Bias may present by the project procedure or observer presence.
	Allows detection of errors, where staff might be unaware.	Observer's personal and interpersonal attributes are also importance, namely (preserving a fair blame culture).
	High response rate with single observer	Less response rates are achieved where the presence of the observer is (in disturbing or breakdown activities).

2.6.2 Assessment of severity (Overview)

Injectable preparation errors (IPEs) occur frequently and they are the type of medication error most likely to outcome in serious injury and death (NPSA, 2009). Direct observational studies in the pharmacy environment estimated preparation error rates of around 0.12% to 8.6% (Escoms et al., 1996; Flynn et al., 1997; Limat et al., 2001; Sacks et al., 2009; Bateman & Donyai, 2010; Serrano-Fabia et al., 2010; Ranchon et al., 2011) with drugs prepared for patients. A small percentage of these errors will result in serious harm outcomes, and even minor errors can be responsible for long-term impact on patients (Taxis and Barber, 2003 and Bateman & Donyai, 2010). Injectable drugs pose specific risks; this is due to their higher complexity and the several phases needed for their preparation, administration and monitoring. Relatively limited investigations have particularly concentrated on injectable error rates in hospital wards, although those

available do verify allegations that error rates are as high as 49%; 48%; 69% and 39.7% (Taxis and Barber, 2003; Taxis and Barber, 2004; Cousins et al., 2005; Crowley, 2006).

An exception is one UK study, which reported no errors detected during the injectable preparation/compounding process in a regional paediatric centre (Naurla et al., 2011). Severe patient outcomes are considered to be over represented among injectable errors when compared with other adverse incidents (Leape et al., 1995). In the UK in 2007, more than 60% of voluntarily reported incidents worldwide that led to death or severe patient harm involved injectable drugs (NPSA, 2009). Studies from the US also explained that injectable medication errors produce a significantly higher rate of correlated deaths than other medication errors (Phillips et al., 2001).

A detailed investigation has been conducted to assess the specific types of errors reported in relation to injectable medicines, in particular those triggering the most severe outcomes. This thesis aimed to investigate the incidence, type, causes and severity of IPEs in pharmacy and hospital environments to classify strategies for minimising the risk of IPEs occurring in the both of these environments.

2.6.3 Research Method

Severity data was obtained following completion of questionnaires. A questionnaire is a data collection approach requiring participants to answer questions offered in a form layout (Bryman, 2012). This method was chosen as an alternative to the Delphi method. The Delphi technique is a group communication procedure used when conducting detailed investigations about specific subjects for the purpose of policy investigation,

aim setting, or when expecting the occurrence of upcoming incidents (Ulschak, 1983; Turoff & Hiltz, 1996; Ludwig, 1997).

The Delphi technique offers a thorough and rigorous analysis of panel members' views, but in practice it can be challenging to arrange to meet all panel members in the same setting at the same time, and the data is also subject to researcher bias and a poor response rate (Beretta, 1996; Mead & Moseley, 2001; Hsu & Sandford, 2007).

Thus, for this research, a self-completed questionnaire delivered via email was selected as the method most likely to meet the research objectives. Table 2.11 describes a number of advantages associated with the self-completion questionnaire method.

Table 2.11: Advantages of the self-completion questionnaire method (Bowling, 2009).

	Advantage
Self-completion questionnaire delivered via email	Self-completion questionnaires delivered via email are being used increasingly in healthcare practice so participants will be aware with the format and understanding of this method
	Reduce risk of changing behaviour and bias by researcher Participants will be able to express their opinions without interference from the researcher or other participants.
	Participants will have time to consider their answers.
	Does not require the presence of the researcher with the participant.
	Does not distract the participants from their usual duties and responsibilities.
	Standardised collection of responses that ensures consistency and can be repeated at a later date.
	Self-completion questionnaires delivered via email are inexpensive
	Self-completion questionnaires represent a large number of responses, so assembly the results will be more representative.

2.6.4 Development of the questionnaire

This research employs a visual analogue scale to rank the severity of medication errors. This is simple to use and is a tool familiar to the majority of healthcare professionals (Dean & Barber, 1999; Taxis & Barber, 2002) (see section 2.4). This approach of measuring the potential for severity was used previously by the General Medical Council for prescribing errors in primary care settings (Avery et al., 2012). It was initially developed by Dean and Barber (1999) to measure the severity of medication errors in the absence of knowledge about patient outcomes. This approach of measuring potential severity was selected here, since it was found to be both valid and credible (Taxis & Barber, 2003; Ameer, 2015). Dean and Barber (1999) suggested that, scoring severity using a panel of at least four experienced healthcare professionals provides a reliable severity index. In June 2016, a pilot study was conducted by an experienced hospital pharmacist to assess how easy the questionnaires were to complete, how long it took to complete them, and whether any improvements could be made in pharmacy aseptic units (questionnaire A) and in hospital wards (questionnaire B). A minor modification was subsequently made to optimise the panel response data and in July 2016, the final questionnaires were ready for distribution in pharmacy aseptic units (questionnaire A) and in hospital wards (questionnaire B).

2.6.5. Selection of Severity panel

This study employed an independent panel technique to collect the opinions of healthcare professionals via self-completed questionnaires delivered by email. The panel comprised five experts: two physicians (a general physician and an oncologist), two pharmacists (a clinical pharmacist and an aseptic pharmacist), and one senior nurse.

The research team chose the panel based on its area of clinical expertise. Each member was invited to complete the questionnaire independently, for observations previously reported as errors in pharmacy aseptic units (questionnaire A) (Appendix 2) and in hospital wards (questionnaire B) (Appendix 2). Each panel members was sent an email requesting their participation in the study. The email gave an overview of what they would be expected to do and what they might be expected to be paid for their time. Each panel member was given a description of the errors observed, and asked to agree or disagree about whether these were indeed errors, using a definition adapted from a previous study (Crowley, 2006). When three or more of the five judges agreed consensus was considered to have been achieved (Ameer, 2015). The participants were then asked to rank the severity of each IPE in terms of its potential to cause clinical harm to a patient on a scale of zero to ten: A mean score between 0.5 and 3.4 indicates a minor level of harm, a score between 3.5 and 6.4 a moderate level of harm, and a score between 6.5 and 9.4 a major level of harm; a score of ≥9.5 indicates potential for death (NPSA, 2008). As none of the errors recorded previously have been disclosed to the patient, the consequences of these errors was unknown. However, a small number of the errors (approximately 10% of the total) (wrong calculation, wrong dose, wrong diluent and faulty labelling) with known patient outcomes were included (NPSA, 2007) to validate the method. The panel members were not made aware of which these errors were. This is a well-established method for obtaining data concerning the severity of an error (Dean & Baber, 1999; Taxis & Barber, 2002; Avery et al., 2012; Ameer, 2015) (see section 2.4).

2.6.6 Data collection

Panel members, who had agreed to participate in the study, were sent a full protocol and questionnaire (Appendix 2); contact details for the research team were also provided in case the participants had any questions. The questionnaire was anticipated to take approximately two hours to complete. The panel members returned their completed questionnaire to the researcher via email within a two-week time frame. On receipt of the completed questionnaires, the panel members received a £50 gift voucher of their choice. The responses were kept confidential to prevent the disclosure of information that could be linked to individual participants.

2.6.7 Data Analysis

This thesis used a validated scale to measure potential clinical harm arising from errors when preparing injectable drugs (Dean & Baber, 1999; Taxis & Barber, 2002; Avery et al., 2012). Before the questionnaires were sent to each healthcare professional, the supervisors (JL; MJ) checked the descriptors for each error very carefully. A coding framework was developed for the severity questionnaire, and the questionnaire data was entered into a Microsoft Excel 2007 Worksheet (Microsoft, Redmond, Washington, US) by the researcher (AA) for analysis. All the data was subsequently double-checked by the researcher to ensure its accuracy on a second occasion. Data extracts from the questionnaires were used to validate whether observations previously reported as errors were indeed errors, and to ascertain the severity of the errors previously reported. Validation of errors was considered to have occurred when three out of the five panel members acknowledged them. If any of the observations previously reported as errors

were deemed not to be errors by three or more panel members, then a new error rate would be calculated according to the following equation (Allan and Barker 1990):

Number of new internal errors × 100 / Number of observations

The mean panel severity score was calculated from scores provided by each of the panel members and then used as an index of severity. If a panel member stated that an incident was not an error, it was assumed they would give it a severity score of zero. A Kruskall-Wallis test was used to identify any significant differences between the severity scores for the different units or wards; a p value = $p<0.05$ was considered statistically significant. After this, Mann-Whitney U-tests were used to compare the median severity scores assigned to the three pharmacy aseptic units and the four hospital wards. As this involved multiple comparisons, a Bonferroni correction was applied, using a significance threshold of <0.017. Mean severity scores and error frequency data for a range of different error types from three aseptic pharmacy units and four hospital wards were then used to determine consequence and likelihood scores, in order to assign an overall risk score that would be analogous to that used by the National Patient Safety Agency (NPSA, 2008) to help prioritise which types of errors to focus on in order to develop risk reduction strategies. Mean severity scores were then mapped to consequence descriptors as follows: Mean severity scores of <0.5 = negligible; 0.5–3.4 = minor; 3.5–6.4 = moderate; 6.5–9.4 = major and ≥9.5 = catastrophic. Each of these consequence descriptors was then associated with a consequence score ranging from 1 (negligible) to 5 (catastrophic). Error frequency data were mapped to NPSA likelihood grades (1 to 5) using already determined NPSA timeframe descriptors of frequency (NPSA, 2008) (see section 2.4.1).

The risk score was calculated for each category of medication error observed. This was done by multiplying the consequence score by the likelihood score. Those panel members responsible for ranking the severity of each IPE verified the final mapping score. The five panel members agreed the approach is reasonable and confirmed that it is easy to assess from the description which of the five fields the error falls into (see section 2.4.1).

2.7 Qualitative study (interview method)

2.7.1 Methodology and study design

The interview is the most usual approach applied in qualitative study (Bryman, 2012). Interviews must be comprehensive and thorough, and should also provide details relating to the research topic (Rubin & Rubin 2011). This research adopted a semi-structured (face-to-face) interview model. According to Creswell (2009), there are four types of interviews: face-to-face, by telephone, by focus group, and by email. Semi-structured interviews have been usually used in health-services study to discover the causes of errors because they allow individuals to describe in their own words how such errors occurred (Creswell, 2009).

In the present study, semi-structured interviews were conducted by the researcher (AA) with pharmacists and nursing staff engaged in internal errors to explore their cause. It is important with this type of interviewing to listen to the participants' opinions about what is important. The aim is to collect rich data about the topic being researched (Bryman, 2012).

The advantage of this type of interview is that it does not rely on specific questions; it is open-ended, concentrates on specific information and actions rather than simply the opinion of the interviewee (King, 2004).

The principal disadvantage of this type of interview, however, is that it is time consuming to develop, conduct, and analyse (King, 2004). Different types of qualitative medication-error detection methods are available with known strengths and weakness; these were summarised by Flynn and Barker, as shown in Table 2.12 (Flynn & Barker, 2007). Weaknesses in these methods justified why they were not chosen for this project (Table 2.12). The topic guide of interview was based on literature and aims of study. The current study employed semi-structured interviews with participants who had been previously observed making one of more errors.

Table 2.12: Qualitative methods for detecting medication errors (from Flynn & Barker, 2007).

Method	Strengths	Weaknesses
Discovery interviews (Recording staff stories)	1. Increase understanding among staff	1. Interviewers must be trained. 2. Problems with interviewee bias. 3. Data analysis is time consuming.
Focus groups	1. A details information of data on experiences and their effect on Staff	1. Researcher needs training. 2. Responses can be effected by more controller persons. 3. Data analysis is time consuming
Web-based comments (free text)	1. Let's staff to write any feedback they want to about the injectable drugs they have prepared. 2. Respondents can be asked to give their views about specific topics. 3. Responses are available for others to read.	1. Not appropriate for staff members that do not have Internet free access. 2. Places must be controlled to prevent unwanted comments.
Staff diaries	1. Can be used to collect comment on staff's journey. 2. Can be used for informal comments	1. Sites a heavy load on staff to record relevant information. 2. Allows producing huge data that is hard to analyse.
Complaints and compliments	1. All Trusts receive some of these, so they can be analysed to identify specific incidents and general trends.	1. Many staff do not make formal complaints, even when things go wrong. 2. Compliments are often given but not in writing.

2.7.2 Data analysis

The objective of the data analysis was to clarify the meaning present by reviewing the transcripts of the interviews. In addition, the analysis phase includes targeted activities designed to comprehend a massive amount of qualitative data (Creswell, 2013). First the data set for analysis was established, and then the in depth data analysis was conducted, before finally the results written up. There are several data analysis methods,

such as thematic analysis of data, interpretative phenomenological analysis, grounded theory and pattern-based discourse analysis (Braun and Clarke, 2013). There are variances present when analysing, describing and interpreting data. The data analysis phase focuses on the inter-relatedness of data and questions, answering the question: "How do things work?" Description of data mostly tackles the question: "What is going on here?" Interpretation of the data answers questions correlated to meaning and context, for example: "What does it all mean?" and "What is to be made of it all?" (Wolcott, 1994; Braun and Clarke, 2006).

2.7.3 Qualitative data analysis methods

There are two techniques employed when approaching study; these are either inductive or deductive (theoretical). When employing an inductive method, the investigator gathers specific data and use it to build a new theoretical framework this can be viewed as transferring from the specific to general. On the other hand, when employing deductive approach the investigator uses a current theory to design a study for data collection and data analysis; this can be viewed as transferring from the general to the specific (Braun and Clarke, 2013). The present study employed the deductive method using Reason's accident causation model as a theoretical framework (Reason, 1990; Ritchie & Spencer, 2002) (see section 2.7.5) to build strategies to reduce the risk of repeated IPEs in the pharmacy environment and on hospital wards.

Before conducting the analysis for this research the most common analytical methods in health research were evaluated. These include: interpretative phenomenological analysis, grounded theory, narrative analysis, discourse analysis, and thematic analysis (Ryan & Bernard, 2008; Creswell, 2013; Braun and Clarke, 2013).

Interpretative phenomenological analysis, involves making a comprehensive investigation of the participant's life-context; this includes exploring their personal experiences, and is concerned with the individual's personal insight or account of a special event (Braun and Clarke, 2013). This thesis avoids the method of interpretative phenomenological analysis, which can only be used to answer research questions about experience and experiential self-report data.

Grounded theory is created from the data itself; the data is systematically collected and analysed during the research process. When conducting a grounded approach, the researcher examines theories as they arise in relation to one another. It is an associative process that targets the generation of theory from data, meaning that data collection and analysis are often intertwined (Ryan & Bernard, 2008; Bryman, 2012). The investigator becomes grounded in the data and generates concepts and answers to explain how the study issues appearances (Ryan & Bernard, 2008). This research avoided grounded theory as an analytical method because of the significance of the related published literature, which the investigator felt required to be read and understood prior to the data collection phase, particularly as it concerns the subject of types, incidence, and the causes of IPEs in the pharmacy environment and on hospital wards. This is essentially a deductive study, in which the published literature plays an important part in mapping the questions asked during the data collection and analysis phases.

Narrative analysis usually examines experience across a specified time frame. Introducing events in story form can be useful for investigators, because stories convey meaning. Meaning is attained by understanding how incidents connect in their original form, not just when running the processes of coding and classification, as with other analytical methods. Every story has a start, middle, and end point, and goals to explain

the participants' lives, as well as the features of the story, such as its meaning, consequences, and total outcome (Creswell, 2013; Braun and Clarke, 2013). This thesis avoided using narrative analysis, because the investigator was asking for a technique that offers a systematic data analysis process.

Discourse analysis focuses on speech patterns, the frequencies of these patterns and their implications. Discourse analysis is the analysis of language that answers questions about why and how language is used in a specific setting. It aims to classify how discourse not only explains the social world but also how it creates or modifies it (Braun and Clarke, 2013). This method was also avoided, as discourse analysis would not deliver the data in a format that provides a firm understanding of types, incidence and causes of IPEs in the pharmacy and hospital environment. Thematic analysis is a qualitative descriptive method of data analysis that is commonly used in qualitative healthcare research (Crowley, 2006; Gale et al. 2013; Vaismoradi et al. 2013; Ameer, 2015). Thematic analysis is "a method for identifying, analysing and reporting patterns (themes) within data" (Braun and Clarke 2006, p.79). A framework approach is some themes employed to thematically analyse face-to-face interview transcripts (Gale et al. 2013). It also stresses the importance of not disregarding previous studies when coding answers. It should be noted that theoretical framework analysis is not content analysis. Content analysis shows results in a quantitative way and was used to calculate the number of code recurrences to ascertain the most common causes of errors (Lawton et al., 2012).

This thesis used thematic analysis, because by identifying multiple themes and codes, it permits an in-depth analysis of the data collected from interviews. It is not difficult to follow, flexible, and involves the numerous details experienced by the qualitative investigator during the data analysis. All these qualities supported the investigator's

choice to follow and use this method of qualitative data analysis. The strengths and weaknesses of using thematic analysis are summarised in Table 2.13. Moreover, different data analysis techniques are available, revealing strengths and weakness; these were presented by Braun and Clarke, as shown in Table 2.14 (Braun and Clarke, 2013).

Table 2.13: Strengths and weaknesses of thematic analysis from (Braun and Clarke, 2013. p180).

Method	Strengths	Weaknesses
Thematic analysis	Easy and flexible in phrase of theoretical framework, study objectives, approaches of data collection and sample size	Flexibility makes it difficult to focus on what phase of the data to concentrate on
	Comparatively easy and quick technique to learn, and perform	Limited interpretive power in an analysis excludes the theoretical framework
	Can helpfully summarise the significant characters of a large sample of data, and deliver a strong description of the data set	Difficult to provide a meaning of connection across data including personal information
	Allows highlighting the similarities and differences across the data arranged	Does not let investigators make claims about language use
	Allows for social interpretations as well as psychological data	
	Findings are mostly accessible to educated members of the general public	
	Can be helpful for creating qualitative analyses appropriate for updating policy development	

Table 2.14: Summary methods for qualitative data analysis (from Braun and Clarke, 2013.p183-198)

Method	Strengths	Weaknesses
Interpretative phenomenological analysis	**1.** Accessible technique for novice qualitative studies. **2.** A standard that resonates strongly with a common sense knowing of what it means to be human and how we experience ourselves. **3.** **3**. Allows a focus on personal experience and the details of that experience.	**1.** Because of the double focus on personal cases and themes across cases, it can lack the depth and richness of substantive thematic analysis. **2.** Lack of theoretical flexibility of thematic analysis. **3.** The lack of clarity in the role of the social cultural context. **4.** Lack of real guidance about higher-level (interpretative) analysis and analysis that is often limited to simply describing participants' concerns.
Grounded theory	**1.** Different forms of grounded theory to suit different theoretical frameworks. **2.** A valuable technique for studies interested in social psychology process (rather than individual experiences). **3.** Several grounded theory procedures such as line-by-line coding and memo writing, which are suitable with almost any kind of qualitative analysis.	**1.** There are so many versions of grounded theory and so many different sets of guidance for doing grounded theory not to mention different terminology that it can be difficult to know where to start. **2.** Some versions of grounded theory procedures are inexplicably complex. **3.** Exhaustive process **4.** Reviewing the literature without developing assumptions. **5.** Limited generalisability.
Narrative analysis	**1.** Ability to reveal the temporal, emotional and contextual facets of lives, to illuminate experience. **2.** Helps others to understand topics by telling stories. **3.** Captures everyday new data.	**1.** Participants might fake the data. **2.** Has no method in the sense of a canonical sequence of prescribed steps to be followed. **3.** No claims are made to have discovered human reality through method.
Discourse analysis	**1.** They take language seriously, treating it as more than simply information transfer. **2.** Several different phases to fit different of topics and research questions. **3.** They provide exciting possibility for understanding the social contexts in and which person psychological life is produced.	**1.** Need to fully understand the theoretical frameworks that discourse analysis relies upon; these can be very complex and take a long time to comprehend (time consuming). **2.** Lack of clear guidance. **3.** Does not produce analysis that can be easily applied to research.

2.7.4 Braun and Clarke thematic analysis

Braun and Clarke (2013) presented a systematic method of thematic analysis involving seven stages. It begins with organising and planning data for analysis. This stage comprises activities such as writing up the collected data, e.g. transcribing interviews. Second, the investigator reads the data obtained to establish an overall impression of what the participant has said. Third, the analysis phase begins by coding the data. Braun and Clarke (2013) explained coding as a procedure of assembling and placing data into units of text before describing the meaning of those units. These units of information have to be gathered into categories and labelled according to the participants' explanations about them. Fourth, the coding produces themes for analysis. Fifth, the process of re-examining themes, creating a map of the temporary themes and substances, and defining the relationships between them. Sixth, stating and naming themes. Seven, interpreting the meaning of the data (writing and finalising the analysis).

This analytical technique was explained by Braun and Clarke (2013) who provided an in-depth description of how thematic analysis is achieved. It is not difficult to follow, flexible, and incorporates numerous details met by qualitative studies during the data analysis phase. All these issues motivated the investigator (AA) choice to follow and employ this method. The following processes, as described by Braun and Clarke (2013) were followed when analysing the data as follows:

1. ***Transcribing the interviews:*** Anonymised audio recordings were transcribed verbatim and checked against the recordings and the investigator's written notes. All the transcripts were then read and double-checked against the recordings by two of the three supervisors (JL; MJ; LJ) who made the necessary modifications

to the written transcripts to confirm whether all the recordings were correctly transcribed.

2. ***Familiarisation with interviews:*** Familiarisation was attained by listening and re-listening to the audio recordings and reading the transcripts and any written notes, to create preliminary thoughts. The process was repeated as many items as necessary.
3. ***Coding and complete; across entire dataset:*** Interviews transcripts were assigned different codes and each unit of the text appointed a related code. These codes were revised by analysing the remaining interviews it required to ensure the data would not be ignored; further added another code under each theme for data that did not fit the code.
4. ***Searching for themes:*** Themes were extracted from the theoretical model namely (active failure; error producing condition and latent condition). Codes were then associated with the most appropriate theme based on the interview data and theoretical description.
5. ***Re-examining themes:*** The created themes were double checked to measure whether they bring into line with coded texts from the entire dataset. The developed framework or thematic map was revised as essential by either merging or gathering together codes.
6. ***Labelling and naming themes:*** At this phase of the analysis, the details of each theme were revised and each theme was labelled and given a name.
7. ***Writing the results:*** Writing up the findings of all the earlier phases was the final phase of the data analysis. This phase was considered a final chance to analyse the data, as the data pulled out from the interviews was interpreted and linked

back to the study objectives and the published literature (Braun and Clarke, 2013).

In this thesis the respondents' transcripts were coded manually. This process was employed to double check the validity of the themes as they developed. NVivo may have been useful, but all forms of data analysis have weaknesses. According to Ishak and Bakar (2012, p.102):

> *"NVivo is just another set of tools that will assist a researcher in undertaking an analysis of qualitative data. However, regardless of the type of software being used, the researcher has to dutifully make sense of all the data him or herself, without damaging the context of the phenomenon being studied. Inevitably, the software cannot replace the wisdom that the researcher brings into the research because at the back of every researcher's mind lies his or her life history that will influence the way he or she sees and interpret the world".*

Therefore, it was decided to check the data analysis manually during the study analysis to enhance the reliability and validity of the results. Before interpreting the results, the analysis was validated by the research supervisors (JL; MJ; LJ).

2.7.5 Theoretical Framework

A theoretical framework has been employed to guide data collection and analysis. In the late 1980s, numerous studies investigated the human and organisational factors that affect safety in healthcare settings. The first investigations focused on the work of ICUs and anaesthetists (Reason, 1995). After some time, the significance of human factors increased throughout various healthcare systems and multiple therapeutic specialities (Vincent et al., 1993; Vincent et al., 1998; Taylor-Adams & Vincent, 2004; Vincent, 2004; Cornish & Jones, 2012). Human Factors in healthcare settings stated as:

> *"Enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities and application of that knowledge in clinical settings"* (Catchpole, 2010. p. 3).

System-factor errors are a result of the conditions under which individuals work. Individual factor errors are deeply integrated within healthcare but by studying a systems approach it is possible to build in defences to prevent mistakes or reduce their impact. The most common MEs were found to result from failures in systems with which clinicians work (Cohen & Shastay, 2008). This view, whereby mistakes mostly result from system failures and not from individual negligence, has become essential to the development of new strategies for addressing safety in healthcare (Leape et al., 2002). System-factor errors are related to the environment where the work is performed and are linked to the understanding that people are not unfailing; as human beings, they will make mistakes, even in the most safety-conscious organisations. Furthermore, the individual condition cannot be altered, but the setting or culture in which individuals work can be (Reason, 2000). The NPSA has chosen to use a system approach to medicines safety (NPSA, 2003). Taxis and Barber analysed the causes of identified injectable MEs using human error theory as a framework (Taxis & Barber, 2003) and found that injectable medicine errors were caused not only by individuals' actions but also by organisational and managerial factors, including training. Reason hypotheses that human error is the result of one or more levels of failure. For this thesis Reason's accident causation model was used as the theoretical framework (Reason, 1990; Ritchie & Spencer, 2002) because of the following:

1. It detects accident causation at different levels of the organisation.
2. It does not blame individuals (Dekker, 2003).

An influential model of accident causation is Reason's Swiss cheese model. In this model, healthcare, with its natural protections, is likened to slices of Swiss cheese, and each slice is associated with a defence or barrier that protects the patient from mistakes. Whilst these barriers are normally effective, there are defects, which appear as holes of altered forms and ranges in different locations in the cheese at altered periods of time. A hole in one slice of Swiss cheese is not an issue but when holes in several slices align as shown in Figure 2.4, then an opportunity for error arises (Reason, 1990; Ritchie & Spencer, 2002).

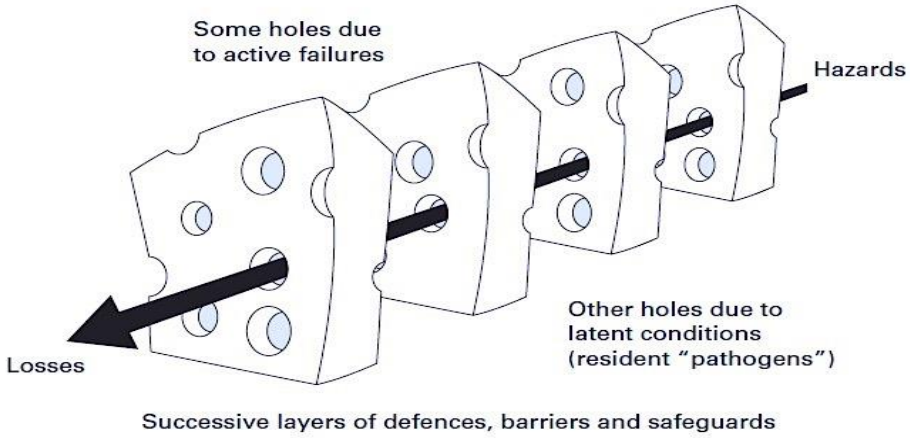


Figure 2.4. Reason's Swiss cheese error causation model (adapted from Reason 2001, p.ii21)

Based on Reason (2000) the holes in the Swiss cheese model start from active failures and latent conditions. Active failures are defined as:

> *"Unsafe acts committed by people who are in direct contact with the patient or system. They take a variety of forms: slips, lapses, fumbles, mistakes and procedural violations. Active failures have a direct and usually short-lived impact on the integrity of the defences"* (Reason, 2000, p. 769).

Active failures can occur in different ways (Anon, 2006):

1. Errors arising from a lack of or slip in concentration
2. Lapses caused by a 'faulty memory'

3. Errors, one of these two: rule-factor, where rules are forgotten or confused, or memory-factor, correlated with a lack of education or training (knowledge factor)
4. Violations that deliberately ignore rules

Latent conditions result from management decisions and are defined as

"The inevitable 'resident pathogens' within the system" (Reason, 2000, p.769).

Latent conditions produce two types of adverse effect:

1. They can cause error-producing conditions (EPCs) within the local workplace. These are situations, which increase the probability of an error. Examples include too few staff members (overworked), staff fatigue at work and time pressure.
2. They can lead to weaknesses in the system's defences, for example, equipment failure and non-applicable procedures (Taylor-Adams et al., 1999).

Latent conditions that have the potential to lead to failure may not be discovered for many years until alignment with an error-producing condition and an active failure results in an accident (Reason, 2000). However, there is a limitation to this theory, as it assumes a fixed position within the organisation (errors often get through the holes, i.e. the holes in the Swiss cheese are always not stays in one place). In addition, it does not give enough information about where the holes in the cheese represent (Dekker, 2003). Vincent et al. (1998) developed a model (Figure 2.5) based on Reason's 'Swiss cheese model', to deliver a better understanding and explanation of the framework of organisational accidents and to facilitate analysis of adverse incidents in healthcare

organisations. As can be seen in Figure 2.5, the chain of the error starts when latent conditions (management or organisational factors) are created by poor management decisions and organisational factors. The latent conditions then spread via different organisational routes to the work environment (e.g. IV treatment room) where mistakes and violation conditions are occur e.g. lack of staffing, high workload, lack of supervision, lack of equipment and patient related condition. To describe the conditions of work and correlated latent conditions which give rise to unsafe acts, Vincent et al. (1998) developed a framework to link related conditions and factors that may help to reduce the risk of unsafe acts for use as a system to analyse and manage the safety performance of healthcare systems. The Vincent framework involved the key elements met in healthcare for example issues related to organisation and management, work environment, individuals (healthcare staff), teamwork, tasks and patients conditions (Vincent et al. 1998). Table 2.15 illustrates why errors occur and some examples clarify how they impact practice (adapted from Vincent et al.2000.p.778).

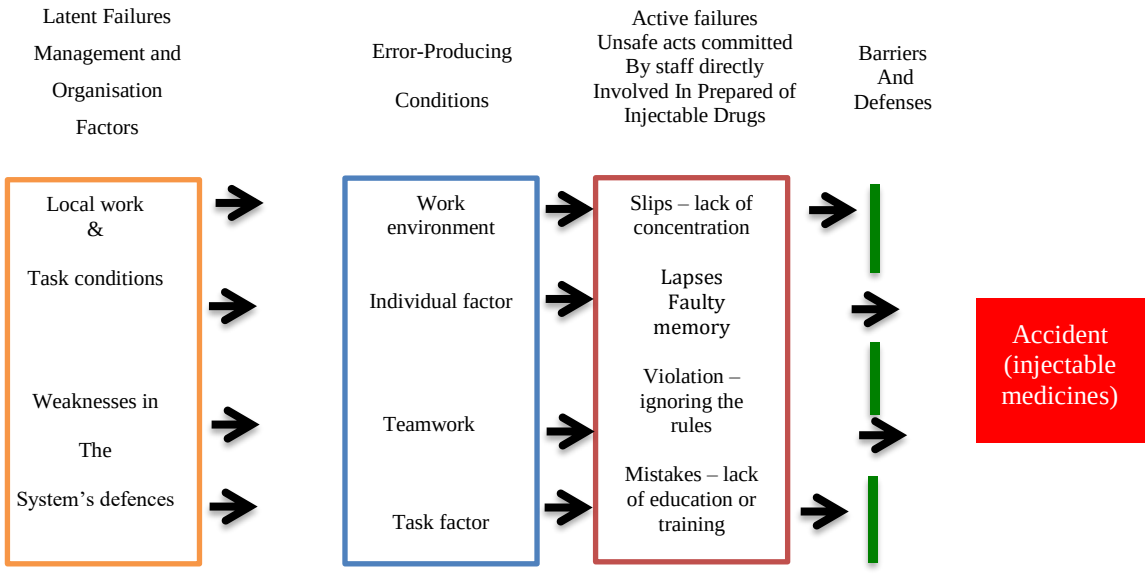


Figure 2.5. Organisational accident model based on work based on work by Reason (from Vincent et al., 1998; p. 1155).

Table 2.15: Outline of factors affecting healthcare systems (adapted from Vincent et al., 2000; p.7781).

Factor types	Affecting contributory factors	Examples
Individual (active failure)	Education/knowledge and experience ; and mental factor	Lack of education/ knowledge or experience; slips; lapses
Work environment factors (error producing conditions)	Number of staff and workload; skills mix; shift patterns; design, availability of equipment/medicines/materials; and supervisory support	Heavy workload; staff shortages or lack of medicines/materials/ equipment
Task factors	Task design and simplicity of structure; availability and use of procedures	Non-availability of protocols; complexity of medicines/equipment's
Patient factors	Difficulty and importance; language communication; personality and parents factors	Very sick patient or language problem
Team factors	Verbal communication; written communication; supervision and looking for help; team workflow (i.e. supervisors)	Poor communication between staff or others departments
Organisational and management factors	Economic resources and restrictions; organisational workflow; rule/polices and objects; safety background and main concern	Absent of a good workflow process for risk reduction
Institutional context	Financial and controlling setting;; clinical carelessness structure for hospitals	Inconstant guidelines/policies, income issues

It has been reported that UK hospital have not realised the important of poor design to patient safety (The Department of Health and The Design Council, 2003; p.18). This can help healthcare to generate procedures and environments that are controlled, suitable and comfortable environments to minimise the likelihood of accidental mistakes.

In research to classify stages where design could increase patient safety in the UK hospitals, some plans were advised that employed a system design method (The Department of Health and The Design Council, 2003).

Further example from safety dangerous industries has been stated the significance of design to increase safety where,

> *"Design is a structured process for identifying problems and developing, testing and evaluating user-focused solutions* (The Department of Health and The Design" Council, 2003; p.9).

In addition, studying from other safety critical industries, for example aircraft, gas or oil industry and nuclear power has exposed the significance of a whole explanation of why and how an error happened (Taylor Adams *et al.,* 1999).

2.8 Conclusion

Chapter two discussed the available data collection methods and outlined the proposed study design and data analysis methods. Numerous data collection methods were debated, for example incident reports, chart reviews, observations, questionnaires and interviews. Reasons were provided for using direct observation as the key quantitative data collection method. These were followed by a discussion of different quantitative methods, for example a postal survey (self-completion), the critical incident technique involving participant observation, chart review, and computerised surveillance. All these quantitative methods were introduced, defined, and the reasons for rejecting or adopting them given. Also, a visual analogue scale was used to rank the severity of the medication errors. Finally, the current study was in line with Braun and Clarke's (2013) qualitative analytical method, which provided a detailed description of how thematic analysis is achieved.

Chapter Three

Investigating Injectable Preparation Errors and Assessing their Severity in Pharmacy Aseptic Units

3.1 Introduction

Aseptic drug preparation is a significant part of service delivery by pharmacy departments that deliver high quality, accurately prepared ready to use injectable. This is a complex and demanding activity that requires qualified personnel, appropriate facilities and close monitoring and control (Royal Pharmaceutical Society (RPS), 2016). In the UK, the principles for aseptic preparation have come under close inspection in recent years (RPS, 2016). Aseptic pharmacy units are required to prepare cytotoxic medicines and total parenteral nutrition (TPN) especially for individual patients. Numerous hospital pharmacies also offer a centralised intravenous additive service (CIVAS) that provides mini-bags or syringes that are prefilled with additives. However, it is still also common practice to prepare medicines in clinical areas as this facilitates administration.

The Breckenridge Report (see section 1.6) recommended that all aseptic products should be prepared in an appropriate workplace under the control of pharmacists (Anon., 2005). While it would be ideal to eliminate ward-based injectable preparation, the lack of influence of pharmacy departments has and the lack of funding has not yet made this possible (Crowley et al., 2004). Injectable drugs, including drugs that are considered to be "high risk," continue to be prepared on hospital wards (Audit Commission, 2001; Anon., 2005). This has caused concern as injectable medicines have become more complex and more prevalent (Root, 2006). This is a multi-professional problem that requires input from a range of relevant specialists. The Royal Collage of Nursing (RCN) has published nursing guidelines on how to work aseptically but these differ from pharmacy practice (RCN, 2106). While injectable drug preparations are usually performed in wards by qualified nurses with expertise in injectable preparation who later administer the medicine

themselves, the Pharmacist remains responsible for all phases of medication treatment (Beaney and Goode, 2003; Beaney et al, 2005).

The pharmaceutical industry could help minimise risk to patients by licensing more doses in a ready-to-administer form that need minimum processing before preparation or use closed systems (RPS, 2016).

3.2 Conditions and Terms for Aseptic Preparation

The number of companies producing licensed medications is insufficient to deliver good healthcare to NHS patients. To resolve this issue, unlicensed injectable medicines can be obtained from two hospital pharmacy sources (Beaney, 2004). These are: Medicines and Healthcare Products Regulatory Agency (MHRA) inspected and licensed manufacturing units acting in compliance with the Medicines Act (1968) and non-licensed units working solely under the control of a pharmacist. Licensed manufacturing units can prepare products in batch and sell them to external organisation (e.g. NHS). Unlicensed manufacturing units prepare products in accordance with a prescription for a named patient (those units operate under a Section 10 exemption of the 1968 Medicines Act). The NHS Pharmaceutical Quality Assurance Committee works together with the MHRA to ensure that good standards are met by both licensed units (that manufacture products and sell to external customers) and unlicensed units (dispensing directly to named patients). Injectable medicines prepared in either of the two types of unit are expected to have the same level of safety (RPS, 2016).

In late 1990s, hospitals were asked to decide whether they required an "aseptic" manufacturing license from the then Medicines Control Agency (MCA) (now the MHRA), or whether they could carry on as they were using an exception to the UK Medicines Act (1968). The exception allows preparation of aseptic medicines to take place provided five standards are met (MCA, 1992):

1. The injectable preparation is run by or under the guidance of a pharmacist, who takes full responsibility for the quality of the final product.
2. The injectable preparation uses solely systems.
3. Licensed sterile medical products are used as ingredients or the ingredients are manufactured sterile in a licensed unit.
4. Injectable medicines are specified a shelf life of one week or less. The shelf life should be supported by stability data.
5. All activities should be in agreement with defined NHS procedure/guidelines.

These terms apply to aseptic products that are prepared to be used directly on patients (MCA, 1992).

In 1993, the Pharmaceutical Quality Control sub-Committee published the first edition of the Quality Assurance for aseptic injectable preparation in unlicensed aseptic preparation units and provided advice to ensure the reliable quality of medicines prepared in unlicensed aseptic preparation units (Quality Control Sub-Committee, 1993). In 1995, these criteria were expanded and updated to take into consideration publications of for example the Farwell Report (Aseptic Dispensing for NHS patients) (Lee, 1996). The term “preparation” is used to represent an activity carried out without a manufacturing license from the

Medicines and Healthcare products Regulatory Agency (MHRA), whereas "manufacture" is used to indicate a licensed activity (Farwell, 1995).

The Farwell report clarified this situation as follows:

> *"The supply or issue of a finished product to the patient or to the person responsible for administering it is dispensing. The manipulation of the product leading to this final presentation is preparation"* [Farwell, 1995, p.4].

The report focused on service providers and the monitoring and application of practice standards and led to the production of a guiding document entitled 'Guidance for aseptic dispensing for NHS patients' (Farwell, 1995). This guide concerns aseptic dispensing, total parenteral nutrition preparation (TPN), central IV additive services (CIVAS), dispensed cytotoxic medicines and radiopharmaceuticals. Injectable preparation is only used when licensed end terminally sterilised products are not available. Preparing these medicines in an aseptic unit provides more sterility assurance than when they are prepared in a ward (Farwell, 1995).

In 1996, the Medicines Control Agency (MCA) started to inspect unlicensed aseptic units working under these guidelines. They reported that 60% of units they investigated had significant deficiencies and that standards were well below those expected of units that carried out unlicensed manufacturing (MCA, 1996). In the same year, the Department of Health released an Executive Letter that required all unlicensed aseptic units to double check their standards (NHS Executive, 1996). Their findings were classified and were made available in another Executive Letter the following year (NHS Executive, 1996). Until that year, unlicensed aseptic units were not obliged to go through an external inspection. This requirement was introduced by the Executive Letter that launched a

programme of external inspection by Regional Quality Assurance Specialists in association with performance management (Lee, 1996). This programme is ongoing and has resulted in important developments in the standards pertaining to, for instance, documentation, training and facilities (Lee, 1996). The NHS Pharmaceutical Quality Assurance (formerly Quality Control) Committee manages the programme of external inspection of unlicensed units and works together with the MHRA to try to ensure consistent standards for licensed and unlicensed aseptic units (Lee, 1996). In 1996, further MHRA assessments were carried out of models of unlicensed NHS units that led to quality improvements. The development of pharmacy aseptic units, which has mainly resulted from the audit procedure, is in line with clinical governance. The UK government policy document entitled 'The New NHS: Modern, Dependable' introduced clinical governance and confirmed the significance of setting and promoting quality standards (NHS Executive, 1997). External inspections were not usually useful for unlicensed aseptic units in the UK before the setting up of standards in 1997 (NHS Executive, 1997). An additional NHS Executive report in 1998 called for the setting of clear national standards and highlighted the necessity for reliable monitoring actions. This applies to both clinical and specialised preparation settings (licensed and unlicensed units) (NHS Executive, 1998). In 1999, the clinical inspection procedures improved and internal inspection procedures of aseptic services were created as a way of maintaining and enhancing service quality (NHS Executive, 1999). Valuable guidelines on the inspection of aseptic services were issued by the NHS Pharmaceutical Quality Assurance Committee in 1999 (NHS Pharmaceutical Quality Control Committee, 1999). In 2000, a significant number of Controls Assurance Reports were presented by the UK Department of Health (NHS Executive, 2000). The reports highlighted the importance of performing to and keeping up standards and revealed the abnormal state of sense of duty

regarding the inspection culture within the NHS. The basic control requirement for injectable drugs is regular inspection of aseptic preparation within the pharmacy department and risk assessment of aseptic preparations in clinical areas (NHS Executive, 2000). The five standards (mentioned above) that need to be met by unlicensed aseptic units concur with NHS rules (Beaney, 2001). The latest modification of these rules was made in 2001 and concerns standards relating to items for short-term use (one day) (Beaney, 2001). Research regarding these requirements shows that the NHS environment is far from typical in terms of aseptic management and that procedures and training practices do not take into account the requirements relating to the quality of the products (Beaney, 2003). Quality assurance of medicines depends on clearly defined policies, facilities, design, equipment, process validation, training and capacity planning. Hence, pharmacy aseptic injectable preparation is strictly controlled, with clear national guidance to ensure the quality of the injectable medicines (Beaney, 2004). In 2004, the UK government updated the NHS pharmacy manufacturing service to bring it in line with clinical governance principles (Beaney, 2004). Further, in order to ensure that the manufacturing process of traditional pharmaceutical drugs, for example terminally sterilised injections and dermatological products, has been updated, licensed units were encouraged to support unlicensed aseptic units that had fewer resources and were working within restrictions (Beaney, 2006). The last decade has seen consistent advance being made in the UK to enhance quality in pharmacy aseptic units, mainly through inspections and governance policies (RPS, 2106).

There is now increasing focus on assessing risk in aseptic preparations being carried out outside pharmacy departments. The aim is to increase the quality of the aseptic preparation programme and decrease the risk to patients.

3.3 Significance of the Research

Injectable medicine preparation is more complex than other preparations and the consequences errors can often be more severe and have immediate effects (Cadman & Park, 1999). Numerous deadly medication errors (MEs) in hospital patients have been attributed to concentrated form (e.g. concentrated potassium chloride injections) or injectable drugs with narrow therapeutic ranges (Argo et al., 2000). The first National Patient Safety Agency (NPSA) patient safety alert concerned IV potassium injectable medicines (NPSA, 2002). Several previous studies (see section 1.7.1) have investigated error rate during injectable medicines preparation, some with a high error rate outcome (Escoms et al., 1996; Flynn et al., 1997; Limat et al., 2001; Parshuraman et al., 2008; Sacks et al., 2009; Bateman & Donyai, 2010; Serrano-Fabia et al., 2010; Ranchon et al., 2011; Dehmel et al., 2011). The preparation stage is the first stage of management process; therefore errors in this stage can lead to serious injuries that harm the patient (Cousins et al., 2012). In addition, ME reports from the UK show that the majority of errors correlated with patient severe harm occurred during the preparation phase (NPSA, 2007). Consequently, it is evident that more efforts are needed to develop the safety of medicine preparation by minimising the errors and harm that may result. This study investigates injectable medicines preparation-related MEs in the pharmacy environment. Furthermore, it will investigate the most effective

interventions to improve the use of high-risk injectable medicines in pharmacy environment.

3.4 Aims and Objectives

This investigation will explore the incidence, type and severity of injectable preparation errors made by staff in three pharmacy aseptic units. Severity scores and error frequency data for different error types will then be used to determine a risk score analogous to that used by the NPSA. Errors with highest risk scores will provide a focus for developing strategies to help prevent these types of mistakes happening again.

3.5 Research Objectives

Specific research objectives for this study are summarised in Table 3.1.

Table 3.1: Research objectives

Research Objectives	Determine the incidence of injectable medicine preparation errors in the pharmacy environment.
	Identify the types of injectable medicine preparation errors in the pharmacy environment.
	Determine the drugs involved in injectable medicine preparation errors in the pharmacy.
	Compare the incidences and types of injectable medicine preparation errors occurring in unlicensed pharmacy units and small and large licensed pharmacy units.
	Confirm that the injectable drug preparation errors observed on hospital wards can be classified as errors.
	Identify the severity of these errors on a scale of 0-10.
	Determine consequence and likelihood scores and assign an overall risk score analogous to that used by the National Patient Safety Agency.

3.6 Overview of Methodology

3.6.1 Study Design

This study adopts the case study methodology to detect and identify injectable drug preparation errors in three pharmacy aseptic units in Wales. A case study (Creswell, 2013) allows this research to investigate and classify injectable preparation errors (IPEs) in detail by studying the data in its environment and in the process of injectable drug preparation. Case studies are typically conducted in the location of the study (in this case, pharmacy aseptic units). They permit an investigation of the whole procedure (how IPEs are classified and why such errors have occurred). Moreover, case studies allow investigators to concentrate on the experience of certain performers, individuals or groups; in this research, the knowledge of pharmacy staff is unit of analysis. In case studies, investigators can collect data using various means, such as direct observation, questionnaires, and semi-structured interviews (Braun and Clarke, 2013). All these aspects of the case study methodology help the objectives of this study (see section 2.5).

3.6.2 Study Setting

This study was conducted within three aseptic processing units in the UK. Units were chosen using purposive sampling. The purposive sampling method is defined as:

> *"The identification and selection of particular individuals who share characteristics relevant to the study, and whom the researcher therefore believes will be most informative in achieving their objectives".* [Smith, 2002, p. l19]

Three Welsh aseptic pharmacy production units that reported error data to the UK National Aseptic Dispensing Error Database were invited to participate in this research. Specifically,

the sample included a small licensed unit (defined as preparing <1000 items per month), a large licensed unit (defined as preparing >1000 items per month) and an unlicensed unit (defined as preparing medicines for specifically named patients). The sites chosen for this research and some of their characteristics are summarised in Table 3.2.

Table 3.2: Characteristics of the three aseptic pharmacy production units chosen from the UK

Unit type	Large licensed unit A	Small licensed unit B	Unlicensed unit C
Computer system	Ascribe	Episys	Chemo care
Products prepared	1.Chemotherapy medication (adult and paediatric) 2. Parenteral nutrition (adult and paediatric) 3.Monoclonal antibodies (MAbs) (Adult) 4.Central intravenous additive (CIVAS)	1.Chemotherapy medication (adult and paediatric) 2. Parenteral nutrition (adult and paediatric) 3.Monoclonal antibodies (MAbs) (adult) 4. Central intravenous additive (CIVAS)	1. Chemotherapy medication (adult and paediatric) 2. Monoclonal antibodies (MAbs) (adult) 3. Specialist (Overall labelling of ready-made injectable)

3.7 Observational Study

3.7.1 Overview

In this thesis, a trained researcher (AA) conducted direct observation (non-participant) at the manufacturing units to determine the incidence and type of mistakes happening during the preparation of injectable drugs. Only participants who agreed to the observation of their practice when preparing injectable drugs were observed. Observation was chosen as the

study method because it is the gold standard method for categorising medication errors (Allan & Barker, 1990) (see section 2.6).

3.7.2 Definition of IPEs and Types of Errors

This thesis adopts the definition of IPEs developed by Crowley (2006) (see section 1.6). This definition was chosen for this research as it delivers a full understanding of what is meant by IPEs and because it was developed through a process of three-round Delphi technique by experts in medicine safety study. There is therefore no need to redevelop the definition given that it has been deemed valid and reliable (Crowley, 2006, pp. 56–66).

The definitions of IPE subtypes that were used in this research are illustrated in Table 3.3. The definitions were developed following a review of previous studies and discussion within the research team (LJ; JL; MJ; AA). The subtype definitions were adapted from Flynn et al., 1997; Limat et al., 2001 and Bateman & Donyai, 2010. The definitions were found to be valid during the pilot study and fit for the aim of this study following a review at one of the selected pharmacy aseptic units.

Table 3.3: Definitions of IPE subtypes used during the observation study (adapted form Flynn et al., 1997; Limat et al., 2001; Bateman & Donyai, 2010).

Type of error	Definition
Wrong preparation technique	*"Aseptic technique was violated (e.g. lack of hand washing, inadequate air injection, inadequate vial venting, inappropriate shaking, inappropriate decontamination of vials and materials, inappropriate syringe selection, not using a filter needle to inject the reconstituted product when this is normal procedure, inappropriate needle use, needle contamination, incorrect dose calculation for final product) or there were deviations from hospital policies and procedures that were not justified and affected the accuracy or sterility of the final product"*
Wrong patient	*"Preparing a prescribed medicine but for the wrong patient"*
Wrong drug	*"A medicine prepared that was not drug prescribed"*
Wrong dose	*"The concentration and volume of medicine used in preparing the final product resulted in a dose that deviated from the prescribed dose by 5%. Moreover the preparation of an extra dose of prescribed medicine".*
Wrong diluent	*"The use of incorrect diluent than that prescribed or recommended by the injectable preparation guidance"*
Wrong route	*"The preparation of correct medication by a route that was not prescribed".*
Omission	*"A medicine set on the IV room was not prepared and there was no sign that a staff member would be preparing the medicine at the appropriate time".*
Wrong reconstitution procedure	*"The volume or solution used to reconstitute the product was contraindicated in the medication's package insert or in the injectable guide or reconstitution was incomplete".*
Unauthorised medicine	*"A medicine that was not prescribed was included in the final product".*
Other	*"Any other mistake that is not stated above including errors such as preparation of a drug that had exceeded its expiry date (wrong expiry date)".*

3.7.2 Development of Observation Schedule

Errors were recorded on an observation schedule adapted from a previous study (James and Bateman, 2013). These authors developed the observation schedule based on the results from a focus group and a published literature of types of injectable-preparation errors (Flynn et al., 1997; Limat et al., 2001; Bateman & Donyai, 2010). Discussions were conducted with pharmacists, pharmacy technicians and pharmaceutical scientists involved in the preparation of injectable drugs. Moreover, they used failure mode and effects analysis (FMEA) as a mapping process by the focus group participants to explore the processes and risks associated with the preparation of injectable drugs. In April 2014, the original observation schedule was piloted by Dr. Lynette James at one of the selected hospitals to verify that all error types were included in the observation schedule and a minor change was made. In May 2014, a simulation of the observation schedule was conducted at the University of Bath; the final version generated following this simulation is the one used for this study (Appendix 3).

3.7.3 Ethical approval

Ethical approval for this research was obtained according to the University of Bath's Research Ethics policy (Appendix 1). The study was registered as an NPSA 20 audit and the investigator (AA) had an honorary contract at each participating site (Appendix 3), so NHS Research Ethics Committee approval was not required. The research was undertaken according to the Research Governance Framework. During observation, the observer (AA) only watched the process of preparing an injectable medicine. The investigator observed the preparation of injectable medicines and recorded the data on the data collection form.

During the observations, the observer ensured he had chosen appropriate location inside treatment room and not in the way of the staff. If error was observed, then the observer politely asked the participant to stop before continuing to prepare the product. This was documented as an IPE. However, if the participant noticed the error prior to preparation and acted without the observer's interference this was not documented as an IPE. If the participant was unsure a medication error mentioned by the observer had occurred, the observer stated that he believed a possible error might have happened. The observer then asked that they get the preparation checked by another qualified member of staff. If they believed there was potential to harm the patient if the preparation were administered, they informed the unit manager. This would allow the unit manager to investigate the incident, and where suitable follow the Trust's incident reporting procedure. In addition, to confirm the consistency of the observations, the observer reviewed all the collected data after completion of the observations and before additional data analysis. This was to ensure that each observation was documented and interpreted reliably. This approach was adopted to reduce unnecessary expenditure of staff time medicines and other consumables. Although there is a theoretical risk that informing a participant of an error early in the preparation process might increase the risk of subsequent errors, in a previous study the subsequent error rate was not found to be significantly affected by stopping the preparation process (Dean and Barber, 2001). Data collection of internal errors and recording of external errors were confidential and anonymous.

3.7.4 Study Participants

Before the commencement of the data collection phase, the researcher (AA) requested permission to observe pharmacy staff involved in the preparation of injectable drugs. Staff members were given an information leaflet (Appendix 4) and a consent form (Appendix 5). Those willing to participate in the study were required to provide written informed consent. Those who did not provide consent were not observed.

3.7.5 Data Collection

The research methodology and data collection method were selected on the basis of a previous study conducted by James and Bateman (2013), which was discussed previously (see section 3.7.2). Critical risk activities included errors transcribing the medical prescription (Rx) to the worksheet, labelling errors, setup errors, errors in making the product, and final checks of injectable-medicine production at each phase. Furthermore, FMEA previously identified wrong patient information, medicine details, dosage and administration instructions, expiry dates, warnings/precautions, and storage details in each phase of preparation (James and Bateman, 2013). Appendix 6 shows a map of the process of preparing injectable drugs as described by the focus group participants (adapted from James & Bateman, 2013). Observation data were collected by spending four working weeks (i.e. Monday - Friday; 20 days in total) at each study unit. Observation in large and small licensed units was carried out from 8am - 5pm and in unlicensed unit from 8am – 2pm; 2pm –5pm for emergency cases. The study period for this research was based on the period covered by a previous study on errors in the preparation of injectable medicines in

Cardiff Hospital (Crowley, 2006). During the data collection period, the investigator observed the preparation process of all injectable drugs (whether or not an error occurred) and recorded data for each drug prepared on a separate observation schedule (Appendix7). Internal errors were observed (direct observation) and external errors that had been made during the observation period were recorded from the standardised UK National Aseptic Dispensing Error Database form (Appendix8) and analysed (Bateman & Donyai, 2010). The data recorded included the types of injectable drugs and the nature of the errors.

3.7.6 Data Analysis

A coding framework was developed to analyse completed observation schedules for injectable preparations that contained errors (James and Bateman, 2013). Coded data for internal and external errors were entered into SPSS for quantitative statistical analysis on the types of internal and external errors; then, a comparison of manual- and SPSS-produced frequency tables was performed to ensure that the data had been entered correctly into more than one The overall rates of internal and external errors were calculated as described by Allan and Barker (1990):

$$\text{The Rate of internal/external errors (\%)} = \frac{\text{Number of actual errors (incorrect in one or more ways)}}{\text{Number of observations}} \times 100$$

A one way ANOVA was used to measure the difference between observed and expected error rates, according to the research hypotheses, which was that the type of aseptic unit

(licensed (large or small) or unlicensed) will not significantly affect the error rate. A $p < 0.05$ was considered statistically significant.

3.8 Severity Study

3.8.1 Overview

This study employed an independent panel of healthcare professional who independently assessed severity through completion of a questionnaire (see section 2.6.3). In order to select which errors to focus on to develop risk reduction strategies, guidance used by the National Patient Safety Agency (NPSA) was adapted to obtain risk assessment scores (NPSA, 2008). Mean severity scores and error frequency data for different error types were used to calculate consequence and likelihood scores. These values were multiplied together to determine the risk assessment score. The risk of an error type is related both to how often it happens and how severe the consequences are. Both need to be considered when deciding on strategies, so the NPSA method was adopted.

3.8.2 Research method

Each member of the panel was given a description of the error and asked to agree or disagree that each observation was an error using definitions adapted from a previous study (Crowley, 2006). Agreement of opinion among three of the five judges was considered a consensus (Ameer, 2015). Then the panel were asked to rank the severity of these errors on a scale of 0 – 10. The Inclusion of four errors of known outcome was included to validate the method. They were asked to return their completed questionnaires to the researcher

within two weeks timeframe for analysis. This technique for measuring severity was selected as it was found to be valid and reliable (Taxis & Barber, 2003) (see section 2.6.4).

1. Determination of Consequence Score

Mean severity scores obtained from three different pharmacy units in this study were mapped onto NPSA consequence descriptors and assigned a consequence score of 1-5 as summarised in Table 3.4. Panel members agreed with alignment of severity scores with consequence scores.

Table 3.4: Mapping of mean severity data on to NPSA consequence descriptors to obtain a consequence score.

Mean severity score	NPSA consequence descriptor	NPSA consequence score
<0.5	Negligible	1
0.5-3.4	Minor	2
3.5-6.4	Moderate	3
6.5-9.4	Major	4
≥9.5	Catastrophic	5

2. Determination of Likelihood Score

Each unit was represented on the NPSA frequency descriptors to get a likelihood score (see section 2.4.1).

$$\textbf{Observed error rate} = \frac{\text{Number of times a type of error occurred each in unit}}{\text{Total observations in each unit}}$$

$$\textbf{Predicted number of errors in one year} = \frac{(\text{Observed error rate} \times \text{Total items prepared in each ward during observation period}) \times 252}{20}$$

Values obtained for the predicted number of errors in one year ((52x5)-8 bank holidays) for each unit were mapped on to NPSA frequency descriptors to obtain a likelihood score of 1–5, as shown in Table 3.5.

Table 3.5: Mapping of error frequency into NPSA time frequency description to obtain likelihood score.

Predicted number of errors in one year	NPSA frequency	NPSA descriptor	NPSA likelihood score
<1	Not expected to occur for years	Rare	1
1-12	Expected to occur at least annually	Unlikely	2
13–51	Expected to occur at least monthly	Possible	3
52–251	Expected to occur at least weekly	Likely	4
>252	Expected to occur at least daily	Almost certain	5

3. Determination of Risk score

Consequence and likelihood scores were multiplied together to calculate a risk score (1-25) and assign a risk grade as shown in Table 3.6 (see section 2.4.1).

Table 3.6: Grading risk score by multiplying consequence score and likelihood score (NPSA, 2008).

Risk score	Assigned grades
1-3	**Minor risk**
4-6	**Moderate risk**
8-12	**High risk**
15-25	**Extreme risk**

3.8.3 Data collection and data analysis

Data collection and data analysis were discussed in detail in Chapter Two (see sections 2.6.6 and 2.6.7).

3.8.4 Data Storage

Raw data will be securely retained for five years before secure destruction. Coded data may be retained indefinitely. All data apart from consent forms will be identifiable by reference number only. Audio recordings will be destroyed once they have been transcribed.

3.9 Results

3.9.1 Results from Observational Study (Demographic Data)

The direct observation of the preparation of injectable medicines at three pharmacy aseptic units in Wales was conducted over 12 weeks (excluding weekends). Each day covered 8 hours of the shift. There were a total of 2112 scheduled injectable medicine doses prepared during the duration of the observations. It was possible to observe 47.2% (n = 997 doses) preparations of scheduled injectable medicines doses, making the data representative. The majority of the preparations were of chemotherapy medicines (n= 641), followed by preparations of monoclonal antibodies (MAbs) (239), total parenteral nutrition (TPN) (n= 87) and others (n= 30).

In total, 27 pharmacy staff members were observed during the 60 days. Table 3.7 presents the overall demographic data in detail. There was good acceptance by all pharmacy aseptic unit staff of this study and all were made aware of the aim of the research. There was no objection by any member of staff to being observed. Unit managers supported the observer with their resources and advice. There were no concerns expressed by the staff due to the presence of the observer.

Table 3.7: Observation study of the preparation of injectable medicines at three pharmacy aseptic units demographic data

Characteristic	Large licensed A	Small licensed B	Unlicensed unit C	Total
Number of days observed	20	20	20	60
Number of staff observed	13	9	5	27
Number of chemo observed	153	207	281	641
Number of adult chemo observed	105	187	275	567
Number of paediatric chemo observed	48	20	6	74
Number of MAbs observed	27	85	127	239
Number of adult MAbs observed	27	85	127	239
Number of paediatric MAbs observed	0	0	0	0
Number of TPN observed	11	76	0	87
Number of adult TPN observed	9	65	0	74
Number of paediatric TPN observed	2	11	0	13
Others injectable medicine observed	12	**6**	12	30
Others adult injectable medicine observed	9	**6**	12	27
Others paediatric injectable medicine observed	3	**0**	0	3

3.9.2 Incidence and Types of Injectable Medicine Preparation Errors in the Pharmacy Environment

Forty-six IPEs were detected. The observer (AA) intercepted one IPE incident before the drug reached the patient at the last point of medication delivery. There were also three IPEs that were caught in time by members of staff being observed or by the second checker of the final product before it was delivered to the patient. These were corrected and were not

included in the count of forty-six IPEs. The three IPEs that were caught in time by the staff concerned wrong route of administration, wrong diluent, and wrong medicine. The incidence of injectable preparation errors that occurred during observation at each unit is shown in Table 3.8.

Table 3.8: Incidence of errors during the preparation of injectable drugs at the three pharmacy aseptic units.

Unit	Large licensed A	Small licensed B	Unlicensed C	Total
Number of Observations	203	374	420	997
Number of Internal Errors	13	16	16	45
Number of External Errors	1	0	0	1
Total Number of Errors	14	16	16	46
Rate of Injectable Preparation Errors	14/203=6.8%	16/374=4.2%	16/420=3.8 %	4.6%

The overall mean rate of IPEs for three units was: 46 errors observation/997=4.6%. There was no significant difference between the incidence of internal errors at units A, B and C (One away ANOVA, f = 0.1223, p. value = 0.8891). However, it should be noted that the rate of errors in the large licensed unit was 1.8 times greater than that in the unlicensed unit. Given that errors (the numerator) were relatively rare, a larger number of observations (the denominator), giving greater statistical power, may have enabled a significant difference between these errors rates to be detected. In particular, fewer observations were completed in the large licensed unit, meaning the estimate of the error rate for this setting is less precise than the estimates for the other two units.

One external error occurred on the labelling of a chemotherapy medicine with the incorrect expiry date being given on the product label. A summary of the injectable preparation errors recorded at units A, B and C is shown in Table 3.9. Errors most commonly occurred during the preparation of chemotherapy medicines (31 errors/641=4.8%).

Table 3.9: A summary of the types of medicine for which injectable preparation errors were recorded at the three pharmacy aseptic units.

Type of medicine error	Large licensed A	Small licensed B	Unlicensed C	Total
Chemo	11	7	13	31
TPN	2	2	0	4
MAbs	0	7	3	10
Other injectable medicines	1	0	0	1
Total	14	16	16	46

Table 3.10 summarises where the injectable preparation errors occurred during preparation. In unit A, errors were made during three phases: worksheet, set up of materials and labelling. In unit B, errors were made during four phases: labelling, worksheet, set up and making up the final product. In unit C, errors were made during two phases: worksheet and making up the final product. The most common occurrence of errors in the preparation phase was at the worksheet preparation stage (24 errors/46=52.1%), but errors were also recorded whilst making up of the final product (12 errors/46=26%); during the setup of materials (9 errors/46=19.5%) and during labelling (1 errors/46=2.1%). At unit C, almost all the recorded errors occurred during the worksheet phase.

Table 3.10: Stages of preparation process where injectable preparation errors occurred at the three pharmacy aseptic units.

Phase	Large licensed A	Small licensed B	Unlicensed C	Total
Worksheet	3	6	15	24
Labelling	0	1	0	1
Set up	4	5	0	9
Making up product	7	4	1	12
Final check	0	0	0	0
Total	14	16	16	46

Table 3.11 summarises the types of injectable preparation errors that occurred at the three aseptic units. According to stage of preparation the most common error made on the worksheet was failure to record the syringe volume (n=14), which for unit C was by far the most prevalent. During the setup of materials, the most common error made was incorrect quantity of syringes (n=5). This error was observed at unit B. The next most common error made was wrong diluent selected (n=3), an error that was observed at unit A. Errors were also recorded whilst making the product. Here, the most common error recorded was wrong dose (n=4), an error that was detected at unit A, followed by signatures of maker missed (n=2), an error that was reported at unit B.

As can be seen in Table 3.11 below, the total number of worksheet errors reported by unit A were can be categorised into three errors types, namely: error in logging expiry data information (n=1), incorrect direction for administration (n=1) and wrong batch number of starting materials (n=1). In unit B, there were two types of worksheet error, namely, wrong batch number of starting materials (n=5) and not attaching label to the worksheet (n=1). In unit C there were two types of worksheet error, namely: wrong batch number of starting

materials (n=1) and missing syringe volume (n=14). In units A and C there were no types of faulty labelling, while in unit B there was only one type of faulty labelling, namely: wrong patient name (n=1).

It is clear that the difference between units in the assembly of starting materials phase that unit A there were two types of assembly errors, namely, wrong dose of drug strength selected to prepare the final product (n=1) and wrong diluent selected (n=3), while in unit B there was one type of assembly errors, that is, the incorrect number of syringes provided (n=5) and in unit C there were no types of errors during set up of materials. When all the errors made in the three units are taken into consideration it can be seen that the last stage of preparing the product are the second common of errors occurred. In unit A there were four types errors recorded during the making up of the final product i.e. incorrect dose (n=4); incorrect expiry date (n=1); incorrect diluent used (n=1) and wrong volume of diluent (n=1). In unit B there were three types of errors made when making up the product and in unit C just one type of errors was detected.

Table 3.11: Types of injectable preparation errors that occurred at the three aseptic units.

Types of injectable preparation errors	Large licensed (A)	Small licensed (B)	Unlicensed (C)	Total
Error Transcribing Rx to worksheet				
Wrong batch number of starting materials	1 (PL3)	5 (PS18; PS27; PS28; PS29; PS30)	1 (PU32)	7
Error in logging expiry date information	1 (PL2)	0	0	1
Incorrect directions for administration	1 (PL5)	0	0	1
Missing syringe volume	0	0	14 (PU33; PU34; PU35; PU36; PU37; PU38; PU39; PU40; PU41; PU42; PU43; PU45; PU46)	14
Not attaching a label to the worksheet	0	1 (PS16)	0	1
Total errors	**3**	**6**	**15**	**24**
Labelling phase				
Wrong patient name	0	1 (PS19)	0	1
Total errors	**0**	**1**	**0**	**1**
Set up of materials				
Wrong dose of drug strength selected to prepare the final product	1 (PL12)	0	0	1
Wrong diluent selected	3 (PL1; PL4; PL14)	0	0	3
Incorrect number of syringes provided	0	5 (PS22; PS23; PS24; PS25; PS26)	0	5
Total errors	**4**	**5**	**0**	**9**
Errors in making up the product				
Wrong dose	4 (PL6; PL7; PL8; PL13)	0	1 (PU31)	5
Wrong expiry date[1]	1 (PL11)	0	0	1
Wrong diluent used	1 (PL9)	0	0	1
Wrong volume of diluent	1 (PL10)	0	0	1
No filters used as specified	0	1 (PS20)	0	1
Signatures of maker not included	0	2 (PS15; PS21)	0	2
Product made on incorrect day	0	1(PS17)	0	1
Total errors	**7**	**4**	**1**	**12**

[1]External error

3.9.3 Severity Assessment of Injectable Preparation Error (IPEs)

A total of forty-six observed errors and four errors from the literature with known outcomes were classified and ranked by an independent panel of five experts.

3.9.4 Confirmation of Errors

There was a high level of agreement between panel members about the errors observed in the three pharmacy aseptic units with absolute agreement in 44 out of the 46 errors. Three of the panel members agreed on the remaining two errors (PL13: PU33), so a consensus was still achieved. These results mean that all the errors were included in the subsequent analysis.

3.9.5 Validation of Method for Rating Error Severity

In this severity scale, a mean severity score < 0.5 indicates negligible level of harm; between 0.5 and 3.4 indicates a minor level of harm; a score between 3.5 and 6.4 represents a moderate level of harm; a score between 6.5 and 9.4 indicates major harm; and a score of ≥ 9.5 indicates the potential for death. Results obtained for the 4 errors with a known patient outcome (PL15, PS32, PU49, and PU50) are shown in Table 3.12. There was agreement between the severity score and the patient outcome for PS32 and PU50 as a severe patient outcome was assigned a high severity score. There was no agreement on PL15 and PU49 as some panel members (mainly the pharmacists) ranked the severity of these errors as greater than that, which was known to occur. However, it should be noted that PU49 was

a morphine error adapted for this study and this confused the panel (see discussion). The correct identification of errors with a severe outcome and the higher severity ranking of errors with a less serious outcome validated the method in this research context.

Table 3.12: Validation of method for ranking error severity.

	Type of Error			
Panel Member	**Calculation error PL15**	**Wrong diluent PS32**	**Wrong dose PU49**	**Faulty labelling PU50**
Error description	Chemotherapy delayed for second day due to incorrect calculation.	A 500 mg dose of clarithromycin was prepared for a patient as an I.V bolus injection instead of diluted in 250 ml of 0.9 % sodium chloride infusion.	Bolus of 10mg morphine prepared at once instead of in small doses of 2mg.	Isoprenaline was drawn up into a syringe but labelled as metaraminol.
Clinical pharmacist	7	7	4	9
Physician	2	7	5	10
Nurse	3	4	6	8
Oncologist	5	7	5	8
Aseptic pharmacist	8	9	8	9
Mean severity score	5	6.8	5.6	8.8
Equivalent panel severity rating	Moderate	Severe	Moderate	Severe
Actual patient outcome	Minor	Severe	No harm	Severe
Agreement / Disagreement between severity rating and actual patient outcome	Disagree	Agree	Disagree	Agree

3.9.6 Severity Ranking of Errors

Table 3.13 shows the mean severity score assigned to the 46 observed errors by the professional healthcare panel. The mean severity ranking assigned by the panel was distributed across two levels of harm: 67.4% (n=31) were assigned a minor level of harm (severity score 0.5-3.4) and 32.6% (n=15) were assigned a moderate level of harm (severity score 3.5-6.4).

The fact that no errors were ranked as severe and that the respondents categorised these errors as causing minor or moderate harm suggests that the risk control mechanisms in pharmacy units are working. The highest severity score error (6.4) occurred in unit A and referred to a wrong expiry date in the labelling phase (PL11). The lowest severity score (0.6) also occurred in unit A and resulted from the recording of the wrong number of doses of drug prepared while making the product (PL13).

For all forty-six errors, the overall mean severity score was 2.9 and the median severity score was 3 (interquartile range (IQR) 1.4; minimum 0.6; maximum 6.4).

Table 3.13: Mean Severity Scores assigned to errors observed in three aseptic units by the panel (n=46).

Unit	REF	Type of error	Description of error	Mean severity score
Large unit (A)	PL1	Wrong diluent	Wrong strength of diluent picked to prepare final product: 5%glucose instead of 10% glucose.	4.6
	PL2	Wrong expiry date	Wrong expiry date of medicine (starting material) on worksheet and label	4.2
	PL3	Wrong batch number	Wrong batch number of medicine (starting material) on worksheet and label	2.2
	PL4	Wrong diluent	Wrong strength of diluent picked to prepare final product: 0.45% sodium chloride instead of 0.9% sodium chloride	4.6
	PL5	Wrong route	Wrong route of administration: 2.6mg in 2.6 ml prepared for I.V. instead of 2.5mg in 1ml for subcutaneous	6.2
	PL6	Wrong dose	Wrong quantity of drug prepared: syringe contained 10mg Daunorubicin in 5ml instead of 20mg in10ml.	4.2
	PL7	Wrong dose	Wrong quantity of drug prepared: final syringe contained 200mg in 2 ml rather than 100mg in 1 ml hydrocortisone.	6
	PL8	Wrong dose	Wrong dose of drug prepared: final syringe contained 85mg/m^2 instead of 130mg/m^2 Oxaliplatin.	6
	PL9	Wrong diluent	Wrong type of diluent and wrong volume of diluent for reconstitution: 1mg of Bortezomib in 1ml water rather than 2.5mg of Bortezomib in 1ml 0.9% sodium chloride	5
	PL10	Wrong diluent	Wrong volume of diluent: 20 ml water used rather than 10 ml water.	4.2
	PL11	Wrong expiry date[1]	The final product expired: out of date drug delivered to ward due to error in logging expiry date in fridge record.	6.4
	PL12	Wrong dose	Wrong strength of drug (starting material): picked to prepare final product (10% magnesium instead of 50% magnesium.	4.8
	PL13	Wrong dose	Wrong number doses of drug prepared: only 1 dose needed. However, 3 extra doses prepared.	0.6
	PL14	Wrong diluent	Wrong strength of diluent picked to prepare final product: 0.45% sodium chloride instead of 0.9% sodium chloride.	5

[1]External error

Continued Table 3.13.

Unit	REF	Type of error	Description of error	Mean severity score for all errors n=46
Small unit (B)	PS15	Worksheet error	Signature of member of staff who labelled product missing from worksheet	2.8
	PS16	Worksheet error	Wrong label affixed to worksheet	3.8
	PS17	Unprescribed medication	Product made on incorrect day	2.2
	PS18	Wrong batch number	Wrong batch number of medicine (Starting material) on worksheet and label.	2.8
	PS19	Faulty labelling	Wrong spelling of patient name on label.	4
	PS20	Wrong preparation technique	Filter needle not used during making TPN: reconstituted Vitlipid +Solvito not added to TPN bag through filter.	5.8
	PS21	Worksheet error	Signature of member of staff who labelled product missing from worksheet.	2.6
	PS22	Assembly error	Not enough syringes provided.	2.4
	PS23	Assembly error	Not enough syringes provided.	2.4
	PS24	Assembly error	Not enough syringes provided.	2.4
	PS25	Assembly error	Not enough syringes provided.	2.4
	PS26	Assembly error	Not enough syringes provided.	2.4
	PS27	Wrong batch number	Wrong batch number of medicine (Starting material) on worksheet and label.	1.8
	PS28	Wrong batch number	Wrong batch number of medicine (Starting material) on worksheet and label.	1.8
	PS29	Wrong batch number	Wrong batch number of medicine (Starting material) on worksheet and label.	1.8
	PS30	Wrong batch number	Wrong batch number of medicine (Starting material) on worksheet and label.	1.8
Unlicensed unit (C)	PU31	Wrong dose	Leakage from vial resulted in dose being too low.	3
	PU32	Wrong batch number	Wrong batch number of medicine (Starting material) on worksheet and label.	2.2
	PU33	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU34	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU35	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU36	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU37	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU38	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU39	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU40	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU41	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU42	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU43	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU44	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU45	Worksheet error	Volume size of syringe missing from worksheet.	1.8
	PU46	Worksheet error	Volume size of syringe missing from worksheet.	1.8

Table 3.14 compares the overall severity ranking with that obtained for each unit. It can be seen that the majority of errors in unit A were categorised as having a moderate level of harm whereas the majority of errors in the B and C units were categorised as having a minor level of harm.

Table 3.14: Overall severity ranking compared with that obtained for each unit.

	Total error rate %	Errors assigned a minor level of harm %	Errors assigned a moderate level of harm %	Errors assigned a major level of harm %
Overall	4.6◆	3.1	1.5	0
Large unit (A)	6.9*	1.0	5.9	0
Small unit (B)	4.3**	3.5	0.8	0
Unlicensed unit (C)	3.8***	3.8	0.0	0

◆46 errors from 997 observations * 14 errors from 203 observations
** 16 errors from 374 observations *** 16 errors from 420 observations

Table 3.15 shows the mean and median severity scores obtained for each pharmacy aseptic unit. It can be seen that panel members assigned higher severity scores to errors in unit A, which correlates with data in Tables 3.14 and 3.15. In order to assess the significance of this test, the median severity scores assigned to each unit were compared using the Kruskal-Wallis test. This gave a $p<0.001$, showing that there were significant differences between units. Subsequently, Mann-Whitney U-tests were used to compare the median severity scores assigned to the three pharmacy aseptic units. As this involved multiple comparisons, a Bonferroni correction was applied, giving a significance threshold of $p=0.017$. The Mann-Whitney U-tests results showed that for unit A vs. unit B, $p < 0.001$; for unit A vs.

unit C, $p < 0.001$ and for unit B vs. unit C, $p = 0.0236$. Hence, the Mann-Whitney U-tests found that the median severity score from unit A was significantly larger than both the B and C units, but there was not a significant difference between the B and C units.

Table 3.15: The Differences in Potential Harm Scores between Three Types of Pharmacy Units.

Pharmacy aseptic unit	Severity score	
	Mean	**Median**
Large unit (A)	4.6	4.5
Small unit (B)	2.7	2.5
Unlicensed unit (C)	1.9	2

Table 3.16 (a, b, c) summarises the frequency of error types and the corresponding severity categories in the three different pharmacy units. In the large aseptic unit (A), the most common types of error were wrong dose and wrong diluent, both of which were categorised as causing a moderate level of harm. In the small aseptic unit (B), the most common types of error related to assembly and batch number, both of which were categorised as causing a minor level of harm. For the unlicensed unit (C), the most common type of error related to the worksheet, which was categorised as causing a minor level of harm.

Table 3.16 (a): Breakdown of the Injectable Drug Preparation Error Severity Scores in large unit (A) (n=14).

Type of Error	Harm Level		Total (n=14)
	Minor	Moderate	
Wrong dose (n=5)	1	4	5
Wrong diluent (n=5)	0	5	5
Wrong expiry date (n=2)	0	2	2
Wrong batch number (n=1)	1	0	1
Wrong route of administration (n=1)	0	1	1
Worksheet error (n=0)	0	0	0
Assembly error (n=0)	0	0	0
Unprescribed medicine (n=0)	0	0	0
Faulty labelling (n=0)	0	0	0
Wrong preparation technique (n=0)	0	0	0
Total	2	12	14

Table 3.16 (b): Breakdown of the Injectable Drug Preparation Error Severity Scores in a Small Unit (B) (n=16).

Type of Error	Harm Level		Total (n=14)
	Minor	Moderate	
Assembly error (n=5)	5	0	5
Wrong batch number (n=5)	5	0	5
Worksheet error (n=3)	2	1	3
Unprescribed medicine (n=1)	1	0	1
Faulty labelling (n=1)	0	1	1
Wrong preparation technique (n=1)	0	1	1
Wrong dose (n=0)	0	0	0
Wrong diluent (n=0)	0	0	0
Wrong expiry date (n=0)	0	0	0
Wrong route of administration (n=0)	0	0	0
Total	13	3	16

Table 3.16 (c): Breakdown of the Injectable Drug Preparation Error Severity Scores in the Unlicensed Unit (C) (n=16).

Type of Error	Harm Level		Total (n=14)
	Minor	Moderate	
Worksheet error (n=14)	14	0	14
Wrong dose (n=1)	1	0	1
Wrong batch number (n=1)	1	0	1
Assembly error (n=0)	0	0	0
Unprescribed medicine (n=0)	0	0	0
Faulty labelling (n=0)	0	0	0
Wrong preparation technique (n=0)	0	0	0
Wrong diluent (n=0)	0	0	0
Wrong expiry date (n=0)	0	0	0
Wrong route of administration (n=0)	0	0	0
Total	16	0	16

3.9.7 Risk scoring and grading of errors

3.9.8 Consequence Score

Results obtained for the different units are shown in Table 3.17 (a, b, c). A consequence descriptor of ‘moderate’ (score 3) was assigned to four types of errors in the large unit, two types of error in the small unit and no types of error in the unlicensed unit. Most of the error types in the large unit were categorised as ‘moderate’ whereas most errors occurring in the small and unlicensed units were categorised as ‘minor’ (score 2).

Table 3.17 (a): Mapping of severity data from the large aseptic unit (A) on to NPSA consequence descriptors to obtain consequence scores.

Type of error (n=14)	Mean severity score	NPSA consequence score	NPSA consequence description
Wrong route of administration (n=1)	6.2	3	Moderate
Wrong expiry date (n=2)	5.3	3	Moderate
Wrong diluent (n=5)	4.6	3	Moderate
Wrong dose (n=5)	4.3	3	Moderate
Wrong batch number (n=1)	2.2	2	Minor

Table 3.17 (b): Mapping of severity data from the small aseptic unit (B) on to NPSA consequence description to obtain consequence scores.

Type of error (n=16)	Mean severity score	NPSA consequence score	NPSA consequence description
Wrong preparation technique (n=1)	5.8	3	Moderate
Faulty labelling (n=1)	4	3	Moderate
Worksheet error (n=3)	3	2	Minor
Assembly error (n=5)	2.4	2	Minor
Unprescribed medication (n=1)	2.2	2	Minor
Wrong batch number (n=5)	2	2	Minor

Table 3.17 (c): Mapping of severity data from the unlicensed aseptic unit (C) on to NPSA consequence description to obtain consequence scores.

Type of error (n=16)	Mean severity score	NPSA consequence score	NPSA consequence description
Wrong dose (n=1)	3	2	Minor
Wrong batch number (n=1)	2.2	2	Minor
Worksheet error (n=14)	1.8	2	Minor

3.9.9 Likelihood Score

Results obtained for the likelihood scores in the three units are shown in Table 3.18 (a, b, c). Two types of error (wrong dose and wrong diluent) were likely to occur at least daily in the large aseptic unit. Errors in the small unit were likely to occur at least weekly or monthly and unlicensed unit one types of error (worksheet errors) were likely to occur at least weekly.

Table 3.18 (a): Mapping of predicted number of errors from large aseptic unit (A) onto NPSA time frequency descriptors to obtain likelihood score.

Type of error	Error rate*	Predicted number of errors in one year**	NPSA frequency description	NPSA likelihood score
Wrong dose (n=5)	0.025	352	Expected to occur at least daily	5
Wrong diluent (n=5)	0.025	352	Expected to occur at least daily	5
Wrong expiry date (n=2)	0.009	127	Expected to occur at least weekly	4
Wrong batch number (n=1)	0.005	70	Expected to occur at least weekly	4
Wrong route of administration (n=1)	0.005	70	Expected to occur at least weekly	4

* Total Observations = 203 ** Total Items prepared = 1119
Almost certain Likely

Table 3.18 (b): Mapping of predicted number of errors from small aseptic unit (B) onto NPSA time frequency descriptors to obtain likelihood score.

Type of error	Error rate*	Predicted number of errors in one year **	NPSA frequency description	NPSA likelihood score
Assembly error (n=5)	0.013	90	Expected to occur at least weekly	4
Wrong batch number (n=5)	0.013	90	Expected to occur at least weekly	4
Worksheet error (n=3)	0.008	55	Expected to occur at least weekly	4
Unprescribed medicine (n=1)	0.003	21	Expected to occur at least monthly	3
Faulty labelling (n=1)	0.003	60	Expected to occur at least monthly	3
Wrong preparation technique (n=1)	0.003	60	Expected to occur at least monthly	3

* Total no. Observation = 374 ** Total no. Items prepared = 550

Likely Possible

Table 3.18 (c): Mapping of predicted number of errors from unlicensed aseptic unit (C) onto NPSA time frequency descriptors to obtain likelihood score.

Type of error	Error rate*	Predicted number of errors in one year**	NPSA frequency description	NPSA likelihood score
Worksheet error (n=14)	0.033	184	Expected to occur at least weekly	4
Wrong dose (n=1)	0.002	11	Expected to occur at least annually	2
Wrong batch number (n=1)	0.002	11	Expected to occur at least annually	2

* Total no. Observations = 420 ** Total no. Items prepared = 443

Likely Unlikely

3.9.10 Risk score

Risk scores assigned to the types of error which occurred in each of the aseptic units are shown in Table 3.19 (a; b; c).

Table 3.19 (a): Risk scores assigned to error type in the large aseptic unit (A)

Type of error (n=14)	Consequence	Likelihood	Risk Score	Assigned grade
Wrong diluent (n=5)	3	5	15	Extreme risk
Wrong dose (n=5)	3	5	15	Extreme risk
Wrong expiry date (n=2)	3	4	12	High risk
Wrong route of administration (n=1)	3	4	12	High risk
Wrong batch number (n=1)	2	4	8	High risk

Table 3.19 (b): Risk scores assigned to error type in the small aseptic unit (B)

Type of error (n=16)	Consequence	Likelihood	Risk Score	Assigned grade
Wrong preparation technique (n=1)	3	3	9	High risk
Faulty labelling (n=1)	3	3	9	High risk
Wrong batch number (n=5)	2	4	8	High risk
Worksheet error (n=3)	2	4	8	High risk
Assembly error (n=5)	2	4	8	High risk
Unprescribed medication (n=1)	2	3	6	Moderate risk

Table 3.19 (c): Risk scores assigned to error type in the unlicensed aseptic unit (C)

Type of error (n=16)	Consequence	Likelihood	Risk Score	Assigned grade
Worksheet error (n=14)	2	4	8	High risk
Wrong dose (n=1)	2	2	4	Moderate risk
Wrong batch number (n=1)	2	2	4	Moderate risk

Most of the errors were graded ‘high risk’ or ‘moderate risk’ but two types of error, which occurred in the large unit that were assigned the grade ‘extreme risk’. Where possible, the highest risk errors for each unit were selected for the development of risk reduction strategies. For the unlicensed unit, strategies were developed for moderate risk errors. However, the strategies proposed for worksheet errors in the small unit may also be applicable to the high-risk worksheet errors observed in the unlicensed unit.

Errors categorised as extreme risk, high risk and moderate risk were selected for the development of risk reduction strategies. Furthermore, the different levels of risk assigned to similar errors in the three units should enable risk reduction strategies for each unit to be prioritised.

3.10 Discussion

The aim of healthcare is to improve the quality of life for patients; this includes reducing and preventing errors in the preparation of injectable medicines used in the treatment of illnesses and injuries. However, numerous errors, both identified and unidentified, are made in the preparation of injectable medicines and these have the potential of harming patients' health and quality of life. Therefore, the aim of this research was to identify the types, incidence and severity of errors in the preparation of injectable drugs in the pharmacy aseptic production unit to calculate a risk score. Errors with the highest risk scores will provide a focus for developing strategies to help prevent these types of mistakes from reoccurring.

This section will discuss quantitative data obtained on the type, incidence and severity of drug preparation errors made in three different pharmacy aseptic units: a large licensed (A), a small licensed unit (B), and an unlicensed unit (C). The overall error rate of internal errors for the three units was 4.6% and the external error rate was 0.09% in the large licensed unit (A). These results showed that the internal and external error rate is higher than that reported in previous UK studies (Bateman and Donyai, 2010) that reported an internal error rate of 0.49% and an external error rate of 0.0025%. This difference could be related to the methods used in their study. For example, Bateman and Donyai (2010) used incidence report details of internal errors from the UK National Aseptic Error Database. Self-reporting depends on staff knowledge that an error has happened. Moreover, staff may not be aware of the reporting process and they may be hesitant to report errors if they fear being blamed. On the other hand, the overall internal error rate in this research is consistent with

the rate reported in a research carried out by Flynn et al. (1997) in the US. The study reported a median internal error rate of 5% in five US hospital pharmacies. The fact that both that study and this one reported a similar error rate could be due to the fact that the same method (direct observation) was used in the two studies. The external error rate found in this research was lower than that found by previous studies conducted in the US and in other countries (Escoms et al., 1996; Limat et al., 2001; Sacks et al., 2009; Serrano- Fabia et al., 2010; Ranchon et al., 2011). In the US, the recorded external error rate was 0.4% (Sacks et al., 2009). In European hospital pharmacy units, the external error rate of IPEs varied between 0.12% and 0.45% of all doses prepared by staff (Escoms et al., 1996; Limat et al., 2001; Serrano- Fabia et al., 2010; Ranchon et al., 2011). As mentioned above, this difference is unsurprising because incident report relies on staff knowledge and experience that an error has happened. Hence incident reporting can underestimate the incidence of preparation errors (Allan & Barker, 1990). The rate of internal error for the different study units was compared using one-way ANOVA. A $p < 0.05$ was considered statistically significant**.** Our results confirmed the hypothesis that there is no significant difference in the incidence of internal errors between the three pharmacy aseptic units.

In a previous study (James & Bateman, 2013) critical risk activities identified by focus group participants included the worksheet phase, label phase, setup of materials, and making products. This tallies with the results of this study, where injectable preparation errors occurred during these phases of preparation. The most common type of medicines where errors occurred were cytotoxic products (31errors/ 46 total number of errors=67%), followed by the monoclonal antibody (MAbs) (10 errors/ total number of errors=22%), parenteral nutrition (TPN) (4 errors/ 46 total number of errors=9%), and others

(subcutaneous hydrocortisone) (1 errors/ 46 total number of errors=2%). This is consistent with Bateman and Donyai's (2010) findings that most error reports related to cytotoxic products (40%), IV additives (27%), parenteral nutrition (TPN) (15%) and other pre-filled syringes (7%). The high number of errors related to cytotoxic products may be due to the fact that these products are made up in high numbers in pharmacy aseptic production units (641/997=64% of all medicines prepared). Also, according to Plumridge et al. (2001), cytotoxic products are hard to prepare and the person preparing the product is required to follow an exact procedure; for this reason, many errors can occur during preparation.

The phases where errors occurred during the preparation process in this study also correlated with results reported previously in the UK (Bateman and Donyai, 2010). For example, the most common error found in this research was the failure to record syringe volumes on the worksheet, followed by wrong batch number recorded on the worksheet phase. The second most common error reported wrong dose during making up the product stage. This is consistent with Bateman and Donyai's findings (2010) that most errors in the preparation process occurred during the worksheet and making the final product. These errors are likely to cause the patient harm. It is possible that such errors are not recognised by staff as being important and may not always be included when self-reporting incidents. This could account for the differences in error rates reported in our study and other studies (Bateman and Donyai, 2010).

One of the limitation of this research is that the findings obtained may not be generalisable to all aseptic preparation units as this study used a purposive sampling method, which leads to a sample that is not random or representative. Moreover, observer bias and changing

behaviour (the Hawthorne effect) of the worker during observations may have affected the accuracy of this study's findings. There is a possibility that staff may have changed their normal behaviour in the presence of the observer during the study (the Hawthorne effect). In 1980, Barker found that the members of staff resumed their normal behaviour three hours into the observation period. The injectable preparation medicines that were to be observed were selected randomly by the researcher; thus, the observer could not foresee and correct any errors that could potentially occur. Therefore, the occurrence of an error in the observed product was due to chance. In addition, the error rate of week 1 was the same as the one for weeks 2, 3 and 4. As clarified in Section 2.2.3, several studies have shown that the use of the observation method to identify medical errors does not affect the results of these studies (Barker and McConnell, 1962; Alan and Barker, 1990; Dean and Barber, 2001; Bowling, 2002; Smith, 2002). Most of the recommendations made in previous studies were adopted in this study. For example, the recommendation for the researcher to spend some time with the staff in the injectable preparation room before they start collecting data; the recommendation to inform the staff of the nature of the study and give them assurances that the results will be confidential; the recommendation to inform the staff about the significance of working with normal behaviour; the recommendation to collect extraneous data to reduce the incidence of altered behaviour (Crowley, 2006) and the recommendation to ignore initial observation data as the effect of the observer minimises over time (Bowling, 2002; Smith, 2002; Ameer, 2015).

The influence of observer bias was reduced through the use of an observation schedule with clearly defined tasks and types of errors, a trained observer and verification of errors with staff at the participating sites.

The second part of this study confirmed that the injectable drug preparation errors previously observed in pharmacy aseptic units could be categorised as errors and ranked the severity of these errors on a scale of 0 to 10. Finally, error severity and error frequency data were used to calculate consequence and likelihood scores and determine a risk score for each error analogous to that used by the National Patient Safety Agency (NPSA, 2008). Errors with the highest risk score will provide a focus for developing strategies to help prevent these types of errors in the future.

This study includes a discussion of the quantitative data obtained from three different pharmacy aseptic units: a large licensed unit, a small licensed unit, and an unlicensed unit. All errors previously observed were classified as errors by the panel and thus 46 errors were included in the analysis. This initial verification of errors was important as errors were documented by just one observer, in contrast to other studies (Dean and Barber, 2001; Barker et al, 2002; Buckley et al, 2007). Having one observer reduces the Hawthorne effect but increases the risk associated with reliance upon the judgement of one researcher. Errors detected by more than one observer are more robust, but the Hawthorne effect will be increased. In this study, an expert panel with five members was selected to assess severity, as mean severity scores should be more reliable than those provided by a single judge (Dean & Baber, 1999; Taxis & Barber, 2003). However, as the actual patient outcome of these errors was unknown, it was important to validate the method in this research context. Therefore, a small number of errors (approximately 10% of the total) with a known patient outcome were included. The panel members were not aware which errors these were. The results showed agreement between severity scores and patient outcome in 50% of the cases.

Although there was also no agreement in 50% of cases, one of these errors (PU49) was poorly described (as noted by one panel member) and both were rated as more severe than the actual patient outcome. This demonstrated that the panel would be unlikely to underestimate the severity associated with an error and thus the researcher was confident that the method was appropriate.

Assessing the severity of injectable drug preparation errors identified in this research was carried out by a panel. This comprised two physicians (a general physician and an oncologist), two pharmacists (a clinical pharmacist and an aseptic pharmacist), and one senior nurse. Injectable drug preparation errors were presented to the panel in the form of a questionnaire; a method, which has been found to be valid and credible (Taxis & Barber, 2003; Ameer, 2015). Dean and Barber (1999) showed that scoring severity using a panel of at least four experienced healthcare professionals is a reliable index of severity. This was the first reliable, validated scoring method to assess the severity of medication errors for which patient outcomes are not known. Their statistical analysis showed that, if any four reviewers from a panel of 30 experienced U.K. pharmacists, medical staff, and nursing staff were used their mean scores would be generalisable to any other four reviewers selected from the same panel. In contrast, some previous studies stated that judges from different health fields of study differ in their assessment of medication errors (William & Talley, 1994; Nixon &Dillon, 1996; Ameer, 2015). However, Dean and Barber (1999) explained that in each of these studies there was only one representative of each professional group, therefore it was impossible to determine whether the differences in scores were attributable to individual differences or professional differences. According to Dean and Barber (1999) there is one main limitation associated with this severity assessment method. A linear scale

was used to assess injectable drug preparation errors severity because these types of scales are easy to use and are known to most health care professionals. However, any assessment of severity must allow for the probability and the extent of harm (Royal Society, 1992). Theoretically, injectable drug preparation error severity should therefore be represented graphically, with extent of patient harm being plotted along the X-axis and the probability of patient harm along the Y-axis. Different medication errors would have different areas under the curve. This approach has been used in the assessment of prescribing errors (Hawkey et al., 1990), where a judge was asked to estimate the probabilities of occurrence of different levels of patient harm. The use of such probability distributions is complex; so, in this study, it was decided to assess injectable drug preparation error severity by using a single score. It is also important to consider the fact that the questionnaire did not explore the cost implications of the errors. Scores obtained in this study may therefore not reflect financial consequences. It was decided that five expert health care professionals should participate in the assessment of the severity of each injectable drug preparation error using a scale numbered from 0-10. The five expert health care professionals should ideally include a doctor, a pharmacist and a nurse. The mean score for each injectable drug preparation errors can then be used as an index of severity and these should be both valid and reliable.

The majority of these errors received a score ranging from minor to moderate severity, which gives the impression that risk control mechanisms in pharmacy units were working. However, after taking likelihood into account, the results showed that two types of errors ranked as extreme risk and seven types of errors ranked as high risk, which indicates that risk control mechanisms in pharmacy units need to be improved. As far as the researcher

is aware, this is the only UK study focused on injectable drug preparation errors observed in pharmacy aseptic units.

In the UK, the majority of MEs reported to the NRLS were associated with no harm (83.1% n=49.714); minor harm (12.6% n=7.6552) and moderate harm (4% n2.391); however, 0.1% were linked with severe harm and 0.1% resulted in death (NPSA, 2009). In comparison, this study determined that 31/46 errors (67.4%) were deemed capable of causing minor harm, and 15/46 errors (32.4%) were deemed to be of moderate harm. None of the 46 errors had a mean score higher than 6.5, suggesting that none of the errors were considered to be severe or fatal. The findings of this research indicate that most of the reported IPEs resulted in a minor level harm (67.4%; n=31). This is comparable to an observational study of medicine administration errors that also showed that incidents resulting in minor harm were the most common in studies using the American NCC MERP Index harm categorisation (Keers et al. 2013). The distribution of errors over mostly two levels of harm correlates with three previous reports. Avery et al. (2012) identified 128 errors (42.4%) as minor, with a score under 3 and another 163 errors (54.0%) as moderate, with a score between 3 and 7. Ameer (2015) reported that 30% of the incidents were associated with minor harm and 67.1% were classified as posing moderate harm. Taxis & Barber (2003) reported that 31% of errors (n=38) were potentially of moderate harm and 13% (n=16) were potentially minor. In this study, there are no errors with a severe score, unlike in other studies, for example, Taxis & Barber (2003), who reported that 3% (n=4) of all observed preparation and administration of intravenous drug errors posed severe harm; Avery et al. (2012), who found that 3.6% (n=11) of all prescribing and monitoring errors posed severe harm and Ameer (2015), who stated that 2.9% (n=12) of all medication administration errors in

Paediatric Intensive Care Unit were graded as potentially causing severe harm. These variations in the results could be attributed to the differences in the cases observed or the study setting in both sets of research. It is often difficult to establish the true level of harm due to the complexity of the conditions under treatment (Chedoe et al., 2012; Ameer, 2015). In addition, differentiation of severity of harm between studies is not easy due to the different standards used to define the levels of harm (Keers et al. 2013). To enable comparison across different systems, standardising harm classification is necessary.

This study used severity data and frequency data to calculate a risk score for the preparation errors observed to provide a focus for developing risk reduction strategies. The results showed that data can be divided into three levels: extreme risk, high risk and moderate risk. In this research, the investigator has chosen to focus on extreme risk and high-risk errors to develop risk reduction strategies for the three different aseptic units. Also, the resulting risk scores suggest that there are different priorities that need to be tackled to reduce errors in each of the units. For example, in the large licensed unit risk reduction strategies should focus on ensuring that the wrong dose and wrong diluent is not supplied; whereas in the small licensed unit the focus should be on preparation techniques and preventing assembly errors. In the unlicensed unit, risk reduction strategies should prioritise avoiding worksheet errors.

In the large licensed unit, two types of errors were graded as posing extreme risk (wrong diluent and wrong dose) and three types of errors were graded as high risk (wrong expiry date, wrong route of administration and wrong batch number). This might be because the large licensed unit prepared more medicines than the small and unlicensed units thus

leading to a higher frequency of potential errors. On the other hand, in the small licensed unit there were five types of errors that were graded as high risk (assembly error; wrong preparation technique; faulty labelling; worksheet error; and wrong batch number). In the unlicensed unit there was just one error classified as being a high-risk error (worksheet error). This is of concern because such errors can have a direct effect on the patient's treatment. Nevertheless, it bears pointing out that there were no cases of wrong drug during this research in contrast to the patient safety incident reports. Furthermore, it is possible that this research did not capture all the IPEs as only 47.2% of the total injectable medicines doses prepared during the observation period were observed. Also there may have been incidents of omitted medicines and others, for example a mismatch between patient and medicine. The presence of the researcher in the preparation room may have helped to minimise some errors. However there is no concrete evidence to prove this interpretation.

The limitation of the study was that the responses received from questionnaires answered closed-ended questions with 'yes / no' or numbers and, as such, did not provide detailed descriptions. Secondly, the questionnaire was sent via email, so no clarification was available for reviewers during completion. Thirdly, the data synthesis would have been more robust if the replies had been collected personally from the healthcare professionals. This would also have improved the level of detail contained in each response. Finally, as discussed in section 2.6.7, the severity questionnaire data entry was completed and checked by the researcher (AA) only. An independent check of the data entry by a second person would have been a more rigorous approach, but the resources to do this were not available.

3.11 Conclusion

A significant number of patient safety incidents occur as a result of injectable medication use in the pharmacy environment. Usually, the highest-risk medicines are those administered by injection, so injectable drugs must be prepared and administered carefully. Patients given injectable drugs should be monitored closely. No difference was found in the injectable preparation errors rate between three different types of aseptic units; there were differences in the stage of the preparation process where the error occurred. There were also differences between the severities of errors in the different units; on average errors, which occurred in the large unit, were ranked as being moderately severe, whereas those in the other units were ranked as being of minor severity. However after accounting for error frequency, two types of error were graded as posing extreme risk in the large unit and seven types of errors were ranked as posing a high risk in the small and unlicensed units.

This analysis has thus provided an important tool for prioritising risk reduction strategies when preparing injectable medicines in the three different pharmacy units, which will improve patient safety. Each error should be analysed to identify the contributing factors; in this way, staff can learn from errors and decide what modifications and strategies must be implemented to prevent the occurrence of similar errors in the future. Furthermore, training needs and design problems should be investigated to minimise the rate and severity of injectable drug preparation errors.

This requires a coordinated approach from practitioners, regulators, and the pharmaceutical industry. Eventually, the reduction and prevention of errors in injectable-medicine preparations will save lives and reduce the cost of health care and the money saved could be used to improve patient safety in UK hospitals.

Chapter Four

A Qualitative Study Investigating the Views of Pharmacy Staff Concerning the Factors Contributing to Injectable Preparation Errors in Pharmacy Aseptic Units

4.1 Introduction

The preparation of injectable medicines is accompanied by extensive risk (Taxis and Barber, 2003; Beaney, 2004; Bateman, 2003; Bateman and Donyai, 2010; James et al., 2016). In 2000, The UK Department of Health (DOH) reported that NHS staff made a number of fatal errors, from which they failed to learn lessons and so prevent such errors from reoccurring. It was established that one out of every ten such errors related to injectable medicines, half of which were avoidable (DOH, 2000). The National Patient Safety Agency (NPSA) suggested that, in order to improve the safety of injectable drugs and minimise risks associated with their preparation, some high-risk injectable (e.g. chemotherapy and TPN medicines) should be prepared under the control of the pharmacy department (Royal Pharmaceutical Society, 2016).

The aseptic preparation of medicines in the UK is undertaken either in units holding a manufacturer's special licence, or in unlicensed units, promoting a satisfactory level of safety combined with regular external audit (see Section 3.2). However, it is possible that errors may occur more frequently than currently believed during the pharmacy preparation of injectable medicines (see section 1.7). The error rate of injectable medicines in the UK ranges from a low of 0.49% (Bateman and Donyai, 2010). However, the causes of these errors are several and varied, with little understanding of the contributing factors. There have been a number of errors within pharmacy aseptic units in the UK (Gandy et al., 1998), i.e. a fatal error occurred in 1994, when the administration of contaminated TPN caused the death of two infants. However, previous studies have revealed very little evidence

concerning errors in pharmacy aseptic units, leading to a need to understand the causes of IPEs, in order to improve safety.

This thesis has adapted Reason's (1990) organisational accidents model (see Section 2.7.5), established to identify the sequence of actions resulting in error. This model considers the actions of staff, and, more significantly, their working conditions, in order to establish the latent factors resulting in such errors (Reason, 1990). Reason's model categorised human contribution to such errors as follows: (1) active failures (i.e. the individual factor); (2) error producing conditions (i.e. the environment factor); and (3) latent failures (i.e. the organisational factor). This model therefore identifies failures with immediate outcomes (i.e. active failures and error producing conditions) potentially leading over the long term to unsafe outcomes (i.e. latent failures) (see Section 2.7.5).

A number of factors contributing to Injectable preparation errors (IPEs) have been reported in the published literature (see Section 1.7.1) related to: (1) the work environment (i.e. workload, destruction or interruption); (2) individual factors (i.e. stress and fatigue); and (3) latent factors (i.e. lack of adequate training) (Limat et al., 2000; Parshuraman et al., 2008; and Bateman & Donyai, 2010).

The procedure for the preparation of injectable medicines is currently little understood, including the risks, as well as the sources of information or guidance employed by staff for problem solving. This current study examines the views and opinions of, as well as the difficulties and solutions faced by, pharmacy staff working in injectable drug preparation on a practical level.

4.2 Significance of the Research

The purpose of preparing injectable medicines within a pharmacy department is to improve the quality of the final product (Hospital Pharmacists Group, 2002). However, as previously discussed, errors still occur during injectable drug preparation in aseptic units in the UK. This is demonstrated in a number of published studies (Bateman and Donyai, 2010) and from data revealed in Chapter Three, in which an observational study provided valuable information concerning the types and frequency of errors, including issues of risk. In order to reduce the risk of mistakes taking place, it is first important to understand the cause. This chapter therefore examines the underlying causes of a number of errors reported in the observational study, focussing on the opinions of the pharmacy staff involved. It also establishes the opinions of staff concerning how such errors can be reduced, in order to develop future preventative strategies.

4.3 Aims and Objectives

As noted above, this study examines the opinions and views of pharmacy staff involved in errors previously observed in three pharmacy aseptic units. The aim of this examination is suggestions ways to minimise the IPEs in three different pharmacy aseptic units. The objectives are the following points:

- Establish the causes of errors observed during the preparation of injectable medicines from the aseptic units by pharmacy staff.
- Identify strategies for minimising the risk of such errors reoccurring.

4.4 Methodology and study design

4.4.1 Overview

Qualitative data can provide a rich source of information and can be effective in explaining the results of quantitative analysis (see Section 2.7). Qualitative research methods have increased since the 1990s, with their use gaining significance in health services as well as pharmacy practice research (Smith, 1998). The qualitative approach is considered appropriate for investigating little known areas, as well as sensitive or complex topics (Creswell, 2013), and to deliver vision and in-depth information concerning complex cases (Bowling, 2009). Qualitative research approaches focus on issues of 'why?' and 'how?' events take place, with the collected data focussing on examining and understanding individuals' thoughts and behaviours. Unlike quantitative methods (which focus on the viewpoint of the investigator and are based on a standardised method), qualitative approaches are more flexible and receptive to the opinions of the respondents (Smith, 1998).

The most frequently employed approaches in a qualitative study include undertaking interviews employing the following methods: (1) face-to-face; (2) telephone; (3) focus group; (4) email; and (5) semi-structured interviews (Bowling, 2009; Creswell, 2013) (see Section 2.7). The most frequently employed methods are semi-structured interviews, which have been established as effective in investigating the perceptions of individuals and how they make sense of their own environment (Bowling, 2009; Creswell, 2013). They are also the most frequently used qualitative method for research related to health services and medical practice (Smith, 1998). Semi-structured interviews are considered a shared

technique, allowing rich data to be collected through communication between the investigator and the interviewee, enabling the investigator to obtain detailed answers relating to the subject under discussion (Ritchie and Lewis, 2003). They are based on a flexible topic guide and contain open-ended questions concerning the topic studied, in order to explore participants' experiences and opinions and to establish their personal views (Creswell, 2013). A focus group is considered a more time efficient method, allowing a number of individuals to be interviewed simultaneously, thus documenting a general view, rather than that of an individual, while some participants may not interview well in group situations (Creswell, 2013) (see Section 2.7).

This thesis employed interview-based research, using a semi-structured interview method. This technique allowed an increasing understanding of the perceptions of pharmacy staff concerning contributing factors of IPEs.

4.4.2 Development of the Interview Schedule

The development of the interview schedule was based on a review of the literature concerning human error theory. It consisted of open questions and topic headings employed by the interviewer to stimulate discussion (Oppenheim, 1992; Smith, 2002), and invited participants to describe: (1) how an error occurred; (2) the contributing factors; and (3) potential strategies to be implemented to prevent any reoccurrence. The interview schedule was reviewed by Dr. Richard Bateman, a Regional Quality Assurance Specialist Pharmacist in East and South East England Specialist Pharmacy Services and Dr. Bateman a member and former Chair of the NHS Pharmaceutical Quality Assurance Committee. A

simulation of the interview was conducted at the University of Bath during May 2014, with supervisor Dr. Lynette James and psychologist Dr. Nick Forbes, resulting in the final interview schedule (Appendix 9).

The interview schedule (see Appendix 9) was developed to collect significant details concerning the contributing factors behind IPEs. This was based on the framework of factors impacting on health practice developed by Vincent et al. (2000) to analyse risk and safety in aseptic pharmacy practice, categorising the following preparation factors: (1) active failure; (2) error producing conditions; (3) environmental conditions; (4) the team; (5) patients; (6) latent factors; and (7) barriers or defences leading to failure. This framework focuses on the significance of developing appropriate medicine safety, leading to a 'no blame culture', enabling lessons to be learnt from any mistakes.

The interview was divided into four main sections. Firstly, participants were asked if they considered specific events had led to errors in the preparation injectable drugs, followed by the identification of such mistakes. Secondly, questions focused on the causes of IPEs, based on the classification of active failure (i.e. individual), error-producing conditions and latent factors identified by Vincent et al. (2000). Thirdly, there was a discussion of the presence of underlying contributing factors, followed by participants being requested to define any failure of barriers or defences indirectly leading to error. Fourthly, there was a discussion of potential strategies to minimise the reoccurrence of errors. In each part, questions were employed to elicit any further explanation, if required. Interviews were audio recorded for a verbatim transcription and the interviewer also took written notes.

4.4.3 Study setting

This study was undertaken within a range of aseptic processing units throughout the UK, and forms one of the first UK investigational studies to actively investigate errors taking place during real working conditions within this complex domain (see Section 3.6.2).

4.4.4 Study Participants

Pharmacy staff who had made injectable medicines preparation errors during the period of observation were invited for interview. Those wishing to participate in this study were provided with a participant information leaflet and consent form (see Appendix 4) and were required to provide written informed consent (see Appendix 5) prior to being interviewed. Due to the qualitative nature of this study, there was no need for a formal sample-size calculation to establish the required number of interviews, while the variation within qualitative research leads to a lack of any specific method of measurement (Pope and Mays, 2000; Guba and Lincoln, 2005). It was anticipated that the investigator would be able to interview all staff who had made an error, with the majority agreeing to be interviewed within forty-eight hours of the error taking place. It was agreed for the purposes of feasibility that the number of interviews should be between six and twelve. Although the interview selection criteria was likely to result in a small sample size, the additional interviews undertaken with nine pharmacy technicians and assistant technical officers was aimed to gather opinions from staff with a range of professional experience and backgrounds. The minimum sample sizes needed to attain saturation in interview-based

study is nine interviews, and hence it was presumed that the determined sample size would be suitable to create relevant themes and codes (Hennink et al., 2017).

4.4.5 Ethical approval

Ethical approval for this study was obtained from the Research Ethics Procedure of the University of Bath's (see Section 3.7.3).

4.4.6 Data Collection

In accordance with previous dispensing error research, participants were interviewed in a private room, using the developed interview schedule, within forty-eight hours of the error-taking place (Gothard et al., 2004; Beso et al., 2005). The interviews were undertaken with technical pharmacists and Assistant Technical Officers (ATOs) in three aseptic pharmacy production units. Each interview lasted approximately forty-five minutes and, with consent from the participant, was audio-recorded using an MP3 player. Audio-recordings of the interviews were transcribed verbatim.

4.4.7 Data Storage

All data remained confidential. Data from interviews were anonymised on transcription and interview recordings were destroyed following transcription (see Section 2.5.4).

4.4.7 Data Analysis

Data was analysed by means of thematic analysis employing the theoretical framework (as described previously in Chapter Two, Section 2.7.3) of Reason's (1990) accident causation model (Reason, 1990; Ritchie & Spencer, 2002). The researcher (AA) and two academic staff members (i.e. Dr. Lynette James and Dr. Julie Letchford) independently scrutinised interview transcripts for: (1) active failures; (2) error producing conditions; (3) latent failures; and (4) barriers/defences. All themes and coded forms of individual, environmental and latent factors, along with defences, barriers and strategies, were extracted from the interviews. The findings were subsequently discussed and a consensus achieved. Transcripts were then analysed manually (see Section 2.7.4).

4.5 Results

The forty-eight hour timeframe was based on previous study investigating dispensing errors (Gothard et al., 2004; Beso et al., 2005). However, due to staff being too busy (or unwilling) to be interviewed, it was not possible to obtain interview data for all preparation errors observed by the researcher in the three pharmacy aseptic units. Therefore, nine interviews (corresponding to nine observed errors) were undertaken with staff involved in injectable preparation errors across the three participating sites, with four interviews conducted in the large unit, three in the small unit, and two in the unlicensed unit.

This led to interviews with five pharmacy technicians (large licensed n=3, small licensed n=2) and three ATOs (large licensed n=1; unlicensed unit n=2), with two of the errors being made by one individual working in the small unit (PS17 and PS21). All participants were full-time employees qualified to prepare injectable medicines, with their experience ranging between one month and over twenty years. Interviews were obtained for the errors summarised in Table 4.1.

Table 4.1 Summary of interviews obtained for detected errors

Ref	Site	Job title	Gender	Type of error	Description of error	Risk score
PL1	A	Pharmacy technician	Male	Incorrect diluent (internal error)	Incorrect strength of diluent picked to prepare final product, i.e. 5% glucose instead of 10% glucose.	Extreme risk
PL12	A	Pharmacy technician	Female	Incorrect dose (internal error)	Incorrect strength of drug (starting material) picked to prepare final product (50% magnesium instead of 10% magnesium).	Extreme risk
PL13	A	ATOs	Male	Incorrect dose (internal error)	Incorrect number of doses of drug prepared with only one dose required, but an additional three doses prepared.	Extreme risk
PL11	A	Pharmacy technician	Male	Incorrect expiry date (external error)	The final product had expired, i.e. an out of date drug was delivered to the ward due to error in logging the expiry date in the fridge record.	High risk
PS16	B	Pharmacy technician	Female	Worksheet error (internal error)	Incorrect label affixed to worksheet.	High risk
PS21	B	Pharmacy technician	Female	Worksheet error (internal error)	Signature of member of staff who had labelled the product missing from worksheet.	High risk
PS17	B	Pharmacy technician	Female	Unprescribed medicine (internal error)	Product made on an incorrect day.	Moderate risk
PU31	C	ATOs	Female	Incorrect dose (internal error)	Leakage from vial resulted in dose being too low.	Moderate risk
PU32	C	ATOs	Female	Incorrect batch number (internal error)	Incorrect batch number of medicine (i.e. starting material) on worksheet and label.	Moderate risk

Fourteen errors were observed in Unit A, with interview data obtained for 30% n=3/10 errors classified as extreme risk and 25% n=1/4 errors classified as high risk. Sixteen errors were observed in Unit B, with interview data obtained for 13.3% n=2/15 classified as high-risk errors and 1/1 error classified as moderate risk. Thus, qualitative data was obtained for all risk grades associated with units A and B. In addition, sixteen errors were observed in Unit C, with interview data being obtained for 2/2 errors classified as moderate risk. Unfortunately no interview data was obtained for high risk errors obtained in unit C that accounted for 14/16 errors observed.

4.5.1 Causes of injectable preparation errors

I. Active Failures

A total of nine active failures were identified by the interviewees (see Table 4.1), classified as lapses, slips, or mistakes. There were two lapses, six slips (one of which related to the external error), and one knowledge-based mistake. Lapses involved forgetting to sign the label and not attaching a label to the worksheet. Typical examples are given below:

> *I find that's when it happens, when you've got someone else labelling, because they will just label and forget to sign to say that they've labelled it.* (PS21)

> *Sticking the label on the back is something that we did with the old system … so it's not something that I should have forgotten.* (PS16)

Slips involved selecting the incorrect strength of drug from the shelves to prepare the final product, and included: (1) selecting the incorrect strength of diluent; (2) withdrawing the incorrect volume of diluent from a vial to prepare the final product; (3) writing an incorrect

batch number of diluent on the worksheet; (4) product made on an incorrect day (i.e. internal errors); and (4) an incorrect expiry date on the product label (i.e. external error). For examples:

> *Magnesium 50% was setup. It was sprayed into the unit. … Another checker came in [and] they realised it was 50%, not 10%. This could have had fatal errors, as it was 5 times the strength it should have been*. (PL12)

> *The expiry date wasn't changed on the computer, so it came out with a later expiry than it should have, and I missed that.* (PL11)

> *Amm. My first day back after annual leave.* (Laughs) *Amm… I didn't think. I had any things else on my mind…amm it's just, amm, amm. Initially it was the kind of thing like the needle sledding on the bung, really I would not say it was stress or anything, it's just, amm, concentrating on what I am doing.* (PU31)

The knowledge-based mistake involved a member of staff unintentionally requesting the incorrect number of hydrocortisone vials for a paediatric patient, having accepted the details populated by the computer generated worksheet without understanding that the number of vials needed to be manually amended for paediatric prescriptions. For example:

> *Okay, so when putting the worksheet through the computer … you have to put the drug in according to the prescription, and you choose the number of vials based on what comes up on the computer. So I picked two, because that [is] what it says to [do]. [I] printed out the worksheet, [then] someone else checked it and they told me that, because it is for a child, it only needs one vial of hydrocortisone, not two.* (PL13)

In large Unit A, at least some of the errors classified as being of extreme risk were caused by two slips and one knowledge-based mistake (i.e. an incorrect strength of diluent picked from the shelves and the preparation of an incorrect strength of drug and incorrect number of doses) as well as a number of errors classified as high risk that were caused by a single

slip (i.e. an incorrect expiry date). In small Unit B, some of the errors classified as high risk were caused by two lapses (i.e. an incorrect label attached to a worksheet, with the signature of the maker being omitted and an incorrect expiry date), while some of the errors classified as being of moderate risk were caused by a single slip (i.e. the product being made on the incorrect day). In unlicensed Unit C, at least some of the errors classified as being of moderate risk were caused by two slips (i.e. leakage from a vial resulting in a dose being too low and an incorrect batch number of medicine (i.e. starting material) being placed on the worksheet and label). This identifies the need to focus on extreme and high risks in understanding causes and developing preventative strategies based on the data from pharmacy aseptic units and suggestions made by pharmacist practitioners.

II. Error producing conditions (EPCs)

Based on the above categories, there were a total of four main Error Producing Conditions (EPCs), and twenty-seven codes. During the interviews, participants stated that error-producing conditions contributed to errors in drug preparation, as demonstrated in Figure 4.1, below.

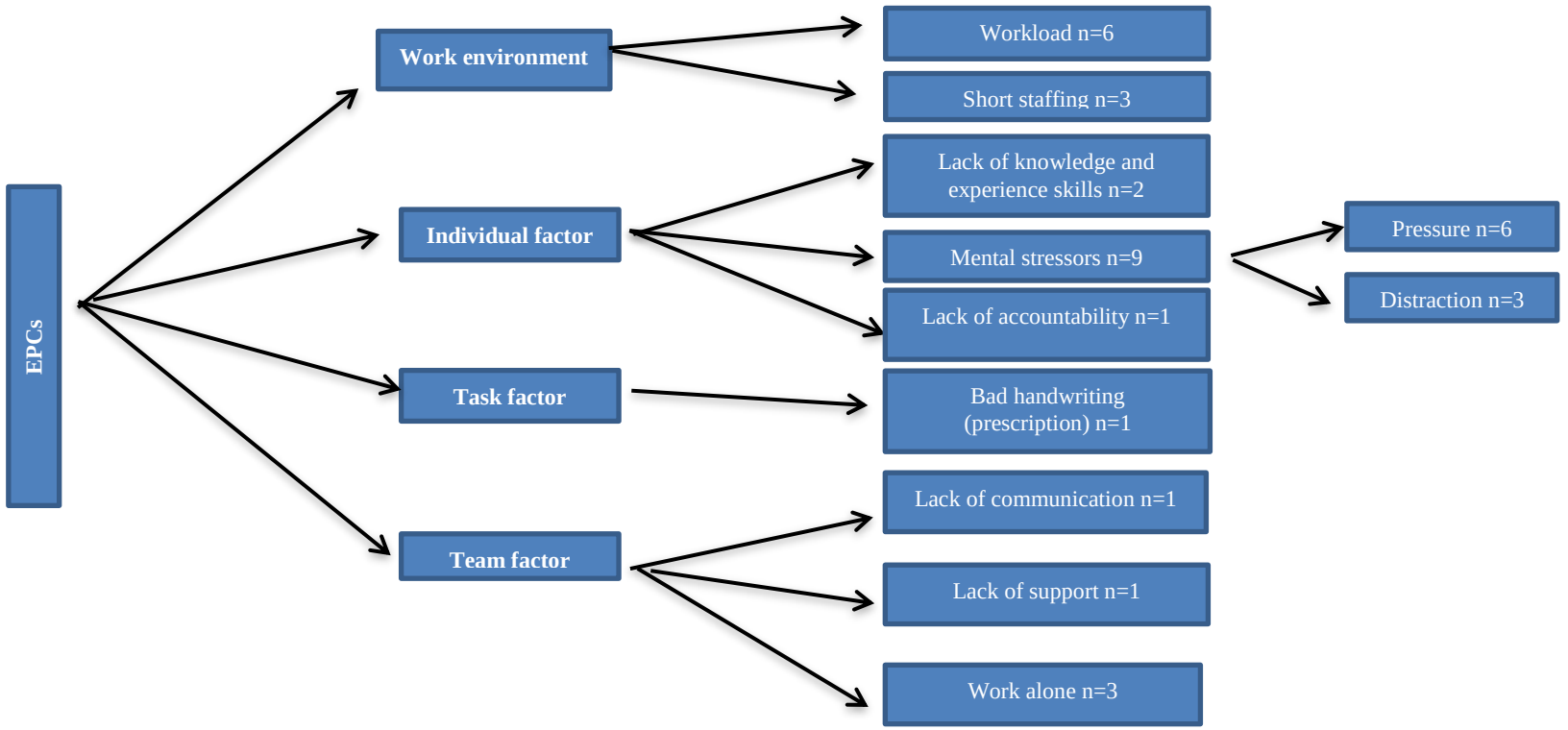


Figure 4.1: Themes and codes for EPCs contributing to the preparation of injectable medicine

1) Working Environment

Issues related to workload contributing to injectable preparation errors were regularly reported in interviews (n=6) using the following terms: *'busy*'; '*busy workload*'; and '*high level of workload'*. A further contributing factor included shortage of staff (n=3): Typical examples are given below:

> *Busy, very busy, hardly anyone about...you haven't got all the staff around you to help.* (PL1)
>
> *I think the workload is too high… I would say for one person. (PU32)*
>
> *Not enough staff in here and you will rush, amm… and maybe you miss something. (PU32)*
>
> *In our area, we have CIVAS next door, and because we are short of staff, I had to make the CIVAS and we knew we had to get TPN up and running because we were busy, we just had so much to do.* (PL12)

2) Individual factors

A number errors (n=3) were identified as resulting from stress and pressure due to the workload inside the aseptic unit during the preparation of the final product (n=6), along with distractions, i.e. the phone ringing and staff speaking. For examples:

> *The product in question actually came in quite late, so we needed to setup under pressure, and it would have been checked under pressure. We were under pressure because it was for a set delivery time of 11.30. So we were trying to make sure it went out at that delivery time, so there was quite a great deal of pressure at all stages.* (PL1)
>
> *It was busy. The phone was going all the time, which means you are constantly on the phone to people outside and pharmacists. So it was quite a busy time.* (PL13)
>
> *Being stressed under pressure and just a genuine mistake. Sometimes you feel like something is going to happen.* (PL12)

An individual factor contributing to two errors was identified as a lack of familiarity with the computer system. Typical examples are given below:

> *I am not really familiar with Episys. I have only ever been shown and I have never used it before by myself.* (PS16)

> *I was quite new to Ascribe, I had just started on Ascribe, and was just learning about putting the worksheets through.* (PL13)

A further individual factor (i.e. a negative attitude to patient safety) contributed to a single error, i.e. a lack of accountability. Staff who were less vigilant demonstrated a lack of responsibility, assuming that that they did not need to be vigilant as there would be additional checks. For example:

> *It wasn't too much of a problem because there are so many checks. There's the check after Ascribe, and then it goes into the unit and is checked there.* (PL13)

3) Task and Team factors

Team and task factors contributing to the manufacture of a medication on the incorrect day, included poor communication between the wards and the aseptic manufacturing unit, along with poor prescribing practices. For example:

> *Sometimes they [prescription charts] come quite sporadically. Some will come on a Thursday, some on a Friday, and they might send some on a Monday, so you're thinking, "all right, they are all for today". Yeah. It was only when I looked in the fridge and I thought "they haven't picked up this patient" that I went and checked the worksheet and the prescription and I thought, "No, this patient is not for today".* (PS17)

A team factor contributing to a single error in one unit consisted of lack of support, i.e. one interviewee stated that of a lack of teamwork resulted from a member of staff being ill or

on annual leave, and that a number of staff were not qualified to help while others had little experience with the system. For example:

> *As a checker, I don't just do the aseptic unit, I do the production side. So, if there's no technician in to check their work, I get called on to check their work, to check aseptic. ... It's just one of those days where you're out there on your own.* (PL1)

Three interviewees identified a further team factor contributing to an error as being lone working, i.e. the interviewee from unit C noted a high workload in the clean room as being a result of an absence of teamwork. Furthermore, the interviewee noted that she/he was a lone worker and did not understand the procedure, thus resulting in the incident: Typical example is given below:

> *Ok ... I know Friday is a very busy day, especially in the afternoon, and I was on my own here in the afternoon doing all the worksheets.* (PU32)

An interviewee from unit A noted a lack of teamwork placing considerable pressure on staff, with some staff being unable to help with the preparation. In unit B however, an error arose as a result of the strong desire of a member of staff to assist his/her team when he/she lacked familiarity with the system. For examples:

> *We have had problems recently about staff not doing the work for various reasons, so there's a lot of pressure on other people...you've got people now just standing there and it's not that they don't know what they are doing, they just don't see the urgency.* (PL12)

> *You just want to help out. You don't want to be sitting around doing nothing. You just want to help out.* (PS16)

A number of conditions in Unit A leading to errors classified as being of extreme risk, resulted from a lack of knowledge, and included: (1) workload; (2) lack of staff; (3) pressure; and (4) distractions or interruptions. Some of the error producing conditions

resulting in high risk errors in unit B included: (1) miscommunication between the pharmacy and the ward; (2) a lack of support; and (3) poor handwriting (i.e. the prescription chart). A number of the error producing conditions in Unit C leading to errors classified as being of moderate risk included lone working. The contributing factors identified above should be used to develop strategies aimed at minimising the reoccurrence of IPEs.

III. Latent conditions

In this current study, twelve codes of latent conditions were identified from two main themes. The interviewees considered that latent conditions contributed to injectable drug preparation errors, as summarised in Figure 4.2. As noted in Chapter Two, this current study is based on Reason's (1990) Swiss cheese error causation model, which was subsequently further developed by Vincent et al. (1998). Thus, all these themes and codes were extracted and defined using the interview data collected as part of this study, and informed by the existing theory.

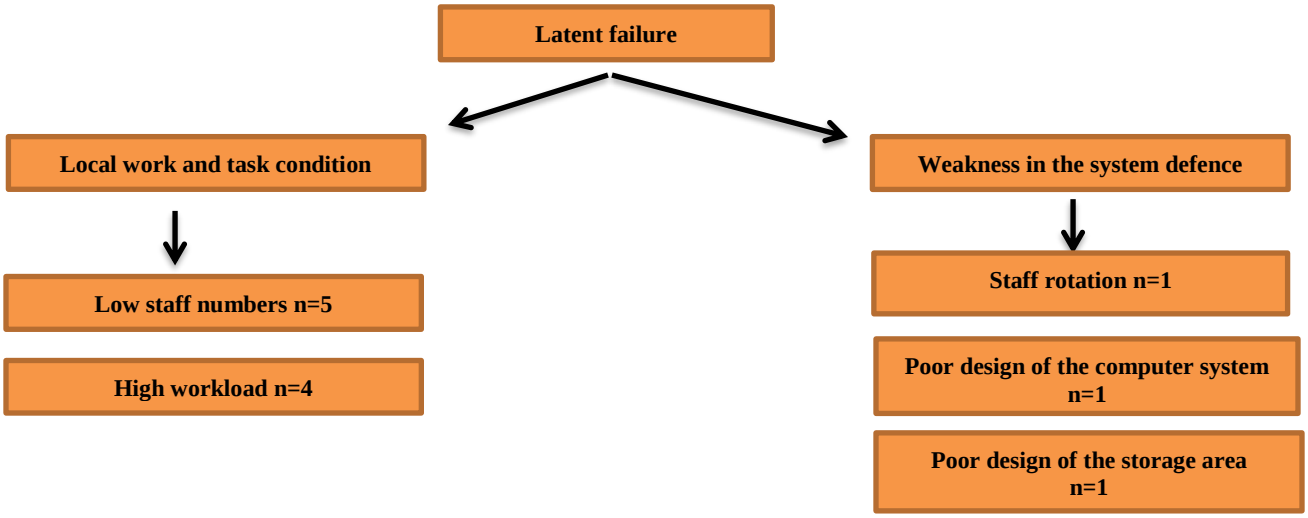


Figure 4.2: Latent conditions quoted as contributing to injectable medicines preparation errors

1) Local work and task conditions

The interviewees classified a number of latent conditions contributing to injectable preparation errors. High workload (n=4), associated with low numbers of staff (n=5), was frequently stated as contributing to such errors. For examples:

> *A lot of expectations, a lot of work, but not enough people. That's not always good. We could do with more people sometimes.* (PL11)

> *So, if you're on your own out there, it's quite busy and with the way things are in the NHS, we haven't got the numbers here. Really, we probably need more people.* (PL12)

2) Weaknesses in the system's defences

A potential cause of error was considered a consequence of staff rotation, due to this leading to a potential lack of ownership, i.e. a requirement from staff to be on the ward at a specific time led to other staff being given responsibility for completing the process of preparing the injectable medicine. For example:

> *It was very busy yesterday. We had quite a lot of work on and with our rotation staff ...myself and* X *work there fulltime, but the rotational staff only come in on certain days. So* Y *was covering on the ward yesterday afternoon, I think she was on the bleep, so she needed to be back in work by two o'clock to cover that. So, because we didn't come out of the unit until ten past one, everything was put in the quarantine shelf and* Y *just came in to sign her bits, and I think that, because I was the one who labelled them, that's when I missed that one.* (PS21)

One participant reported poor design of the computer system as resulting in a single error. For example:

> *I was quite new to Ascribe, but there's nothing there to tell you that it only needs one vial and even people more experienced than me still make that mistake.* (PL13)

The design of the storage area inside the unit was mentioned by other participants as contributing to the selection of incorrect drug vials and/or the incorrect strength of diluent. Typical example is given below:

> *They are all together, all the sodium, the water and the glucoses, they are all together. They are different strengths but it is very easy to quickly go and grab the wrong one.* (PL 1)

Latent factors associated with errors classified as extreme risk included: (1) a high workload; (2) the low number of staff; (3) the layout of storage room; and (4) a poorly designed computer system, i.e. the strength of diluent picked from shelves, an incorrect strength of drug and an incorrect number doses of drug prepared. A number of latent factors associated with the errors classified as high risk resulted from: (1) staff being overworked; (2) insufficient staff to undertake work on the aseptic product; (3) staff rotation; and (4) poor design of the computer system, i.e. the final product expired; an out of date drug was delivered to the ward as the result of an error in logging the expiry date in the fridge record; an incorrect label was attached to worksheet; the signature of the maker was missing; and an incorrect expiry date. A number of latent factors associated with errors classified as moderate risk resulted from staff rotation and high levels of work undertaken with an inadequate number of staff, i.e. (1) product made on incorrect day; (2) leakage from vial resulting in the dose being too low; and (3) an incorrect batch number for the medicine (i.e. starting material) being placed on the worksheet and label. It is thus possible to establish error reduction strategies in response to the data obtained for active failures, along with EPC and latent conditions and suggestions from pharmacy practitioners.

IV. Barriers and defences

The interviewees suggested a number of strategies to reduce the risk of errors during the preparation of injectable medicines, including training (n=3) lasting between six months to one year. Typical examples are given below:

> *I think when people from the production side come across, there's not enough training there. When I first started as an ATO, I shadowed someone, so I would be with that person all day for months and months, but people from production have just been dropped in the ocean [to] sink or swim. We haven't really got a training person here. I mean* X *does it, but she's not always here.* (PL12)

> *Just the initial training, like I said, having proper training plans in place for new starters, and new people to the department, so they can gain experience and have a six month probationary period in the area before being trusted with lifesaving drugs.* (PL1)

Training included: (1) shadowing staff in the manufacturing unit; (2) visiting the ward to observe medication being given to patients; and (3) the provision of a dedicated trainer. For example:

> *One-to-one training, and the three-check rule, so if people are observed and made aware of the errors and they understand, I think that's the biggest thing. [To] understand that it's important you double check yourself that it's correct.* (PL12)

A second strategy identified by two interviews consisted of double-checking. They suggested that this minimises the risk of errors during the preparation of injectable medicines (n=2). Typical examples are given below:

> *We need to highlight the fact that we must check the date and that it's not just technicians that are putting through the worksheets and the labels. I think the pharmacists clinically...need to check that date as well...and also say to us: "this is a different date to the others, can we check and chase it up?" So yeah, we just need to put [that] in place and be vigilant.* (PS17)

A further interviewee suggested that an observation strategy could be used to reduce the risk of errors (n=1). For example:

> *So maybe if someone watched me for a bit, to see what I was doing, that might have prevented that error as they would have seen that it was for children, and therefore I should only have used one vial*. (PL13)

It was recommended that pharmacists and checking technicians should confirm the date on the prescription with the date the medicine is to be administered to the patient, in order to avoid a product from being prepared on the incorrect date (n=1). For example:

> *We need to correspond more with the medical day unit ... We need to communicate more with them, not just rely on them to contact us. I think we need to contact them as well, like we do with* X... Y... *We phone them. If they haven't phoned us by quarter past ten, we phone them to say: "Do you know who's cancelled?" or "What's going on?"* (PS17)

There was also a suggestion to increase in the number of staff inside the clean room, in order to resolve the issue of time pressure and workload and thus minimise the risk of drug preparation errors (n=3). For example:

> *Umm... I think more staff is needed, that's all*. (PL11)

One interviewee raised the issue of computer software as contributing to one error, suggesting that the programming of alerts into the aseptic computer software could warn users and prevent errors (n=1). For example:

> *Maybe something on the software, so if this and this are together, then a warning comes up.* (PL13)

Two interviewees suggested strategies to minimise the risk of preparation errors in relation to injectable drugs, including the separation on storage shelves of drugs that are similar and different strengths of the same drug (n=2), along with the use of colour coding (n=1). Typical examples are given below:

> *Yeah, separate the 10% and 50%, label the boxes so they are nowhere near each other and separate them with big notices saying 'please check the product'.* (PL1)

> *So, I think colour coding of different products would be good, but it's to do with companies and money isn't it? Changing packaging could be pretty pricey.* (PL12)

In addition, it was suggested that errors could be avoided (n=1) by improving the working environment through the designation of a quieter room with no phones for checking the worksheet and labelling. Typical example is given below:

> *We could have a quieter room, or a room just for doing checking that's not got a phone that acts as the main phone, so it's not ringing constantly, and that people don't come in every five minutes and use the computer. Just having a quieter room would make a lot of difference, because you can concentrate without being interrupted every two minutes*. (External error; PL11)

4.6 Discussion

This study investigated errors made by staff working in three pharmacy aseptic units, along with their views of how such errors occurred and how they might be avoided. The results demonstrated that errors can be divided into a number of different classifications: (1) issues relating to the work environment limiting the ability of staff to prepare injectable medicines; (2) individual factors; and (3) errors resulting from management decisions. This ensured that errors could be readily be divided according to Reason's (1990) organisational accident causation model (Vincent et al., 1998).

This study has established that the most commonly cited contributors to the occurrence of injectable preparation errors consisted of a low level of staffing accompanied by high workload. Previous research in pharmacy aseptic units (which were based on the self-reporting of errors) failed to identify any correlation between rates of error and workload (Escoms et al., 1996; Flynn et al., 1997). The current results are, however, consistent with a UK study by Limat et al. (2001), which examined the impact of workload on errors taking place during the preparation of chemotherapy injections. It was reported that a daily workload of over sixty preparations undertaken by a single member of staff posed a significant risk factor for error ($p=0.016$). Successful human resource management can (as previously reported) minimise the occurrence of errors during injectable preparation by ensuring: (1) the competency of staff; (2) reducing workload pressure inside the aseptic unit; and (3) addressing the issue of a lack of staff (Radde, 1982).

A considerable number of research participants reported that stress or pressure contributed to IPEs, relating to: (1) inadequate staffing; (2) lone working; (3) high workloads; (4) distraction; and (5) miscommunication. Recommended strategies for minimising stress-related injectable preparation errors include: (1) enhanced human resource management to ensure adequate staffing and skill mix; (2) development of guidance on handling distractions; (3) removing telephones from the production unit; and (4) varying staff activities, thus allowing for mental breaks from risk-critical activities (Radde, 1982).

The factors perceived as contributing to preparation errors in this study were similar to those identified in previous studies (Bateman and Donyai, 2010), including mistakes by individual members of staff, distraction, interruption, and inadequate training. Two of the participants interviewed in this study (from both the large licensed and small licensed units) viewed the occurrence of incidents as relating to a lack of familiarity with the computer system inside the aseptic unit, resulting from insufficient training. This finding is consistent with previous studies (Crowley, 2006; James et al., 2008, Bateman and Danyai, 2010), indicating a need to establish a clear training programme for all pharmacy staff, in order to minimise injectable preparation errors for the aseptic unit (NPSA, 2012). There is a lack of standardisation across NHS Trusts in the training of pharmacy staff in the process of preparing injectable medicines. However, standardised approved training programmes are available for teaching technicians to: (1) undertake accuracy checks of worksheets; (2) set up drugs and diluents; and (3) undertake volume checks and double checks of used vials. It could also be possible to establish a similar standardised training programme for aseptic preparation, in order to reduce injectable preparation errors, alongside the ongoing

validation of all pharmacy staff. James et al. (2008) suggested the following additional strategies to minimise the risk of errors:

1) Regular meetings with staff preparing injectable drugs, in order to highlight potential errors.

2) Attendance of conferences by staff involved with injectable drug preparation.

3) Displaying of posters highlighting the risk of injectable preparation errors.

The interviewees in this current study clarified that distractions and interruptions consisted of: (1) ringing telephones; (2) being called upon by other staff; and (3) conversations taking place inside the room. The interviewees put forward a number of suggestions on methods of resolving these issues and reducing the risk of injectable preparation errors in aseptic pharmacy units, i.e. the creation of a quiet room, without a telephone, specifically designated for writing worksheets, labelling, and checking products. This is similar to a number of aseptic pharmacy units, which have already removed telephones from the unit to the pharmacy help desk (Andalo, 2002 and Subramoney, 2009). A number of prescription alerting systems have been instated in some pharmacy departments, in order to avoid distractions by allowing ward staff to determine when the prescription has been received and the final product completed (Andalo, 2002).

In accord with previous studies (Crowley, 2006; James et al., 2008), participants in this current study identified the cause of a number of errors as the close placement within a storage area of drugs with similar names, as well as those of a similar strength. It has been

estimated that 28% of medication errors reported annually to the USA Institute for Safe Medication Practices (ISMP) were attributed to similar packaging, leading to instructions by regulatory and patient safety bodies on the labelling and packaging of medicines (MHRA, 2003; NPSA & Helen Hamlyn Research Centre, 2006; Council of Europe Expert Group on Safe Medication Practices, 2007). However, a proportion of drug packaging fails to comply with these instructions. The NHS Pharmaceutical Quality Assurance Committee has established a risk assessment procedure to avoid the purchasing of medicines with similar packaging (Alldred, 2006), including purchasing from different manufacturers. Interviewees from Wales recommended separating sound-alike, or similar strength, starting materials onto different shelves, in order to minimise incidents. In addition, it was suggested that colour-coded packaging should be used in the storage area to separate different drugs and diluents used to prepare products, along with the employment of bar-code identification of the selected drug during the checking phase. This is consistent with previous studies from a hospital in Wales, which recommended the separation of drugs of similar strength or colour-coded packaging (Crowley, 2006; James et al., 2008).

Between fourteen and sixteen errors classified as high risk were identified in the unlicensed unit, along with between two and sixteen errors classified as moderate risk for patients. The majority of these consisted of worksheet errors, potentially due to medication being dispensed directly to named patients where the final check formed the main stage of the checking process.

A summary of the errors categorised as extreme risk, high risk, and moderate risk has led to the development of risk reduction strategies for each unit, as summarised in tables 4.2,

4.3, and 4.4. These were developed from the results of the interviews conducted with participants in the three different pharmacy aseptic units, as well as in published literature (Flynn et al, 1997; Limat et al., 2001; Ferner & Aronson, 2006; Bateman & Donyai, 2010). Tables' 4.2, 4.3 and 4.4 reveal that individual, EPC and latent factors can contribute to injectable preparation errors in the pharmacy environment. The main factors identified in large unit A involved inadequate training of pharmacy staff concerning the complexity of some injectable preparations requiring complex calculations, i.e. paediatric doses (PL13). The results of the current study confirm the findings of published literature in terms of the lack of training in preparing injectable drugs for aseptic manufacture staff, while only limited studies have specifically studied the contributing factors of errors related to injectable medicine preparation in pharmacy aseptic units (Bateman and Danyai, 2010).

The main factors in small Unit B related to difficulties related to the design of pharmacy computer systems, with one participant noting a lack of training on the new system, including in relation to the differences between the old and new system. The observed error was therefore due to the lack of clarity as to where the label was affixed to worksheet, i.e. being on the front in the previous system, but being now placed on the back (PS16). As stated above, interviewees identified the issue of a lack of appropriate training, and that the Trust needs to check the training methods for staff prior to, and following, competency.

The main factors in unlicensed Unit C concerned the heavy workload and low number of staff working in the aseptic pharmacy unit. Two interviewees identified difficulties in working in a unit as the result of a lack of staff, and the need for additional staff to minimise

the reoccurrence of IPEs. One interviewee identified the high air pressure in a vial due to the resultant leakage of liquid (i.e. the drug), resulting in too low a dose (PU31). The interviewee further stated that heavy workload and low levels of staff led to a lack of breaks, and recommended that supervisors should allocate specific break times to all members of staff, to be taken regardless of the amount of work needing to be completed.

This current study has a number of limitations. Firstly, in qualitative interview studies, a small sample size can limit the results. However, due to the lack of any new themes developing during in the final interviews, the sample size was considered effective for the current study. Furthermore, a number of significant similarities exist between the results of the current and previous studies employing either an interview technique or different methodologies to identify the causes of IPEs (Limat et al., 2001; Bateman and Donyai, 2010).

Secondly, the current study focussed on only one aspect of each unit (i.e. the large, small and unlicensed units). This may lead to the pharmacists' views being limited to the study site and thus lacking in generalisability to other sites. But, as numerous of the participants had previously worked in other pharmacy units, they may have provided varied opinions that reduced the impact of this weakness.

Thirdly, interviews were undertaken within forty-eight hours of the error occurring, leading to the potential for the interviewee to fail to recall some of the events leading up to the mistakes. Furthermore, as noted above, an interviewee can prove reticent in describing the actual event leading to the error, due to a fear of being held responsible (Creswell, 2009).

Issues may also arise concerning the reliability of data, as the perceptions of individual staff may have been influenced by transference of blame from themselves to others (i.e. own bias). However, the interview responses were consistent with those of published literature (Limat et al., 2001; Bateman and Donyai, 2010).

Finally, a number of interviewees were pharmacy checkers and therefore subject to desirability bias, i.e. "participants tendency to present a favourable image of themselves" (Van de Mortel, 2008, p.102). Such bias may lead to altered responses concerning the IPEs in their units, due to their position of responsibility. In addition, pharmacy staff may also have given a more positive response when questioned about their individual factors. However, as participants were informed of the benefits of such study in improving the safety of medication, and were encouraged to suggest suitable solutions, this may have had a limited impact on this research. Furthermore, many of the individual factors contributing to errors were volunteered by the interviewees themselves, i.e. inadequate levels of knowledge and training.

This current study supports previous studies reporting a correlation between errors and contributing factors, leading to a need for additional studies to: (1) explore the nature and role of each factor leading to IPEs; and (2) provide improved understanding of the relationship between these factors. Future research should also focus on set interferences, resulting in significant long-term improvements in medication safety. A number of studies have identified the most common contributors to IPEs as being workload and staffing levels. However, there remains a lack of relevant information relating to aetiology, and any

potential combination with further factors (i.e. interruptions and distractions), leading for a need for additional investigation into the role of such factors in IPEs.

Interviewees identified pharmacy computer software as contributing to IPEs. An interviewee from the large licensed unit stated that a lack of guidance concerning computer software (PL13) used to prepare worksheets resulted in an incorrect quantity of drug vials being requested on the worksheet. On the other hand, the Episys system [(employed in a small licensed unit to prepare worksheets for cytotoxic and central IV additive services (CIVAS) medication)] was considered as being clear, due to relating worksheet preparation to label generation, i.e. incorrect information would show on the worksheet if entered into the computer system during label generation. Episys automatically calculates the volume of diluent needed to prepare medicines and clearly indicates the preparation procedure. In 2014, an examination of the Episys system shown that it minimised the number of steps and the potential for error in the preparation of worksheets and labels, while enhancing efficiency by minimising the time taken to prepare worksheets and labels (Tyrell, 2014). Nevertheless, Episys presently relies on the manual entry of a batch number by the system operator, leading to potential errors relating to incorrect batch numbers appearing both on the label attached to the worksheet and the batch record book. This identifies a need for the software to automatically generate a batch number, while also being linked with the hospital patient administration system, thus ensuring that the patient's registered hospital number and name appears on the label and worksheet, and so minimise errors. Episys software is capable of supporting this function, however it was not operational at the small

licensed unit during the period of data collection. The Episys system if therefore an example of how software can prevent errors, but only if implemented properly.

A considerable number of the participants in this study reported issues relating to the design of pharmacy computer systems, including worksheet errors resulting from a lack of clarity as to: (1) when the expiry date should be noted; (2) whether a product had been made on the correct day; and (3) a failure to specify whether product had been transferred to the ward. Issues related to worksheets could be improved by introducing an electronic preparation system already activated (Episys) in some areas of the Trust forming the focus of this current study. Further studies should therefore assess whether an electronic preparation system (Episys) addresses worksheet errors, including reducing those related to both timing and the expiry date.

This study has supported previous studies in identifying the contribution to IPEs of low staffing levels and skill mixes, in particular in units preparing a high number of injectable medicines (i.e. large Unit A and small Unit B), including inadequate training for the preparation of injectable medicines. A large number of studies reported the negative impact on medication safety of workload and staffing levels, identifying that an increased level of staffing (of experienced staff in particular), was associated with improved patient outcomes and reduced medication errors. However, the data analysis of a small number of UK studies has supported the relationship between medication errors and the proportion of experienced staff available (Limat et al., 2006; Bateman and Danyai, 2010). However, there remains a need for staff managers and institutional management to focus on the issue of staffing

levels, and further studies employing more robust methods are required to establish ideal staffing levels (taking the shift patterns into consideration) for the three different pharmacy aseptic units. Further work is also needed to quantify the relationship between the proportion of experienced staff within a team and the level of medication preparation errors.

Interviewees in this current study identified the lack of adequate training and assessment provided by the Trust, i.e. the need for additional training in the practical aspect of injectable preparation, rather than learning from their peers, which included bad practice, such as deviation from policies and guidelines (Taxis and Barber, 2003). It is thus vital that staff (and in particular new staff) are given appropriate training, in order to improve patient safety and reduce errors. This can be achieved by re-evaluation of the competency examinations undertaken by staff prior to being approved to prepare medicines. Continuous education programmes should also be considered, in order to ensure that staff knowledge of medicines is up to date. Furthermore, a checker also emphasised the importance of the re-evaluation of competency for preparing injectable medicines at regular intervals (PL1). Further work is thus required to evaluate the Trust's training programmes and assess their influence on staff skills and knowledge.

The issue of the microbial contamination of the prepared injectable medicines was outside the scope of this current thesis, however, it has now gained additional attention following the deaths of several babies who had received total parenteral nutrition (TPN) contaminated with Bacillus cereus prepared by ITH Pharma (British pharmaceutical company) (MHRA,

2014). Commercial and NHS aseptic production units continuously monitor environmental conditions and microbial growth in clean rooms, and further work is now required to study the incidence, types, severity and causes of microbial contamination of injectable medicines prepared in the pharmacy environment.

Technicians were identified as being involved with the majority of errors, due to being most frequently involved in the preparation of injectable drugs. The majority of errors were detected by pharmacists (Bateman and Danyai, 2010), suggesting that the inclusion of pharmacists can play an important role in recognising and addressing the training needs of technicians. Future work is essential to assess whether the presence of pharmacists during preparation could reduce the rate of IPEs in the aseptic pharmacy environment.

4.7 Conclusion

The preparation of injectable medication forms a common, high-risk task within the pharmacy department. Previous studies have reported the frequency of medication errors during the preparation stage. The semi-structured interviews in this current study explored the views, opinions and experiences of pharmacy staff in relation to: (1) the preparation of injectable medicines; (2) the resources and methods employed to prepare injectable drugs; and (3) how those factors could be minimised. A previous study of this aspect had been untaken within the research Trust, revealing that IPEs have a number of correlating factors contributing to errors. The results of this current study have revealed that factors contributing to IPEs include individual, work environment and latent (i.e. organisational or managerial). Therefore, both organisations and individual staff share responsibility for ensuring the safe preparation of medication for patients.

Classified factors focused on: (1) the work environment (e.g. high workload; low number of staff; distractions and interruptions; and staff rotation); (2) the task of medication preparation, primarily related to prescribing quality (i.e. illegible hand writing); (3) inadequate checking by the checker; (4) individual factors (e.g. lack of knowledge; lack of familiarity with the unit or medications; and mental stressors, such as pressure or distraction/interruptions); (5) issues within teams (i.e. lack of communication, or miscommunication between pharmacy and ward, and supervision); and (6) latent factors (e.g. inadequate staff training and lack of feedback concerning medication errors).

This current study has confirmed the main factors identified in previous studies, and the need to address these factors to improve the safety of medication preparation. Future research should investigate the nature and contribution of such factors, in order to prioritise efforts to reduce IPEs rates within the three different pharmacy aseptic units, including the outcomes of long-term developments in medication safety.

This study has proposed a number of strategies for minimising error. The significant factors for those managing pharmacy aseptic units are as follows: (1) errors within both large and small units were attributed to distractions, interruptions and inadequate training; (2) errors within unlicensed units were attributed to lone working and a high workload, combined with low staffing levels. This study has therefore identified a number of recommendations in relation to: (1) training of pharmacy staff; (2) the effective use of programmed computer alert systems; and (3) improving systems supporting the management of safe medicines. Future studies should therefore examine the influence of these risk reduction strategies on errors related to injectable preparations.

Table 4.2: Risk-reduction strategies for active failure; EPC and latent failure to minimising the risk of IPEs in the large unit A.

Type of error	Class of contribution factor	Cause of error	Strategies
Incorrect diluent (internal error) PL1	Active failure	Slip (i.e. similar packaging)	Separating similar packaged medications on shelf; standardising colour signs for medications; bar-code verification of medicine/diluent identify at accuracy check.
	EPC	1.Work environment (i.e. high workload)	1. Setting priorities of work by pharmacy staff.
		2. Mental stressor (i.e.destruction/ interruption)	2. Designation of a quiet room without telephones for filling worksheets, labelling and checking products and installation of prescription tracking systems capable of being accessed by ward staff, to see whether the prescription is ready for collection from pharmacy.
		3. Team factor (i.e. lone worker)	3. Plan workforce to ensure adequate staff and skill mix and listing staff to do specific responsibilities.
	Latent failure	Incorrect layout of the storage areas	Ensure adequate lighting; separate look-alike, or sound-alike drugs on pharmacy shelves and fridges; underline drug names on pharmacy shelves and fridges.
Incorrect dose (Internal error) PL12	Active failure	Slip: 1. Look-alike, sound-alike drug names	1. Separating drugs which look or sound-alike on drug shelves; highlighting problem drug names on shelf labels; educating staff concerning easily confused drugs.
		2. Similar packaging	2. As for incorrect diluent (PL1).
	EPC	Mental stressor (i.e. pressure)	Rotating dispensary staff responsibilities may reduce stress, fatigue and risk associated with prolonged task performance; improved workforce planning; prioritisation of workload with products made in advance if appropriate
	Latent failure	Inadequate staffing	Workforce planning to determine adequate staffing levels
Incorrect number of drug doses prepared (internal error) PL13	Active failure	Mistake based knowledge (i.e. design of computer system)	Setting up software to calculate the volume of drug required to prepare product during worksheet preparation.
	EPC	Individual factor (i.e. lack of knowledge and skill)	Teaching technicians to: undertake accuracy checks of worksheets; set up the starting materials; volume check and double check of used vials; and enable staff to attend conferences and view posters demonstrating the risk of injectable preparation errors, i.e. techniques of showing error results and risk reduction strategies to ensure they are up to date.
	Latent failure	1. Inadequate skill mix among staff	1. Ensuring staff are familiar with standard operating procedures; standardising the training of staff; development of validation procedures to ensure that staff transferring from different hospitals are competent to work in manufacturing units.
		2. Design of computer systems	2. Careful design of pharmacy computer screens, i.e. programming alerts into computers to highlight worksheets for paediatric patient overdoses.

Continued Table 4.2

Type of error	Class of contribution factor	Cause of error	Strategies
Incorrect expiry date (external error) PL11	Active failure	Slip Inadequate checks (i.e. failure to identify the incorrect expiry date on label)	Independent accuracy check of dispensed medicines performed by pharmacist or accredited checking technician; double checking of expiry dates; posters specifying expiry dates for products attached to walls in checking area.
	EPC	1. Work environment (i.e. high workload, in combination with low number of staff) 2. Mental stressor (i.e.destruction/ interruption)	1. Setting priorities of work by pharmacy staff and workforce planning to determine adequate staffing levels. 2. As for incorrect diluent (PL1).
	Latent failure	1. Design of pharmacy computer systems 2. Inappropriate training	1. Programming alerts in computers to check expiry dates. 2. Improved training on which drugs last twenty-four hours and when the expiry date should be altered.

Table 4.3: Risk-reduction strategies for active failure; EPC and latent failure to minimising the risk of IPEs in the small Unit B.

Type of error	Class of contribution factor	Cause of error	Strategies
Worksheet error (internal error) PS16	Active failure	Lapse Forgot to attach label to worksheet	Highlighting red box where staff need to attach label and reminding staff to attach labels
	EPC	1.Work environment (i.e. high workload) 2. Mental stressor (i.e. pressure) 3. Team factor (i.e. lack of teamwork)	1. Setting priorities of work by pharmacy staff. 2. As for incorrect dose (PL12). 3. Scheduling staff to undertake specific duties; encouraging staff to assist colleagues if they have completed their work earlier than anticipated; allocating office duties to staff with repetitive strain injuries.
	Latent failure	Design of pharmacy computer systems	Highlighting box where staff need to attach label.
Worksheet error (internal error) PS21*	Active failure	Lapse Forgot to sign worksheet	Highlighting red boxes where staff need to sign; reminding staff to sign
	EPC	Work environment (i.e. high workload)	Setting work priorities by pharmacy staff.
	Latent failure	Design of pharmacy computer systems	Highlighting boxes where staff need to sign.

Continued Table 4.3

Type of error	Class of contribution factor	Cause of error	Strategies
Unprescribed medicine (internal error) PS17*	Active failure	Slip Inadequate checks (i.e. Product made on incorrect day)	Pharmacists and accuracy checking technicians to check the date product is to be prepared during clinical and worksheet checks.
	EPC	1. Team factor (i.e. poor communication with wards) 2. Task factor (i.e. prescription clarity)	1. Verifying dates of treatments for patients. 2. Standardising the format of hospital prescriptions across Trusts; development of prescribing standards.
	Latent failure	1. Design of pharmacy computer systems 2. Lack of training	1. Electronic prescribing and electronic transfer of prescriptions. 2. Training prescribers to write prescriptions.

*2 errors made by 1 person interviewed.

Table 4.4: Risk-reduction strategies for active failure; EPC and latent failure to minimising the risk of IPEs in the unlicensed Unit C

Type of error	Class of contribution factor	Cause of error	Strategies
Incorrect dose (internal error) PU31	Active failure	Slip Vial pressure (i.e. leakage from vial resulted in dose being too low)	Reminding staff medicines to be kept slightly below the ambient air pressure to prevent the contents of vials from leakage.
	EPC	1.Work environment (i.e. high workload) 2. Mental stressor (i.e. pressure)	1. Setting priorities of work by pharmacy staff. 2. As for incorrect dose (PL12).
	Latent failure	Inadequate training	Increased and improved skills training.
Incorrect batch number (internal error PU32	Active failure	Slip Design of computer software (i.e. incorrect batch number of medicine (starting material) on worksheet and label)	Computer software to automatically generate batch number.
	EPC	1.Work environment (i.e. high workload) 2. Mental stressor (i.e. pressure) 3. Team factor (i.e. lone worker)	1. Setting priorities of work by pharmacy staff. 2. As for incorrect dose PL12. 3. As for incorrect diluent PL1.
	Latent failure	Design of pharmacy computer systems	Programming alerts into computers to highlight batch numbers on worksheets and labels.

Chapter Five

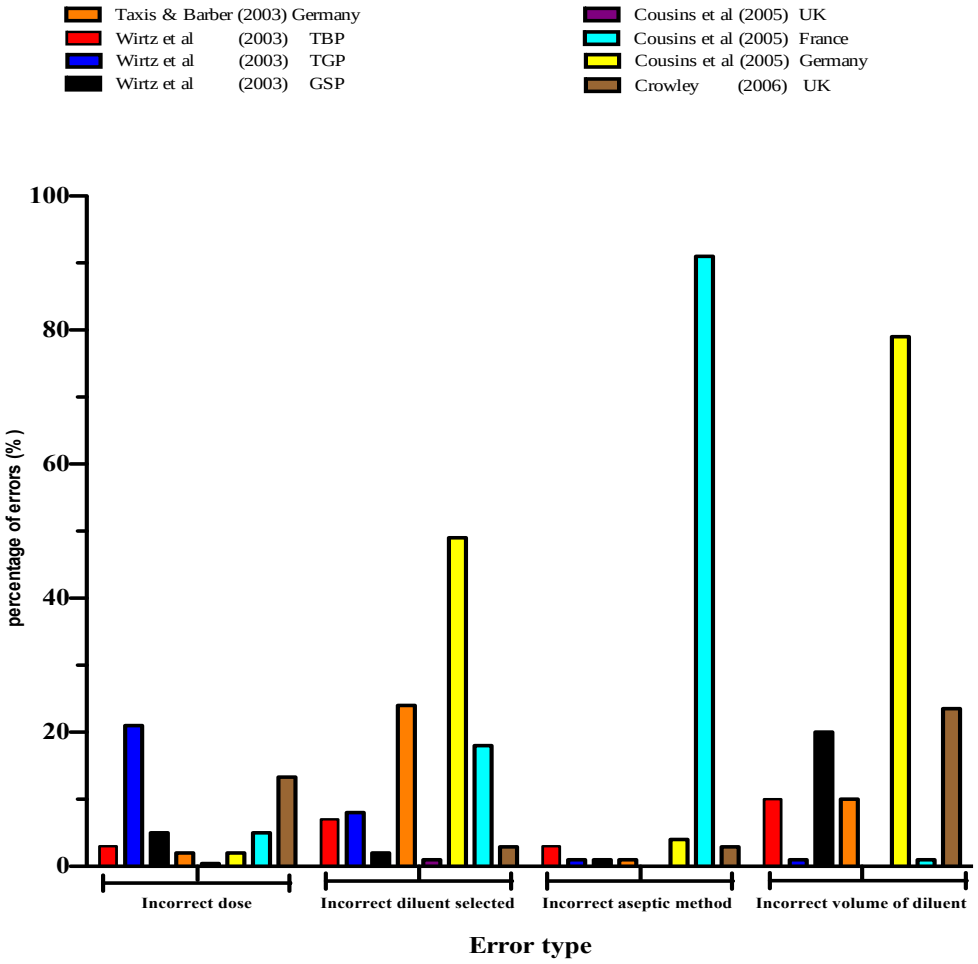
Investigating Injectable Preparation Error Rates and Assessing their Severity on Hospital wards

5.1 Introduction

The purpose of medical treatment is to improve the status of the patient and to ensure the care process takes place with a minimum of harm. Such incidents can occur during the therapeutic delivery of medicines (Allan and Barker, 1990). Treatment with injectable medicines is beneficial for patients only if the conditions for their safe use are applied by both the relevant NHS organisation and their staff. Medication errors can arise at any phase of the treatment process, including when prescribing, preparing or administering the medicine. Injectable preparation errors (IPEs) can result in serious harm to patients with dire economic consequences (Cohen, 2007).

In the United Kingdom hospitals, injectable medicines are prepared mainly by nurses in a clean but not sterile environment **(**Beaney and Black, 2012). The Breckenridge report (1979**)** outlined the risks linked with the preparation of injectable medicines in hospital wards. Since that time, several incidents have been reported involving errors in the preparation of injectable medicines on hospital wards, and there are enduring fears over the risk of medicines being contaminated (Beaney and Goode, 2003). The present review considers studies conducted in Europe in detail.

The most common types of IPEs in hospitals' clinical areas, as reported in UK and European studies, appear in Figure 5.1.



Notes:
TBP: Traditional British ward pharmacy service.
TGP: Traditional German ward pharmacy service.
GSP: German satellite pharmacy service.

Figure 5.1: Most common types of injectable preparation errors in the hospital clinical areas

The reviewed literature showed that the most commonly reported errors regarding injectable preparation are use of incorrect dose, incorrect diluent, incorrect aseptic method, and incorrect diluent volume (Figure 5.1). The rate of errors affecting ward-based injectable drug preparation was reported as high 53% (see section 1.6) and, while the consequences of most of these errors are minor, some errors result in serious harm to patients (Taxis and Barber, 2003).

A further issue is that the environment in which injectable medicines are prepared is not sterile and drug products can become contaminated. For example, one study showed that 7 of the 20 containers prepared on the wards were contaminated with *Staphylococcus*, a skin microorganism (Beaney and Goode, 2003). The risk of microbiological contamination is much greater when making preparations in an uncontrolled environment such as a ward, compared with a pharmacy aseptic unit where air is filtered and staff are clothed to prevent contamination of the product (Beaney and Goode, 2003). The authors suggested that risks to patients can be reduced by:

- Enhancing the treatment room - e.g. aseptic cleaning, hand washing, and putting on gloves and aprons before preparation.
- Applying non-touch techniques during medicine preparation.
- Reducing the time between the preparation and administration (so that any contaminant has minimal time to grow) (Beaney and Goode, 2003).

These guidelines represent a challenge to nurses, due to their working environment. Nevertheless, NHS Trusts are expected to ensure the above processes/policies be put in place to guide preparation techniques, regardless of the working environment (Crowley et al., 2004).

In 2007, the National Patient Safety Agency became aware of the continuing high level of errors reported regarding injectable medicines. This led them to issue a patient safety alert regarding hospital wards, requiring the NHS to carry out six actions (see section 1.6). These principles remain relevant, and form the basis of current procedures imposed when preparing injectable medicines. Additionally, the Department of Health (2008) Clean, Safe Care initiative was based on these principles, although it applies more widely than simply to the preparation of injectable medicines (DOH, 2008).

As mentioned above, in pharmacies the preparation of injectable medicines is expected to be performed in a well-established environment, such as an aseptic preparation room. However, environment and work process controls in hospital wards are less strict in the hospital ward environment, and as a result, medication errors are more frequent (Beaney and Goode, 2003; Crowley, 2006; Beaney, 2010), as is microbiological contamination leading to infection (Beaney and Black, 2012).

Other studies performed outside Europe (Abbasinazari et al., 2012; Shamsuddin and Shafie, 2012; Nguyen et al., 2013; Vaismoradi et al., 2013), establishing the errors that arise during the preparation or administration of injectable medicines in hospital clinical areas have posited that use of the incorrect diluent, incorrect dose calculation, and incorrect preparation techniques are the most common errors. The conclusion of these studies is that the expertise of pharmacists should be consulted when preparing injectable medicines to minimise errors. Thus, nurses should ideally work together with the pharmacy department to report possible incidents and minimise the risks to patients.

In this project the researcher investigated the incidence, types, causes and severity of internal errors, which occurred during the preparation of injectable drugs in clinical settings. The researcher then proposed interventions to reduce the types of errors, which were associated with extreme and high-risk.

5.2. Significance of the study

Risks to patients are greater when injectable medicines are prepared in hospital wards, than they are when prepared in the hospital pharmacy (Beaney and Black, 2012). Therefore, there is a need for studies to expand our current understanding of those factors influencing errors during injectable drug preparation in clinical areas, to learn more about how incidents threatening patient safety arise. Only by discussing these factors can applicable solutions be developed to improve patient safety. Thus, this project was designed to meet the requirements of Patient Safety Alert 20 to investigate the preparation of injectable medicines (NPSA, 2007).

The majority of studies summarised in the literature review reported error rates based on the sum of all recorded preparation or administration errors, divided by the sum of the prepared or administered drug doses observed. These studies evaluated both preparation and administration errors for intravenous drugs on specific wards (e.g. intensive care units and surgical wards) and reported a wide range (i.e. 7–53%) of error rates during preparation, although this variability could have partly resulted from different study durations. Another explanation for the wide range in reported percentages might be the use of different definitions for what constitutes an error. In terms of their limitations, many of the reviewed studies did not extensively investigate the IPEs, resulting in a lack of comprehensive descriptions of error characteristics. In response, the proposed study seeks to partly resolve the above, for the following reasons:

1. The proposed study can improve the detection of the incidence of errors during injectable drug preparation in hospital clinical areas. Many previous studies focused on injectable preparation and administration errors. For example,

Crowley (2006) specifically examined IPEs, yet did not interview the nurses involved in making these errors. By contrast, the proposed observational study and follow-up interviews and questionnaires will be conducted with staff who committed errors, to provide an in-depth understanding of the underlying causes of IPEs and, more importantly, raise staff awareness and promote patient safety.

2. Previous studies often did not classify the severity of errors; to it is hard to know the consequences of previously observed errors rates. An in-depth assessment of errors can help identify possible strategies to avoid similar errors happening in the future, and thus improve patient safety. In response, this project assessed the severity of injectable drug preparation errors recorded on hospital wards following direct observation.

5.3 Aims and objectives

The aim of this study was to determine the types, incidence, and severity of errors made by nurses in four wards located at two different hospitals (two wards in each hospital), during the preparation of injectable medicines, to allow for the development of strategies to prevent the most common and most severe errors.

5.4 Research Objectives

Research objectives for this study are to:

1. Determine the incidence of injectable medicine preparation errors on hospital wards.
2. Identify the types of injectable medicine preparation errors on hospital wards.
3. Determine the medicines involved in injectable medicine preparation errors on hospital wards.

4. Compare the incidence and types of injectable medicine preparation errors occurring on four wards.
5. Confirm that the injectable drug preparation errors observed on the hospital wards can be classified as errors.
6. Assess the severity of these errors on a scale of 0-10.
7. Determine consequence and likelihood scores, to assign an overall risk score analogous to that used by the National Patient Safety Agency.
8. Use the data to put forward error reduction strategies for errors associated with the highest risk scores

5.5 Overview of methodology

5.5.1 Study Design

This study adopted a case study design, as defined in chapter two. The case study approach allows an investigator to closely investigate the data within a certain setting (in this case, the hospital's wards). In general, a case study approach selects a small environmental area (i.e. a ward) or a very small group of individuals (i.e. nurses) as subjects. Case studies explore and investigate real-life phenomena through a detailed analysis of data, providing a number of incidents or conditions and describing their relationships. In practice, a case study design allows the investigator to perform an observational study in the environment in which errors are occurring. A case study design was chosen for the proposed research because it is a flexible and practical approach (Creswell, 2009). The study employed a quantitative methodology when identifying the types and incidents of errors made during the preparation of injectable medicines (Flynn et al., 1997; Wirtz et al., 2003; Parshuram et al., 2008), Neergaard et al., 2009) (see section 2.6.1).

5.5.2 Study setting

This study was conducted in two clinical areas at two UK hospitals. One was a large teaching hospital with 1,500 beds, and the other was a medium-size district general hospital with 650 beds. The sample included both surgical and general medicine wards.

The observational study was carried out over a total of eight weeks; four weeks of observations were completed on a medical ward and four weeks on a surgical ward (see Table 5.1). The observer (AA) witnessed the preparation of injectable medicines between 11am and 8:30pm Monday to Friday. These times were chosen following discussion with ward managers, who explained that where possible, injectable medicines were not given during the morning drug round (8am), as staff are busy giving many oral medicines and performing other tasks at this time. Therefore, data were collected during the times of day when injectable medicines are most likely to be prepared.

A standard observation schedule was drawn up based on relevant local policy namely [Aseptic Non Touch Technique (ANTT) Staff Workbook, 2015; Management Policy: Prescribing, Preparing and Administrating Injectable Medicines in Clinical Areas, 2015 and Hospitals Injectable Medicines Administration Guide, 2010] and national policies [Royal College of Nursing (RCN), Standards for Infusion Therapy, 2016 and IV Policy: Medicines Code: Administration of Intravenous Drugs, 2016]. Any deviation from the procedures set out in these polices was recorded as an error.

Table 5.1: Characteristics of the four wards chosen for this study

	Surgical ward (S)	Medical ward (C)	Medical ward (B)	Surgical ward (H)
Number of beds	30 beds, arranged in 4 bays of 6 beds (2 male bays and 2 female bays) and 6 single side rooms.	22 beds which included three single-sex bays of four beds each and ten single rooms.	32 beds that treat patients with chronic/acute respiratory diseases and 6 bedded isolation suite that cares for patients with complex infectious diseases, including HIV and TB.	32 beds that treat patients with a range of general surgery conditions, especially hernia surgery.
Products prepared	1. Antibiotics. 2. Analgesics. 3. Insulin. 4. Antiemetics. 5. Adrenaline. 6. Phytomenadione. 7. Furosemide. 8. Digoxin. 10. Pabrinex. 11. Coagulation Factor VIII Complex (Human). 12. Electrolyte infusions (e.g. sodium chloride 0.9%).	1. Antibiotics. 2. Analgesics. 3. Insulin. 4. Antiemetics. 5. Adrenaline. 6. Phytomenadione. 7. Furosemide. 8. Digoxin. 9. Pabrinex. 10. Coagulation Factor VIII Complex (Human). 11. Electrolyte infusions (e.g. sodium chloride 0.9%).	1. Antibiotics. 2. Analgesics. 3. Insulin. 4. Antiemetics. 5. Heparin sodium 6. Phytomenadione. 7. Diuretics. 8. Digoxin. 9. Pabrinex. 10. Methylprednisolone. 11. Magnesium sulfate. 12. Hydrocortisone. 13. Enoxaparin. 14. Acyclovir. 15. Sodium ferric gluconate 16. Electrolyte infusions (e.g. sodium chloride 0.9%).	1. Antibiotics. 2. Analgesics. 4. Antiemetics. 5. Calcium Gluconate. 6. Midazolam. 7. Amiodarone. 8. Aminophylline 9. Ranitidine. 10. Pabrinex. 11. Enoxaparin. 12. Acyclovir. 13. Electrolyte infusions (e.g. sodium chloride 0.9%).

5.6 Observational data

5.6.1 Overview

A trained investigator (AA) was present on each of the four wards for two weeks, in order to observe the process of preparing injectable medicines. Previous studies conducted a total of between 68 and 430 observations (Wirtz et al., 2003; Taxis & Barber, 2003; Crowley, 2006; Ong, 2013). Initial hospital visits suggested it would be possible to observe 35-45 preparations during an 8-hour shift. It was therefore decided to carry out observations on each ward for a two week period (ten working days), thus giving 350-450 observations per ward, as this would result in a large number of observations than previous studies. In addition, two weeks on each ward was the longest period of time for it was practical to collect data.

Direct observation, the so-called 'the gold standard method' (Allan & Barker, 1990) (see section 2.6.1), was used to determine the incidence and types of errors that occur when preparing injectable medicines, and data was collected using a standard structured observation schedule (Appendix 10). Direct observation is a valuable tool, which enables investigators to record actual events, instead of trusting reports that might not accurately represent what has been happening (Allen & Barker, 1990; Dean & Barber, 2001; Bowling, 2002; Smith, 2002; Carthey, 2003; Bryman, 2004), as has been the method previously (Hoppe–Tichy et al., 2002; Crowley, 2006). The study participants might feel under pressure, or uncomfortable about being observed when preparing injectable medicines. However, study participants who felt uncomfortable or stressed are unlikely to consent to participate in research. Throughout the data collection process, and with participants' consent, the investigator watched, but did not interrupt,

nursing staff as they prepared injectable drugs. The investigator recorded all the injectable medicines prepared on the observation schedule, noting any errors at the preparation stage, the location of the error, and a description of the type of error. The mistakes observed by the investigator were kept confidential, and identified using a reference number; no personal information was collected on the observation schedule. The observations commenced at the point when the equipment was collected and went on until the drug was ready to administer. To enable calculation of the total number of errors per year (see section 5.8.2), for the duration of the ten day observation period, nursing staff recorded the total number of injectable medicines prepared in each 24 hour period.

The observations took place from Monday to Friday, between 11 am and 8:30 pm, as recommended by Crowley (2006). During that time, the investigator observed all the drugs that were prepared; however, the investigator did not observe the nightly drug round; a notable limitation of this observational study. Another major limitation of the observational method is the observer effect, or Hawthorne effect, whereby "the presence of the researcher, and the knowledge that the study is taking place, may influence the behaviours of the individuals being observed" (Smith, 2002; p. 168). This effect can restrict the validity of an investigation, although according to Bowling (2002) and Smith (2002), several strategies can be used to minimize it. The researcher applied some of these strategies; for example, communicating with staff in the area of study before the data collection stage and collecting as much data as possible (Bowling, 2002; Smith, 2002).

5.6.2 Definition of IPEs and Types of errors

A variety of definitions have been used to describe IPEs in previous research, as summarised in Table 5.2. This study adopted Crowley (2006) definition. The advantages of adopting a consistent definition include allowing comparison of IPEs. By drawing on data from Crowley's study in particular, this study can take advantage of that study's links with the Patient Safety Alert 20 (Crowley, 2006).

Table 5.2: A summary of previous studies definitions of injectable drug preparation error

Study	Definition
Wirtz et al. (2003), p. 105 UK	*"Any deviation in preparation of an IV dose from the original prescription, or any act in the preparation that deviates from the manufacturer's instructions or the hospital's drug policy"*
Wirtz et al. (2003), p. 106 Germany	*"The German hospitals researched had no medicine policy, so the leaflets produced by the manufacturer (Fachinformation), which were mainly designed for health care professionals, were used as the definition of correct practice. Errors identified by nurses and patients and corrected before administration were not recorded as errors".*
Taxis and Barber (2003), p. 816 Germany	*"A deviation in preparation of a drug from a doctor's prescription, the hospital's IV policy, or the manufacturer's instructions"*
Cousins et al. (2005), p. 191 UK	*"A deviation in the preparation of a medicine from a doctor's prescription, hospital intravenous procedures, or the manufacturer's instructions"*
Crowley (2006), p. 138 UK	*"The preparation of an injectable medication that deviates from the prescription; manufacturer's guidelines; nationally or locally agreed-upon policy, procedure, or guidance; or generic standards for clean or aseptic preparation"*
Dehmel et al. (2011), p. 1312 Germany	*"Drug concentration deviates from intended concentration"*

The definitions of IPEs subtypes used in this study are showed in Table 5.3. The subtype definitions were also adapted from Crowley (2006), and have been approved by the study team (JL; MJ). Definitions were found to be valid during the pilot study phase, and appropriate for the purpose of this research following a review at one of the selected hospital wards.

Table 5.3: Definitions of IPEs subtypes used during the observation study adapted from (Crowley, 2006.p.143; 144).

Type of error	Definition
Wrong medicine	*"A dose of medicine prepared that was not the drug prescribed is an error".* *"Where manufacturers' instructions for preparation of a branded or generic product are identical, use of either is acceptable (i.e. not an error)".*
Wrong dose	*"Preparing a wrong dose product or wrong strength infusion. (Where products are made from whole vials e.g. amoxicillin 250mg from a 250mg vial, no deviation from this dose would be allowed. Where a fraction of a dose unit is required, or any other measurement, any discrepancy greater than ±10% from the dose would be an error)".*
Diluent error	*"Deviation from the manufacturer and/or hospital's instructions on the choice, or volume, of a diluent, solvent or infusion fluid, without documented patient-specific instructions".*
Un-prescribed error	*"Preparing for a patient an injectable medication that is not prescribed (excludes flushes)".*
Wrong route	*"Preparing an injectable dose using the wrong route of administration is an error, e.g. preparing a medication dose for administration intravenously when it is prescribed by another route (i.e. S.C or I.M)".*
Wrong addition /mixing	*"Failing to fully reconstitute a product during preparation, or adhere to the mixing instructions. (This includes failure to dissolve the powder, failing to activate a mini bag plus infusion device that has a vial of powder attached, or vigorously shaking a medication that foams e.g. Factor VIII and teicoplanin)".* *"Inappropriate addition to a syringe/infusion container (e.g. adding to a rigid or flexible bag hanging on an IV infusion stand, or not mixing thoroughly after addition)".*
Calculation error	*"Any calculation mistake that produces a preparation (± 10% dose instructed) is an error".*
Allergy	*"Preparing an IV medication for a latex-allergic patient without either avoiding latex exposure, or not following hospital guidelines, where available, on the care of latex-allergic patients".*
Wrong storage	*"Using an IV ingredient that has not been stored according to instructions, without verifying its suitability with pharmacy before preparation (e.g. using a product needing refrigeration that was left at room temperature overnight)".*
Faulty labelling	*"Faulty labelling is an error. (Labels are required for all infusions. Labels for bolus doses are needed when more than one dose is prepared, or the prepared dose is put down or passed to another practitioner, or where administration is delayed)".*

Continued Table 5.3:

Type of error	Definition
Incompatibility error	*"Adding a medicine to a syringe/infusion already containing a drug with which the medicine is incompatible".* *"Preparing a medication, in an incompatible container (e.g. insulin, glyceryl trinitrate)".* *"Adding an IV medicine to a blood product or compounded (ready to administer) parenteral nutrition where there is not locally documented acceptability".*
Expired / degraded or unknown expiry	*"Preparing a medication using an expired ingredient".* *"Preparing a medication using degraded or unsuitable ingredient (includes cracked emulsions; solutions with unintended particles or discolouration; damaged containers)".* *"Using a previously opened IV multi dose container, where the date of first use is not documented".* *"Using a single use IV ingredient whose tamper-evident seal has been broken (e.g. an IV infusion previously removed from the outer wrapper)".*
Wrong preparation technique	*"Chemotherapy preparation must never occur in general clinical areas, without additional specialist facilities (e.g. isolator)".* *"Re-using an intravenous medication that is licensed for single use on a subsequent occasion, or another patient, unless there is a written hospital policy authorising this, is an error (e.g. using an infusion bag to withdraw flushes for more than one patient)".* *"Not filtering a product when the manufacturer's instructions or hospital policy state the product must be filtered (e.g. phenytoin)".* *"Filtering a product whose stability may be adversely affected by this process (e.g. using a 0.22micron filter with a lipid)".* *"Not changing the filter needle before adding to a syringe or infusion, having drawn up medication through a filter needle to prevent contamination of the product is an error".* *"Pouring the IV medication into unsterile cup to aid drawing up is an error".* *"Failing to take appropriate infection control precautions after an injury during preparation is an error (e.g. continuing preparation without changing the needle after a needle-stick injury)".* *"Breach of 'no touch' technique, where the operator touches areas that might cause contamination such as the syringe tip or needle hub is an error".* *"Gross disregard for clean/aseptic technique during IV medication preparation is an error e.g. dropping an uncapped syringe and needle on the floor and continuing preparation without any corrective action".*

5.6.3 Development of the Observation Schedule

A list of the required variables needed to assess whether an error had occurred was based on the type of IPE, as set out in the framework established in section 5.6.2. This data, together with information from relevant local (i.e. ANTT Staff Workbook, 2015; Management Policy: Prescribing, Preparing and Administrating Injectable Medicines in Clinical Areas, 2015 and Hospitals Injectable Medicines Administration Guide, 2010) and national policies (RCN, Standards for Infusion Therapy, 2010), was used to adapt and a schedule used previously (Crowley, 2006). The final observation schedule aimed to collect data pertaining to the error and not to investigate the staff, as no personal information was recorded. In November 2015, a draft observation schedule was designed (Appendix 11) by the researcher and reviewed by Dr. Lynette James and Dr. Julie Letchford at the University of Bath to verify that all error types were included. Minor improvements were made to the design, based on feedback from the author's supervisors. In March 2016, a trial observation to pilot the schedule was conducted on a general medical and surgical ward with the staff and managers' permission. Further minor changes were made to the observational schedule to improve its data recording capacity, before it was then used on the hospital wards. In April 2016, the final draft of the data collection tool was ready for use (appendix10).

5.6.4. Ethical approval

This project has been approved in accordance with the University of Bath's ethics procedures (Appendix 1). The study was conducted as a service evaluation at each participating NHS organisation in England, with the approval of the relevant medicine governance committees. Individual patient consent to view their medication record was

not granted, because the studies were approved as either audit (pharmacy aseptic units) or service evaluations (hospital wards), and consent is not a requirement in these situations. This is in line with similar research conducted in the UK recently as it is not practical to gather consent from everyone, especially in the case of ill patients (Blandford et al, 2016; Furniss et al, 2018; Lyons et al, 2018). The investigator was also given an honorary contract at each participating site, sharing the same duties of care and responsibilities as the other members of staff employed by the NHS organisation (Appendix 12). All the activities, discussions, and details of the personnel and patients witnessed by the investigator were kept strictly confidential.

The data collection of IPEs was confidential and any errors were identified by reference number only. During the study, a temporary list of staff names and reference numbers were compiled to facilitate the study operation. This list was stored securely and confidentially, and destroyed once the data collection was complete and the interviews transcribed. Demographic data was also stored confidentially and only reported in aggregate form. Electronic files were stored exclusively in the University of Bath's secure data management facility. All hard copies (e.g. written consent forms) were stored in a locked filing cabinet at the University of Bath.

The results of the project were shared with each organisation in the form of a written report, however participating individuals were not identifiable.

5.6.5 Study Participants

Prior to data collection the investigator (AA) requested permission to observe nursing staff, at which time a suitable schedule for observations was agreed. Two weeks prior to the observations, the investigator distributed an information leaflet to all the nursing

staff likely to be preparing injectable medicines during the study period. Before each nurse's first observation, they were provided with an explanation of the aim of this research, stating that it was a protocol study (appendix 13), based on distribution of participant information leaflet (appendix 14) and face-to-face discussions, and that they would need to provide their written consent (Appendix 15). Moreover, it was explained that nurses who did not provide their consent would not be observed. It was also noted that the investigator would behave in a professional non-judgemental way, and that the researcher would only intervene if the error would be likely to harm to the patient, and in such cases their personal information would not be recorded. The nursing staff were also asked to inform the patients, or their representatives, if questioned about the study, that the investigator would not be interfering in their care management and is merely observing the nurse. Furthermore, the investigator took training from one of the senior clinical pharmacists and a sister to collate experience about the medication preparation procedure and drug charts.

5.6.6 Data collection

The observer (AA) introduced himself to the members of staff on the clinical ward, and discussed convenient times (11am and 8:30pm) on weekdays to conduct the data collection. Written consent was obtained from those willing to participate in the study. Preliminary observations were carried out to familiarise the observer with preparation process and how the clinical ward typically operated when not under scrutiny. When familiarisation was attained, the data collection process was commenced. The observations were carried out for 10 days on each ward (from 11am to 8:30pm) excluding weekends, between September 2015 and November 2015. The author conducted all of the observations.

As mentioned above, the data collection form was designed according to that previously used by Crowley (2006). The investigator observed the preparation of injectable medicines and recorded the data on the data collection form. During the observations, the observer ensured he had chosen appropriate location inside treatment room and not in the way of the nurses. If error was observed, then the observer politely asked the nurse to stop before continuing to prepare the product. This was documented as an IPE. However, if the nurse noticed the error prior to preparation and acted without the observer's interference this was not documented as an IPE. If the nurse was unsure a medication error mentioned by the observer had occurred, the observer stated that he believed a possible error might have happened. The observer then asked that they get the preparation checked by another qualified member of staff. If they believed there was potential to harm the patient if the preparation were administered, they informed the ward pharmacist. This would allow the pharmacist to investigate the incident, and where suitable follow the Trust's incident reporting procedure. In addition, to confirm the consistency of the observations, the observer reviewed all the collected data after completion of the observations and before additional data analysis. This was to ensure that each observation was documented and interpreted reliably.

5.6.7 Data analysis

A coding framework was developed for the observation schedule, and the coded data was later entered into Microsoft Excel (2007; Microsoft, Redmond, Washington, US) for analysis. The overall rate of errors in the preparation of injectable medicines was calculated as defined by Allan and Barker (1990), as follows.

Overall error rate (%)

The number of doses with one or more error / Number of observations x 100

Medicine specific error rate (%)

Number of preparations of specific drug that contained an error/number of observations for that drug preparation x100

Percentage of preparations associated with error for specific drug (%)

Number of errors for a specific drug / Number of observations × 100

Frequency tables were created for the types of errors and their occurrence in the preparation process, and a One-Way ANOVA test was used to measure the differences between wards. Any result in which $p \leq .05$ was considered statistically significant.

In a subsequent phase of the project, any observed errors were retrospectively graded for severity by a panel consisting of experienced healthcare professionals (two doctors, two pharmacists and a nurse) using a method validated by Dean and Barber (1999).

5.7 Severity Study

5.7.1 Overview

Injectable medicines preparation consists of a chain of multiple phases, and any mistake during these represents a potential or actual risk to the patient. Few studies have examined the severity associated with IPEs in hospitals' wards (Taxis and Barber, 2003; Cousins et al., 2005; Beaney, 2006). The aim of this study is to assess the severity of errors previously observed in four wards and calculate a risk score. Using consequence and likelihood scores analogous to that used by the National Patient Safety

Agency (NPSA). Errors with highest risk scores were provide a focus for developing strategies to help prevent these types of errors from occurring again (see section 2.6.2).

5.7.2 Research Method

A professional healthcare panel carried out the assessment of the severity of the IPEs reported in this study. The panel consisted of a general doctor, an oncologist, a clinical pharmacist and an aseptic pharmacist, and one senior nurse (see section 2.6.3).

5.7.3 Development of the Severity Study

The severity questionnaire was similar to that used for assessing errors in pharmacy aseptic units. Each potential error was confirmed and its severity determined via a widely used validated method, appropriate for situations where the actual patient outcome is unknown, as in this study (Dean and Barber, 1999) (see section 2.6.4).

5.7.4 Selection of Severity Panel

A panel of two senior general physicians, two senior pharmacists and one senior nurse completed a questionnaire containing a brief description of each potential error independently. They were asked individually to:

- Confirm or refute each potential error; and
- Score the potential clinical significance of each potential error on a scale from 0 (no harm) to 10 (death).

The five individual severity scores obtained for each error were then used to calculate a mean severity score for each error (see section 2.6.4).

5.7.5 Risk scoring and grading of errors

To select which errors merited focus to develop strategies for risk reduction, the guidelines of the National Patient Safety Agency (NPSA) were adopted to obtain risk assessment scores (NPSA, 2008). Mean severity scores and error frequency data for the different types of error were used to calculate consequence and likelihood scores, which were multiplied to calculate risk assessment scores (see section 2.4.1).

5.7.6 Consequence score:

The mean severity scores obtained for each ward were mapped onto the NPSA consequence descriptors and assigned a consequence score of 1–5, as summarised in Table 5.4.

Table 5.4: Mapping of mean severity data on to NPSA consequence descriptors to obtain a consequence score.

Mean severity score	NPSA consequence descriptor	NPSA consequence score
<0.5	Negligible	1
0.5–3.4	Minor	2
3.5–6.4	Moderate	3
6.5–9.4	Major	4
≥9.5	Catastrophic	5

5.7.7 Likelihood score:

The frequency of each type of error was used to calculate an observed error rate and predict the number of errors likely to occur in one year (see section 2.5.6).

$$\textbf{Observed error rate} = \frac{\text{Number of times a type of error occurred each in ward}}{\text{Total observations in each ward}}$$

$$\textbf{Predicted number of errors in one year} = \frac{(\text{Observed error rate} \times \text{Total items prepared in each ward during observation period}) \times 365}{10}$$

Values obtained for the predicted number of errors in one year for each ward were mapped on to the NPSA frequency descriptors to obtain a likelihood score of 1–5, as shown in Table 5.5.

Table 5.5: Mapping of error frequency into NPSA time frequency description to obtain likelihood score.

Predicted number of errors in one year	NPSA frequency	NPSA descriptor	NPSA likelihood score
<1	Not expected to occur for years	Rare	1
1-11	Expected to occur at least annually	Unlikely	2
12–51	Expected to occur at least monthly	Possible	3
52–364	Expected to occur at least weekly	Likely	4
>365	Expected to occur at least daily	Almost certain	5

5.7.8 Risk score:

Consequence and likelihood scores were multiplied to calculate the risk scores (1–25) and assign a risk grade, as shown in Table 5.6 (see section 2.4.1).

Table 5.6: Grading risk score by multiplying consequence score and likelihood score (NPSA, 2008).

Risk score	Assigned grades
1–3	**Low risk**
4–6	**Moderate risk**
8–12	**High risk**
15–25	**Extreme risk**

5.7.9 Data collection and data analysis

Data collected was analysed using Microsoft Excel 2007 (Microsoft, Redmond, Washington, US) programme. All the data collected from the panel was independently entered by the researcher and checked by the supervisors to ensure the quality of data entry (see section 2.6.6). The data set was then analysed as previously described (see section 2.6.7).

5.7.10 Data storage

Raw data will be securely retained at the University of Bath for five years before secure destruction. All the analysed data was anonymised (see section 2.5.4).

5.8 Results

5.8.1 Results from Observation Study

During the study period, 2602 scheduled injectable medicine doses were prepared in total. The researcher was present for 40% of each 24 hour period and observed the preparation of a similar proportion of the total number of doses (44.1%) of these. The majority of the doses were intravenous (IV) doses (n=1042), followed by subcutaneous (SC) doses (n=105) and intramuscular doses (IM) (n=1). The most common preparations were antibiotic medicines (n= 391); there were also electrolyte infusions (n=341) (e.g. sodium chloride 0.9%), and enoxaparin (n=90). Table 5.7 provides a summary of the data. In total, 66 nurses participated in the observations during the eight-week study.

All nursing staff reacted well to the study and expressed an interest in its aims. None expressed concern about being watched. The senior nurse and the physicians on the ward supported the observer with their resources and suggestions. Although not systematically collected, on two occasions, the parents of the patients commented to the observer that they were pleased the study was being carried out. None of the patients' relatives or ward managers expressed any concerns about the researcher's actions.

Table 5.7: Summary of injectable medicines preparation observed in each ward

Characteristic	**Surgical ward** (S)	**Medical ward** (C)	Medical ward (B)	Surgical ward (H)	Total
Number of days observed	10	10	10	10	40
Number of staff observed	17	11	15	23	66
Number of antibiotics observed	83	47	144	117	391
Number of electrolyte infusions observed	43	57	118	123	341
Number of heparins doses observed	2	7	68	44	121
Number of analgesics observed	28	8	9	27	71
Number of antiemetics observed	2	14	24	21	61
Number of diuretics observed	3	6	18	2	29
Number of aciclovir sodium doses observed	0	2	15	2	19
Number of corticosteroids doses observed	1	2	16	0	19
Number of Pabrinex doses observed	1	0	11	3	15
Number of chemotherapy dose observed	0	10	0	0	10
Number of Hartmann's solution infusions observed	2	0	3	5	10
Number of digoxin doses observed	2	4	2	2	10
Number of phytomenadione doses observed	2	0	6	0	8
Number of hyoscine butylbromide doses observed	0	1	4	3	8
Number of calcium gluconate 10% infusions observed	3	0	0	2	5
Number of potassium chloride infusions observed	0	4	0	1	5
Number of insulin doses observed	2	0	2	0	4
Number of magnesium sulphate infusions observed	0	0	4	0	4
Number of coagulation factor VIII complex (human) doses observed	0	3	0	0	3
Number of calcium folinate doses observed	0	3	0	0	3
Number of ranitidine doses observed	0	0	0	3	3
Number of adrenaline doses observed	1	0	0	0	1
Number of human albumin solution (Zenalb) infusions observed	1	0	0	0	1
Number of human normal immunoglobulin (Privigen) infusions observed	0	1	0	0	1
Number of sodium ferric gluconate doses observed	0	0	1	0	1
Number of aminophylline infusions observed	0	0	0	1	1
Number of amiodarone doses observed	0	0	0	1	1
Number of chlorphenamine doses observed	0	1	0	0	1

5.8.2 Incidence and Types of Injectable Medicine Preparation Errors in the Hospital wards

Three hundred and seventy two (372) IPEs were recorded from the 1148 dose preparations observed. The observer intercepted all the IPE incidents before the patients received the drug. There were also 13 IPEs that were corrected by the nurse being observed or by the second nurse responsible for checking the preparation before delivering it to the patient. These corrected errors were not included in the total of 372 IPEs. The 13 IPEs that were detected in time by the nurse were: wrong dose (n=3); faulty labelling (n=2); wrong diluent (n=5), and wrong medicine (n=3). The incidence of IPEs that occurred during the observations on each ward are shown in Table 5.8.

Table 5.8: Incidence of errors during the preparation of injectable drugs in each ward

	Surgical ward (S)	Medical ward (C)	Medical ward (B)	Surgical ward (H)
Total number of injectable medicine preparations over 10 days (24 hours/day)	393	365	981	863
Number of observations	176	170	445	357
Number of errors	45	44	150	133
Rate of errors	25.5%	25.8%	33.7%	37.2%

There was no significant difference in the incidence of errors between the medical and surgical wards (One way ANOVA, f = 0.8706, p. Value (P) = 0.5264). The overall rate of IPEs for the four wards was 32.4%.

Table 5.9-5.12 show the IPEs, which occurred on the surgical ward (S), the medical ward (C) the medical ward (B) and the surgical ward (H) respectively. Errors were most commonly occurred during the preparation of antibiotics, electrolyte infusions, analgesics and antiemetics.

Table 5.9: A summary of the injectable drug preparation errors that occurred in the surgical ward (S) (n=176).

Surgical ward (S)								
Type of medicine	Route	Number of drug observations	Number of errors	Medicine specific error rate (%)	Percentage of preparations associated with error for specific drug (%)	Number of observation		
						With 1 error	With 2 error	With 3 error
Adrenaline	I.V.	1	2	100%	0.5%	0	1	0
Phytomenadione	I.V.	2	4	100%	1.1%	0	2	0
Furosemide	I.V.	3	4	100%	1.7%	2	1	0
Ondansetron	I.V.	2	2	100%	1.1%	2	0	0
Insulin	I.V.	2	2	100%	1.1%	2	0	0
Tazocin	I.V.	13	7	54%	3.9%	7	0	0
Teicoplanin	I.V.	2	1	50%	0.5%	1	0	0
Meropenem	I.V.	2	1	50%	0.5%	1	0	0
Amoxicillin	I.V.	29	14	48%	7.9%	7	2	1
Co-amoxiclav	I.V.	11	4	36%	2.2%	4	0	0
Paracetamol	I.V.	10	1	10%	0.5%	1	0	0
Metronidazole	I.V.	22	2	9%	1.1%	2	0	0
Morphine sulphate	I.V.	12	1	8%	0.5%	1	0	0
Sodium chloride 0.9%	I.V.	43	0	0%	0%	0	0	0
Digoxin	I.V.	2	0	0%	0%	0	0	0
Fentanyl	I.V.	5	0	0%	0%	0	0	0
Gentamicin	I.V.	3	0	0%	0%	0	0	0
Pabrinex	I.V.	1	0	0%	0%	0	0	0
Human albumin solution (Zenalb)	I.V.	1	0	0%	0%	0	0	0
Heparin	I.V.	2	0	0%	0%	0	0	0
Calcium Gluconate 10%	I.V.	3	0	0%	0%	0	0	0
Hartmann’s solution	I.V.	2	0	0%	0%	0	0	0
Dexamethasone	I.V.	1	0	0%	0%	0	0	0
Clarithromycin	I.V.	1	0	0%	0%	0	0	0
Tramadol	I.M.	1	0	0%	0%	0	0	0

For nine of the drugs delivered on the surgical ward (S) the preparation error rate was ≥47% (Table 5.9). The most common of these were antibiotics (e.g. Tazocin and Amoxicillin) as these were amongst those drugs most frequently prepared. Other drugs where errors were of importance included adrenaline and insulin due to potential toxicity.

Table 5.10: A summary of the injectable drug preparation errors that occurred in the medical ward (C) (n=170).

Medical ward								
Type of medicine	Route	Number of drug observations	Number of errors	Medicine specific error rate (%)	Percentage of preparations associated with error for specific drug (%)	Number of observation		
						With 1 error	With 2 error	With 3 error
Melphalan	I.V.	3	4	100%	1.7%	2	1	0
Coagulation Factor VIII Complex	I.V.	3	3	100%	1.7%	3	0	0
Amoxicillin	I.V.	3	3	100%	1.7%	3	0	0
Teicoplanin	I.V.	3	3	100%	1.7%	3	0	0
Digoxin	I.V.	4	4	100%	2.3%	4	0	0
Cyclizine	I.V.	7	4	57%	2.3%	4	0	0
Tazocin	I.V.	29	16	55%	9.4%	11	1	1
Paracetamol	I.V.	4	2	50%	1.1%	2	0	0
Furosemide	I.V.	6	2	33%	1.1%	2	0	0
Morphine sulphate	I.V.	4	1	25%	0.6%	1	0	0
Co-amoxiclav	I.V.	4	1	25%	0.6%	1	0	0
Sodium Chloride 0.9%	I.V.	57	1	2%	0.6%	1	0	0
Ondansetron	I.V.	2	0	0%	0%	0	0	0
Privigen	I.V.	1	0	0%	0%	0	0	0
Metronidazole	I.V.	1	0	0%	0%	0	0	0
Meropenem	I.V.	3	0	0%	0%	0	0	0
Gentamicin	I.V.	3	0	0%	0%	0	0	0
Hydrocortisone	I.V.	1	0	0%	0%	0	0	0
Hyoscine butylbromide	I.V.	1	0	0%	0%	0	0	0
Levomepromazine hydrochloride	S.C.	5	0	0%	0%	0	0	0
Aciclovir sodium	I.V.	2	0	0%	0%	0	0	0
Heparin	I.V.	7	0	0%	0%	0	0	0
Calcium folinate	I.V.	3	0	0%	0%	0	0	0
Chlorphenamine	I.V.	1	0	0%	0%	0	0	0
Potassium chloride	I.V.	4	0	0%	0%	0	0	0
Dexamethasone	I.V.	1	0	0%	0%	0	0	0
Clarithromycin	I.V.	1	0	0%	0%	0	0	0
Methotrexate	I.V.	2	0	0%	0%	0	0	0
Cyclophosphamide	I.V	2	0	0%	0%	0	0	0
Thiotepa	I.V.	1	0	0%	0%	0	0	0
Disodium Pamidronate	I.V.	1	0	0%	0%	0	0	0
Idarubicin	I.V.	1	0	0%	0%	0	0	0

For eight of the drugs on the medical ward (C), the preparation error rate was ≥50% (Table 5.10). The most common of these was Tazocin, as this drug was amongst those most frequently prepared. Other drugs of importance include melphalan, factor VIII, digoxin and paracetamol, due to potential toxicity.

Table 5.11: A summary of the injectable drug preparation errors that occurred in the medical ward (B) (n=445).

Medical ward (B)								
Type of medicine	Route	Number of drug observations	Number of errors	Medicine specific error rate (%)	Percentage of preparations associated with error for specific drug (%)	Number of observation		
						With 1 error	With 2 error	With 3 error
Sodium ferric gluconate	I.V.	1	1	100%	0.2%	1	0	0
Digoxin	I.V.	2	2	100%	0.4%	2	0	0
Clarithromycin	I.V.	1	1	100%	0.2%	1	0	0
Heparin	I.V.	17	17	100%	3.8%	17	0	0
Insulin	I.V.	2	2	100%	0.4%	2	0	0
Ondansetron	I.V.	15	13	87%	2.9%	13	0	0
Amoxicillin	I.V.	19	14	74%	3.1%	7	2	1
Tazocin	I.V.	36	24	67%	5.4%	19	1	1
Pabrinex	I.V.	11	7	64%	1.6%	7	0	0
Furosemide	I.V.	18	11	61%	2.5%	11	0	0
Meropenem	I.V.	24	13	54%	2.9%	13	0	0
Phytomenadione	I.V.	6	3	50%	0.7%	3	0	0
Levofloxacin	I.V.	9	4	44%	0.9%	4	0	0
Ceftazidime	I.V.	23	8	35%	1.8%	8	0	0
Methylprednisolone	I.V.	6	2	33%	0.4%	2	0	0
Hydrocortisone	I.V.	10	3	30%	0.7%	3	0	0
Magnesium sulfate	I.V.	4	1	25%	0.2%	1	0	0
Paracetamol	I.V.	9	2	22%	0.4%	2	0	0
Aciclovir sodium	I.V.	15	3	20%	0.7%	3	0	0
Teicoplanin	I.V.	5	1	20%	0.2%	1	0	0
Co-trimoxazole	I.V.	7	1	14%	0.2%	1	0	0
Levomepromazine	S.C	7	1	14%	0.2%	1	0	0
Metronidazole	I.V.	7	1	14%	0.2%	1	0	0
Sodium chloride 0.9%	I.V.	118	13	11%	2.9%	13	0	0
Enoxaparin	S.C	51	2	4%	0.4%	2	0	0
Vancomycin	I.V.	7	0	0%	0.0%	0	0	0
Gentamicin	I.V.	6	0	0%	0.0%	0	0	0
Hartmann's solution	I.V.	3	0	0%	0.0%	0	0	0
Metoclopramide	I.V.	2	0	0%	0.0%	0	0	0
Hyoscine butylbromide	I.V.	4	0	0%	0.0%	0	0	0

For twelve of the drugs on the medical ward (B), the preparation error rate was ≥50% (Table 5.11). The most significant of these were antibiotics, as these drugs were

amongst those most frequently prepared. Other drugs of significance were heparin; ondansetron; meropenem and sodium chloride 0.9%.

Table 5.12: A summary of the injectable drug preparation errors that occurred in the surgical ward (H) (n=357).

Surgical ward (H)								
Type of medicine	Route	Number of drug observations	Number of errors	Medicine specific error rate (%)	Percentage of preparations associated with error for specific drug (%)	Number of observation		
						With 1 error	With 2 error	With 3 error
Aminophylline	I.V.	1	2	100%	0.5%	0	1	0
Amiodarone	I.V	1	1	100%	0.3%	1	0	0
Morphine sulphate	I.V.	9	9	100%	2.5%	9	0	0
Tramadol	I.V.	2	2	100%	0.5%	2	0	0
Tazocin	I.V.	47	43	91%	12.0%	43	0	0
Cyclizine	I.V.	16	14	88%	3.9%	14	0	0
Amoxicillin	I.V.	7	5	71%	1.4%	5	0	0
Flucloxacillin	I.V.	24	15	63%	4.2%	10	1	1
Oxycodone andmidazolam	S.C.	2	1	50%	0.3%	1	0	0
Co-trimoxazole	I.V.	6	3	50%	0.8%	3	0	0
Ondansetron	I.V.	4	2	50%	0.5%	2	0	0
Calcium gluconate	I.V.	2	1	50%	0.3%	1	0	0
Gentamicin	I.V.	7	3	43%	0.8%	3	0	0
Meropenem	I.V.	6	2	33%	0.5%	2	0	0
Vancomycin	I.V.	3	1	33%	0.3%	1	0	0
Pabrinex	I.V.	3	1	33%	0.3%	1	0	0
Ranitidine	I.V.	3	1	33%	0.3%	1	0	0
Ceftazidime	I.V.	5	1	20%	0.3%	1	0	0
Sodium chloride 0.9%	I.V.	123	24	20%	6.7%	24	0	0
Enoxaparin	S.C	39	2	5%	0.5%	2	0	0
Teicoplanin	I.V.	2	0	0%	0.0%	0	0	0
Digoxin	I.V.	2	0	0%	0.0%	0	0	0
Paracetamol	I.V.	16	0	0%	0.0%	0	0	0
Furosemide	I.V.	2	0	0%	0.0%	0	0	0
Co-amoxiclav	I.V.	2	0	0%	0.0%	0	0	0
Metronidazole	I.V.	6	0	0%	0.0%	0	0	0
Hyoscine butylbromide	I.V.	3	0	0%	0.0%	0	0	0
Levomepromazine	S.C.	1	0	0%	0.0%	0	0	0
Aciclovir sodium	I.V.	2	0	0%	0.0%	0	0	0
Heparin	I.V.	5	0	0%	0.0%	0	0	0
Potassium chloride	I.V.	1	0	0%	0.0%	0	0	0
Hartmann's solution	I.V.	5	0	0%	0.0%	0	0	0

There were twelve drugs administered on the surgical ward (H) for which the preparation error rate was ≥50% (Table 5.12). The drugs involved in the highest proportion of errors were antibiotics, as these drugs were amongst those most frequently prepared. Additionally, other drugs of note were morphine and cyclizine. A description of each of the individual errors that occurred on all four wards, is shown in Appendix 16 with reference to the following violated policies:

- ANTT: (ward S and C) Aseptic Non Touch Technique Staff Workbook, 2015.

- IV Policy: (ward S and C) Medicines Code: Administration of Intravenous Drugs, 2016.

- RCN: Royal College of Nursing, Standards for Infusion Therapy, 2016.

- University College London Hospital (UCL): (ward B and H) UCL Hospitals Injectable Medicines Administration Guide, 2010.

- Medicine Management Policy (ward B and H): Prescribing, Preparing and Administrating Injectable Medicines in Clinical Areas, 2015.

Errors occurring on the four wards were grouped into two categories and numerous subcategories, as shown in Table 5.13 The most common contamination-related health and safety issues on the four wards were that the area was not clean and tidy before and during injectable dose preparation, protective clothing was not worn (apron and gloves), and staff failed to prepare drugs using the correct aseptic non-touch technique.

The most common errors that occurred during dose selection and preparation were faulty labelling and not using a filter needle when specified.

Some preparation errors were common to all four wards. These included missing signatures, failure to perform a double check, and vigorously shaking drug vials to help the product to dissolve. A common error on medical ward (C) was that the treatment area was not clean and tidy and that drugs were prepared by an open window. A common error on the surgical ward (S) was violation of ANTT, and failure to wear the correct protective clothing. A common error on medical ward (B) was preparing the product outside the treatment room in unsuitable location, such as at the nurses' station. A common error on surgical ward (H) was that a filter needle was not used with products packaged in a glass ampoule.

Table 5.13: Description types of errors that occurred at the four wards.

Type of errors	Surgical ward (S)	Medical ward (C)	Surgical ward (H)	Medical ward (B)	Total
Contamination, health and safety issues					
Treatment area not cleaned and not tidy before and during injectable dose preparation.	7	3	17	17	44
Aseptic non-touch technique "ANTT" not followed.	4	1	16	18	39
Apron not worn.	5	0	16	16	37
Product prepared in unsuitable location such as nurse reception.	1	0	6	20	27
Gloves not worn.	1	0	16	9	26
Not swabbing septum on vial with alcohol.	1	0	0	8	9
Injectable dose prepared in area with open window.	0	6	0	0	6
Total errors	**19**	**10**	**71**	**88**	**188**
Dose selection and preparation					
Faulty labelling.	1	0	26	19	46
No filters used as specified.	1	2	21	20	44
Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	2	4	9	5	20
Strongly shaking a drug that foams/bubbles	4	9	0	5	18
No second checker	4	8	1	1	14
Signature of second checker who checked product missing from the label.	4	7	0	0	11
Wrong dose	2	0	2	4	8
Wrong medicine used.	2	1	0	2	5
Wrong volume of diluent used.	1	0	2	2	5
Forgetting to sign the drug chart/label by the maker.	3	1	0	0	4
Omitted dose	1	0	0	3	4
Incorrect expiry date.	0	2	0	0	2
Wrong diluent used.	1	0	0	0	1
Signature of nurse who checked product missing from drug chart.	0	0	0	1	1
Calculation error.	0	0	1	0	1
Total of errors	**26**	**34**	**62**	**62**	**184**

5.8.3 Severity assessment of injectable preparation error (IPEs)

A key aim of this research was to confirm that observed injectable drug preparation errors could be categorised as errors, and then to rank the severity of these errors on a scale of 0 – 10. A total of 372 observed errors were classified and ranked by an independent panel of five experts.

5.8.4 Confirmation of errors

All panel members agreed that all the observed cases could be classified as errors. All the errors were therefore included in the subsequent severity analysis (45 errors on surgical ward (S), 44 errors on medical ward (C), 133 errors on surgical ward (H), and 150 errors on medical ward (B)).

5.8.5 Severity ranking of errors

Appendix 16 shows the mean severity score assigned to each of the 372 observed errors by the panel of healthcare professionals. The mean severity ranking assigned by the panel was distributed according to three levels of harm: minor harm (13.1%; n = 49), moderate harm (79.5%; n = 296), and major harm (7.2%; n = 27). The results showed that some errors were assigned a major level of harm, suggesting the risk control mechanisms in the hospital wards are dysfunctional. The highest severity score error (8.6) occurred in the surgical ward (S) and resulted from an incorrect volume of diluent for an insulin infusion (S38). The lowest severity score (2.4) occurred on two wards: the surgical ward (S) and the medical ward (C). On both wards the lowest severity score was attributed to a missing signature on a product label by the nurse who checked the product (S21, S22, S33, S37, C54, C55, C56, C66, C67, and C72). For all 372 errors,

the overall mean severity score was 5.2, and the median severity score was 5 (interquartile range: 3.7; minimum: 2.4; maximum: 8.6.

5.8.6 Severity Ranking of Errors

Table 5.14 presents the overall severity grading for errors observed on each ward. The majority of errors on four wards were assigned a moderate level of potential harm, as has previously been observed (Taxis and barber, 2003; Wirtz et al. 2003; Taxis and Barber, 2004). Furthermore, there was no significance difference between the numbers of errors of each level of severity on each ward (one away ANOVA) f = 0.5481, p. Value (P) = 0.6633).

Table 5.14: Overall severity rate compared with those obtained for each ward (n=372).

	Total error rate %	Errors assigned a minor level of harm %	Errors assigned a moderate level of harm %	Errors assigned a major level of harm %
Overall	32.4◆	4.4 (n = 50)	25.7 (n = 295)	2.3 (n = 27)
Surgical (S)	25.5*	6.8 (n = 12)	17.0 (n = 30)	1.7 (n = 3)
Medical (C)	25.8**	4.7 (n = 8)	18.2 (n = 31)	2.9 (n = 5)
Surgical (H)	37.3***	4.5 (n = 16)	31.1 (n = 111)	1.7 (n = 6)
Medical (B)	33.7****	3.1 (n = 14)	27.7 (n = 123)	2.9 (n = 13)

◆372 errors from 1148 observations * 45 errors from 176 observations ** 44 errors from 170 observations *** 133 errors from 357 observations ****150 errors from 445 observations

Table 5.15 shows the mean and median severity scores obtained for each of the hospital wards. Panel members assigned higher median severity scores to errors on the medical ward (C). In order to assess the significance of this test, the median severity scores assigned to each ward were compared using the Kruskall-Wallis test. This gave a result of p=0.181, showing no significant difference between the severity of the errors observed on the four wards.

Table 5.15: The mean and median potential harm scores for the four types of hospital wards.

Hospital ward	Severity score	
	Mean	Median
Surgical (S)	4.9	5.0
Medical (C)	5.3	6.0
Surgical (H)	5.3	5.0
Medical (B)	5.2	5.0

Table 5.16 (a, b, c, d) summarises the frequency of errors by type, and the related categories of severity in the four hospital wards. In the surgical ward (S), the most common type of error was gross disregard for cleanliness or clutter in the treatment room, which was assigned a moderate level of harm. Faulty labelling represented the second-most common type of error, which was assigned a minor level of harm in 86% of instances, and in 14% of instances a moderate level of harm. In the medical ward (C), the most joint common type of error was gross disregard for cleanliness or clutter in a treatment room, which was assigned a moderate level of harm in 78% of instances and in 22% of instances a major level of harm. Air bubbles not expelled before checking volume was also the joint most common concern assigned in 66.7% of instances a moderate level of harm, and in 33.3% of instances a major level of harm. In the surgical ward (H), six main types of error were identified: faulty labelling, a filter needle not used, gross disregard for cleanliness or clutter in the treatment room, breach of ANTT, unused apron, and unused gloves. Faulty labelling was the most common type of error, which in 85% of instances was considered assigned a moderate level of harm and in 15% of instances a major level of harm. For medical ward (B), the most common types of error were inappropriate location of medicine preparation and a filter needle not being used, both of which were assigned a moderate level of harm. Also, it can be noted from Table 5.16 (a, b, c, d) that each error type tends to have just one severity level, however some spanned two severity levels. These suggest that error type is more important than

drug in determining severity. For example harm level of faulty labelling in surgical ward (S43) was moderate because additional 200 mg added to infusion but label not changed. On the other hand the harm level of faulty labelling in surgical ward (S33) was minor due to the signature of nurse who checked product missing from label.

Table 5.16 (a): Breakdown of injectable drug preparation error severity scores in the surgical ward (S) (n = 45).

Type of Error	Harm Level			Total (n = 45)
	Minor	Moderate	Major	
Gross disregard for clean/ uncluttered treatment room	0	7	0	7
Faulty labelling	6	1	0	7
Unused apron	6	0	0	6
Air bubbles not expelled before volume checked	0	4	0	4
No double check	0	4	0	4
Breach of ANTT	0	3	0	3
Undissolved powder left in vial	0	2	0	2
Wrong dose	0	2	0	2
Wrong medicine	0	1	1	2
Wrong diluent	0	0	2	2
Unused gloves	0	1	0	1
Rubber septum not wiped	0	1	0	1
Filter needle not used	0	1	0	1
Inappropriate location of medicine preparation	0	1	0	1
Signature of nurse who prepared product missing from drug chart	0	1	0	1
Omitted medicine	0	1	0	1
Wrong expiry date	0	0	0	0
Calculation error	0	0	0	0
Total	12	30	3	45

Table 5.16 (b): Breakdown of injectable drug preparation error severity scores in the medical ward (C) (n = 44).

Type of Error	Harm Level			Total (n = 44)
	Minor	Moderate	major	
Gross disregard for clean/ uncluttered treatment room	0	7	2	9
Air bubbles not expelled before volume checked	0	6	3	9
Faulty labelling	8	0	0	8
No double check	0	8	0	8
Undissolved powder left in vial	0	4	0	4
Filter needle not used	0	2	0	2
Wrong expiry date	0	2	0	2
Breach of ANTT	0	1	0	1
Wrong medicine	0	1	0	1
Wrong dose	0	0	0	0
Wrong diluent	0	0	0	0
Rubber septum not wiped	0	0	0	0
Inappropriate location of medicine preparation	0	0	0	0
Signature of nurse who prepared product missing from drug chart	0	0	0	0
Omitted medicine	0	0	0	0
Unused apron	0	0	0	0
Unused gloves	0	0	0	0
Calculation error (n = 0)	0	0	0	0
Total	8	31	5	44

Table 5.16 (c): Breakdown of injectable drug preparation error severity scores in the surgical ward (H) (*n* = 133).

Type of Error	Harm Level			Total (*n* = 133)
	Minor	Moderate	major	
Faulty labelling	0	22	4	26
Filter needle not used	0	21	0	21
Gross disregard for clean/ uncluttered treatment room	0	17	0	17
Breach of ANTT	0	16	0	16
Unused apron	16	0	0	16
Unused gloves	0	16	0	16
Undissolved powder left in vial	0	9	0	9
Inappropriate location of medicine preparation	0	6	0	6
Wrong dose	0	2	0	2
Wrong diluent	0	1	1	2
No double check	0	1	0	1
Calculation error	0	0	1	1
Air bubbles not expelled before volume checked	0	0	0	0
Wrong expiry date	0	0	0	0
Wrong medicine	0	0	0	0
Rubber septum not wiped	0	0	0	0
Signature of nurse who prepared product missing from drug chart	0	0	0	0
Omitted medicine	0	0	0	0
Total	16	111	6	133

Table 5.16 (d): Breakdown of injectable drug preparation error severity scores in the medical ward (B) (n = 150).

Type of Error	Harm Level			Total (n = 150)
	Minor	Moderate	major	
Inappropriate location of medicine preparation	0	20	0	20
Filter needle not used	0	20	0	20
Faulty labelling	0	17	2	19
Breach of ANTT	0	14	4	18
Gross disregard for clean/ uncluttered treatment room	0	16	1	17
Unused apron	14	2	0	16
Unused gloves	0	9	0	9
Rubber septum not wiped	0	8	0	8
Undissolved powder left in vial	0	5	0	5
Air bubbles not expelled before volume checked	0	1	4	5
Wrong dose	0	4	0	4
Omitted medicine	0	2	1	3
Wrong diluent	0	2	0	2
Wrong medicine	0	1	1	2
No double check	0	1	0	1
Signature of nurse who prepared product missing from drug chart	0	1	0	1
Calculation error	0	0	0	0
Wrong expiry date	0	0	0	0
Total	14	123	13	150

5.8.7 Risk scoring and grading of errors

5.8.8 Consequence score:

The results obtained for the different wards are given in Table 5.17 (a, b, c, d). A consequence descriptor for 'major' (score 4) was assigned to one type of error on surgical ward (S), medical ward (C), and medical ward (B), and to two types of error in surgical ward (H). Most error types in all the wards were categorised as 'moderate' (score 3). In surgical ward (S), two types of error were categorised as 'minor' (score 2) (i.e. faulty labelling and unused apron), whereas one type of recorded error was identified as minor (score 2) on medical ward (C) (i.e. faulty labelling). On surgical ward (H) and medical ward (B), one type of error (i.e. unused apron) was assigned a minor consequence descriptor (score 2).

Table 5.17 (a): Mapping of severity data from the surgical ward (S) on to NPSA consequence descriptors to obtain consequence scores.

Type of error (*n* = 45)	Mean severity score	NPSA consequence score	NPSA consequence description
Wrong diluent (*n* = 2)	7.6	4	Major
Omitted medicine (*n* = 1)	6.4	3	Moderate
Air bubbles not expelled before volume checked (*n* = 4)	6.2	3	Moderate
Gross disregard for clean/ uncluttered treatment room (*n* = 7)	6.0	3	Moderate
Breach of ANTT (*n* = 3)	6.0	3	Moderate
No double check (*n* = 4)	5.4	3	Moderate
Unused gloves (*n* = 1)	5.4	3	Moderate
Wrong medicine (*n* = 2)	5.3	3	Moderate
Undissolved powder left in vial (*n* = 2)	5.2	3	Moderate
Wrong dose (*n* = 2)	5.0	3	Moderate
Rubber septum not wiped (*n* = 1)	4.8	3	Moderate
Inappropriate location of medicine preparation (*n* = 1)	4.6	3	Moderate
Signature of nurse who prepared product missing from drug chart (*n* = 1)	4.6	3	Moderate
Filter needle not used (*n* = 1)	4.4	3	Moderate
Faulty labelling (*n* = 7)	3.0	2	Minor
Unused apron (*n* = 6)	2.8	2	Minor

Table 5.17 (b): Mapping of severity data from the medical ward (C) on to NPSA consequence descriptors to obtain consequence scores.

Type of error (*n* = 44)	Mean severity score	NPSA consequence score	NPSA consequence description
Air bubbles not expelled before volume checked (*n* = 9)	6.5	4	Major
Gross disregard for clean/ uncluttered treatment room (*n* = 9)	6.4	3	Moderate
Wrong expiry date (*n* = 2)	6.4	3	Moderate
Wrong medicine (*n* = 1)	6.2	3	Moderate
Undissolved powder left in vial (*n* = 4)	6.0	3	Moderate
Breach of ANTT (*n* = 1)	5.8	3	Moderate
No double check (*n* = 8)	5.6	3	Moderate
Filter needle not used (*n* = 2)	4.4	3	Moderate
Faulty labelling (*n* = 8)	3.0	2	Minor

Table 5.17 (c): Mapping of severity data from the surgical ward (H) on to NPSA consequence descriptors to obtain consequence scores.

Type of error (*n* = 133)	Mean severity score	NPSA consequence score	NPSA consequence description
Calculation error (*n* = 1)	7.6	4	Major
Wrong diluent (*n* = 2)	7.1	4	Major
Faulty labelling (*n* = 26)	6.2	3	Moderate
Gross disregard for clean/ uncluttered treatment room (*n* = 17)	6.2	3	Moderate
Undissolved powder left in vial (*n* = 9)	5.9	3	Moderate
Breach of ANTT (*n* = 16)	5.8	3	Moderate
Wrong dose (*n* = 2)	5.8	3	Moderate
Unused gloves (*n* = 16)	5.6	3	Moderate
No double check (*n* = 1)	5.4	3	Moderate
Inappropriate location of medicine preparation (*n* = 6)	4.8	3	Moderate
Filter needle not used (*n* = 21)	4.4	3	Moderate
Unused apron (*n* = 16)	2.9	2	Minor

Table 5.17 (d): Mapping of severity data from the medical ward (B) on to NPSA consequence descriptors to obtain consequence scores.

Type of error (*n* = 150)	Mean severity score	NPSA consequence score	NPSA consequence description
Air bubbles not expelled before volume checked (*n* = 5)	6.5	4	Major
Wrong medicine (*n* = 2)	6.3	3	Moderate
Faulty labelling (*n* = 19)	6.2	3	Moderate
Gross disregard for clean/ uncluttered treatment room (*n* = 17)	6.2	3	Moderate
Wrong diluent (*n* = 2)	6.1	3	Moderate
Breach of ANTT (*n* = 18)	6.0	3	Moderate
Undissolved powder left in vial (*n* = 5)	5.8	3	Moderate
Wrong dose (*n* = 4)	5.7	3	Moderate
Unused gloves (*n* = 9)	5.5	3	Moderate
No double check (*n* = 1)	5.4	3	Moderate
Rubber septum not wiped (*n* = 8)	5.0	3	Moderate
Omitted medicine (*n* = 3)	5.0	3	Moderate
Inappropriate location of medicine preparation (*n* = 20)	4.8	3	Moderate
Filter needle not used (*n* = 20)	4.4	3	Moderate
Signature of nurse who prepared product missing from drug chart (*n* = 1)	4.0	3	Moderate
Unused apron (*n* = 16)	3.0	2	Minor

5.8.9 Likelihood score

The results obtained for the likelihood scores for the four wards are shown on Table 5.18 (a, b, c, d). The majority of error types were likely to occur at least daily on surgical ward (H) and medical ward (B). For surgical ward (S), 81% of errors were likely to occur at least weekly, and 19% at least daily. Most (56%) of the errors on medical ward (C) were likely to occur at least weekly and 44% at least daily.

Table 5.18 (a): Mapping of predicted number of errors from surgical ward (S) onto NPSA time frequency descriptors to obtain likelihood score.

Type of error (*n* = 45)	Error rate*	Predicted number of errors in one year**	NPSA frequency description	NPSA likelihood score
Gross disregard for clean/ uncluttered treatment room (*n* = 7)	0.040	574	Expected to occur at least daily	5
Faulty labelling (*n* = 7)	0.040	574	Expected to occur at least daily	5
Unused apron (*n* = 6)	0.034	488	Expected to occur at least daily	5
Air bubbles not expelled before volume checked (*n* = 4)	0.023	330	Expected to occur at least weekly	4
No double check (*n* = 4)	0.023	330	Expected to occur at least weekly	4
Breach of ANTT (*n* = 3)	0.017	245	Expected to occur at least weekly	4
Wrong diluent (*n* = 2)	0.011	158	Expected to occur at least weekly	4
Wrong medicine (*n* = 2)	0.011	158	Expected to occur at least weekly	4
Undissolved powder left in vial (*n* = 2)	0.011	158	Expected to occur at least weekly	4
Wrong dose (*n* = 2)	0.011	158	Expected to occur at least weekly	4
Unused gloves (*n* = 1)	0.005	72	Expected to occur at least weekly	4
Rubber septum not wiped (*n* = 1)	0.005	72	Expected to occur at least weekly	4
Inappropriate location of medicine preparation (*n* = 1)	0.005	72	Expected to occur at least weekly	4
Signature of nurse who prepared product missing from drug chart (*n* = 1)	0.005	72	Expected to occur at least weekly	4
Filter needle not used (*n* = 1)	0.005	72	Expected to occur at least weekly	4
Omitted medicine (*n* = 1)	0.005	72	Expected to occur at least weekly	4

* Total observations = 176 ** Total items prepared = 393

Almost certain Likely

Table 5.18 (b): Mapping of predicted number of errors from medical ward (C) onto NPSA time frequency descriptors to obtain likelihood score.

Type of error (*n* = 44)	Error rate*	Predicted number of errors in one year**	NPSA frequency description	NPSA likelihood score
Air bubbles not expelled before volume checked (*n* = 9)	0.053	706	Expected to occur at least daily	5
Gross disregard for clean/ uncluttered treatment room (*n* = 9)	0.053	706	Expected to occur at least daily	5
Faulty labelling (*n* = 8)	0.047	626	Expected to occur at least daily	5
No double check (*n* = 8)	0.047	626	Expected to occur at least daily	5
Undissolved powder left in vial (*n* = 4)	0.024	320	Expected to occur at least weekly	4
Wrong expiry date (*n* = 2)	0.012	160	Expected to occur at least weekly	4
Filter needle not used (*n* = 2)	0.012	160	Expected to occur at least weekly	4
Wrong medicine (*n* = 1)	0.006	80	Expected to occur at least weekly	4
Breach of ANTT (*n* = 1)	0.006	80	Expected to occur at least weekly	4

* Total observations = 170 ** Total items prepared = 365

Almost certain Likely

Table 5.18 (c): Mapping of predicted number of errors from surgical ward (H) onto NPSA time frequency descriptors to obtain likelihood score.

Type of error (*n* = 133)	Error rate*	Predicted number of errors in one year**	NPSA frequency description	NPSA likelihood score
Faulty labelling (*n* = 26)	0.073	2299	Expected to occur at least daily	5
Filter needle not used (*n* = 21)	0.059	1858	Expected to occur at least daily	5
Gross disregard for clean/ uncluttered treatment room (*n* = 17)	0.048	1511	Expected to occur at least daily	5
Breach of ANTT (*n* = 16)	0.045	1417	Expected to occur at least daily	5
Unused gloves (*n* = 16)	0.045	1417	Expected to occur at least daily	5
Unused apron (*n* = 16)	0.045	1417	Expected to occur at least daily	5
Undissolved powder left in vial (*n* = 9)	0.025	787	Expected to occur at least daily	5
Inappropriate location of medicine preparation (*n* = 6)	0.017	535	Expected to occur at least daily	5
Wrong diluent (*n* = 2)	0.006	189	Expected to occur at least weekly	4
Wrong dose (*n* = 2)	0.006	189	Expected to occur at least weekly	4
Calculation error (*n* = 1)	0.003	94	Expected to occur at least weekly	4
No double check (*n* = 1)	0.003	94	Expected to occur at least weekly	4

* Total observations = 357 ** Total items prepared = 863

Almost certain Likely

Table 5.18 (d): Mapping of predicted number of errors from medical ward (B) onto NPSA time frequency descriptors to obtain likelihood score.

Type of error (*n* = 150)	Error rate*	Predicted number of errors in one year**	NPSA frequency description	NPSA likelihood score
Inappropriate location of medicine preparation (*n* = 20)	0.045	1611	Expected to occur at least daily	5
Filter needle not used (*n* = 20)	0.045	1611	Expected to occur at least daily	5
Faulty labelling (*n* = 19)	0.043	1540	Expected to occur at least daily	5
Breach of ANTT (*n* = 18)	0.040	1432	Expected to occur at least daily	5
Gross disregard for clean/ uncluttered treatment room (*n* = 17)	0.038	1361	Expected to occur at least daily	5
Unused apron (*n* = 16)	0.036	1289	Expected to occur at least daily	5
Unused gloves (*n* = 9)	0.020	716	Expected to occur at least daily	5
Rubber septum not wiped (*n* = 8)	0.018	644	Expected to occur at least daily	5
Air bubbles not expelled before volume checked (*n* = 5)	0.011	399	Expected to occur at least daily	5
Undissolved powder left in vial (*n* = 5)	0.011	399	Expected to occur at least daily	5
Wrong dose (*n* = 4)	0.009	322	Expected to occur at least weekly	4
Omitted medicine (*n* = 3)	0.007	251	Expected to occur at least weekly	4
Wrong medicine (*n* = 2)	0.004	143	Expected to occur at least weekly	4
Wrong diluent (*n* = 2)	0.004	143	Expected to occur at least weekly	4
No double check (*n* = 1)	0.002	72	Expected to occur at least weekly	4
Signature of nurse who prepared product missing from drug chart (*n* = 1)	0.002	72	Expected to occur at least weekly	4

* Total observations = 445 ** Total items prepared = 981

Almost certain Likely

5.8.10 Risk score:

The risk scores assigned to the various error types occurring on the hospital wards are shown in Table 5.19 (a, b, c, d).

Table 5.19 (a): Risk scores assigned to error type in the surgical ward (S)

Type of error (*n* = 45)	Consequence	Likelihood	Risk Score	Assigned grade
Wrong diluent (*n* = 2)	4	4	16	Extreme risk
Gross disregard for clean/ uncluttered treatment room (*n* = 7)	3	5	15	Extreme risk
Air bubbles not expelled before volume checked (*n* = 4)	3	4	12	High risk
No double check (*n* = 4)	3	4	12	High risk
Breach of ANTT (*n* = 3)	3	4	12	High risk
Wrong medicine (*n* = 2)	3	4	12	High risk
Undissolved powder left in vial (*n* = 2)	3	4	12	High risk
Wrong dose (*n* = 2)	3	4	12	High risk
Unused gloves (*n* = 1)	3	4	12	High risk
Rubber septum not wiped (*n* = 1)	3	4	12	High risk
Inappropriate location of medicine preparation (*n* = 1)	3	4	12	High risk
Signature of nurse who prepared product missing from drug chart (*n* = 1)	3	4	12	High risk
Filter needle not used (*n* = 1)	3	4	12	High risk
Omitted medicine (*n* = 1)	3	4	12	High risk
Faulty labelling (*n* = 7)	2	5	10	High risk
Unused apron (*n* = 6)	2	5	10	High risk

Table 5.19 (b): Risk scores assigned to error type in the medical ward (C)

Type of error (*n* = 44)	Consequence	Likelihood	Risk Score	Assigned grade
Air bubbles not expelled before volume checked (*n* = 9)	4	4	16	Extreme risk
Gross disregard for clean/ uncluttered treatment room (*n* = 9)	3	5	15	Extreme risk
No double check (*n* = 8)	3	5	15	Extreme risk
Undissolved powder left in vial (*n* = 4)	3	4	12	High risk
Wrong expiry date (*n* = 2)	3	4	12	High risk
Filter needle not used (*n* = 2)	3	4	12	High risk
Wrong medicine (*n* = 1)	3	4	12	High risk
Breach of ANTT (*n* = 1)	3	4	12	High risk
Faulty labelling (*n* = 8)	2	5	10	High risk

Table 5.19 (c): Risk scores assigned to error type in the surgical ward (H)

Type of error (*n* = 133)	Consequence	Likelihood	Risk Score	Assigned grade
Calculation error (*n* = 1)	4	4	16	Extreme risk
Wrong diluent (*n* = 2)	4	4	16	Extreme risk
Faulty labelling (*n* = 26)	3	5	15	Extreme risk
Filter needle not used (*n* = 21)	3	5	15	Extreme risk
Gross disregard for clean/ uncluttered treatment room (*n* = 17)	3	5	15	Extreme risk
Breach of ANTT (*n* = 16)	3	5	15	Extreme risk
Unused gloves (*n* = 16)	3	5	15	Extreme risk
Undissolved powder left in vial (*n* = 9)	3	5	15	Extreme risk
Inappropriate location of medicine preparation (*n* = 6)	3	5	15	Extreme risk
No double check (*n* = 1)	3	4	12	High risk
Wrong dose (*n* = 2)	3	4	12	High risk
Unused apron (*n* = 16)	2	5	10	High risk

Table 5.19 (d): Risk scores assigned to error type in the medical ward (B)

Type of error (*n* = 150)	Consequence	Likelihood	Risk Score	Assigned grade
Air bubbles not expelled before volume checked (*n* = 5)	4	5	20	Extreme risk
Inappropriate location of medicine preparation (*n* = 20)	3	5	15	Extreme risk
Filter needle not used (*n* = 20)	3	5	15	Extreme risk
Faulty labelling (*n* = 19)	3	5	15	Extreme risk
Breach of ANTT (*n* = 18)	3	5	15	Extreme risk
Gross disregard for clean/ uncluttered treatment room (*n* = 17)	3	5	15	Extreme risk
Unused gloves (*n* = 9)	3	5	15	Extreme risk
Rubber septum not wiped (*n* = 8)	3	5	15	Extreme risk
Undissolved powder left in vial (*n* = 5)	3	5	15	Extreme risk
Wrong dose (*n* = 4)	3	4	12	High risk
Omitted medicine (*n* = 3)	3	4	12	High risk
Wrong medicine (*n* = 2)	3	4	12	High risk
Wrong diluent (*n* = 2)	3	4	12	High risk
No double check (*n* = 1)	3	4	12	High risk
Signature of nurse who prepared product missing from drug chart (*n* = 1)	3	4	12	High risk
Unused apron (*n* = 16)	2	5	10	High risk

The majority of the errors that occurred were graded 'high risk'; however, 12 types of error (i.e. gross disregard for clean/ uncluttered treatment room, inappropriate location of medicine preparation, unused gloves, wrong diluent, calculation error, air bubbles not expelled before volume checked, filter needle not used, breach of ANTT, rubber septum not wiped, undissolved powder left in vial, no double check and faulty labelling), were assigned the grade 'extreme risk'. Extreme risk errors were detected on all four wards however surgical ward (H) and medical ward (B) had the highest number of extreme risk errors.

Errors categorised as representing an extreme risk were selected for the development of risk reduction strategies. Specific risk scores assigned to these errors should enable prioritisation of risk reduction strategies for each ward.

5.9 Discussion

Direct observation of the injectable medication preparation process was conducted at two UK hospital sites. Observations were conducted using a validated and reliable method (Dean and Barber, 2001), and a list of IPE definitions based on that developed by Crowley (2006). An observational method to identify IPEs in practice has been used previously to study IPEs in UK hospitals (Wirtz et al. 2003; Taxis & Barber, 2003; Crowley, 2006).

During the observation, the researcher only observed the process of preparing an injectable medicine and did not interfere with the process unless an error was observed. If the investigator observed an error, then the relevant staff member was informed; they

then followed standard procedure to correct the error. If after carrying out the observations and interviews, the investigator had reason to doubt the fitness to practice of a member of staff, then this was discussed with the supervisory team (which includes two registered pharmacists with experience working in the NHS). If the supervisory team agreed there were grounds to be concerned about a member of staff's fitness to practice; they disclosed this to the relevant ward manager.

For the study, a total of 66 nurses were observed, while preparing 1148 doses from a possible 2602 schedule of doses, over 40 days. The observer witnessed and reported 372 IPEs, denoting an error rate of 32.4%. A panel of five healthcare professionals separately reviewed all 372 IPEs. The panel agreed that an error had occurred in 100% (n= 372) of the cases recorded by the researcher. The panel were consulted to validate the errors to ensure reliability as the observer carried out the observations autonomously. Other similar studies have used two or more observers to validate the data (Dean and Barber; Crowley, 2006).

To put these results in context, recent systematic reviews of studies using the same method have found an error rate of 35% in UK hospitals (McLeod et al., 2013), and 48% worldwide (Keers et al., 2103). The overall error rate (32.4%) for the preparation of injectable medicines was similar to that previously reported in a UK study carried out using the same methodology (39.7%) (Crowley, 2006). This error rate is higher than that reported in some previous studies in the UK and Europe hospitals. For example, error rates of 7.4%, 22%, and 19% were reported by Taxis & Barber, 2003, Wirtz et al., 2003 and Taxis & Barber, 2004, respectively. Perhaps the reason is that the current study focuses only on the preparation of injectable medicines in contrast to

previous studies (Taxis & Barber, 2003; Wirtz et al., 2003; Taxis & Barber, 2004), which have been very focused on the administration of injectable medicines rather than on injectable preparations. The overall error rate in drug preparation and administration was reported as 25% (Bruce and Wong 2001) in a UK-based study, rising to 69.7% in Australia (Cousins et al. 2005, Westbrook et al. 2011). The error rates for IPEs may differ between studies due to differing definitions of what constitutes an error, the prescribing and preparation systems set out, dates permitted, and the settings and methods used to identify IPEs. Hence, comparisons between studies may be unrepresentative (Allan and Barker 1990; Wirtz et al. 2003; Taxis & Barber, 2003; Crowley, 2006; Ferner 2009).

Another finding of this study was that of the 372 IPEs, 186 (50%) were associated with antibiotics. This error rate is comparable with that in other studies in the literature investigating IPEs (Wirtz et al. 2003 and Crowley, 2006). Antibiotic medicines are commonly used in hospitals. In 1995, Wilson et al. stated that antibiotics were the medicine class most associated with medical errors (13%, 30/233) and that 29% of these could be considered highly preventable. In the same year (1995), Bates et al reported that antibiotics were the second medication class most frequently associated with errors (25%, n=59), of which 11% (n=46) were preventable. In the following year, Rose et al. (1996) identified that 44% (48/109) of all the errors reported over five years at a large paediatric hospital involved antimicrobial agents (Ross et al., 2000). Furthermore, an analysis by Winterstein et al. (2004), at a US teaching hospital, found 42% (n=100) of the 240 preventable medical errors prospectively classified by different specialist healthcare providers related to antibiotics. In 2006, Otero-Lopez et al. found 23% (11/48) of the preventable ADEs classified were associated with antibiotics. In the UK,

Ashcroft and Cooke (2006) analysed ME reports over a 26-month period at a large teaching hospital (1000 beds) and found 14% of 495 submitted incidents related to antibiotics. Additionally, antibiotic related errors are common in paediatric medicine. In 2008, with regard to an observational study at a paediatric hospital in New Zealand, Kunac and Reith stated that antibiotics were subject to an error rate of 21% of all orders. A three and a half year research study on elderly patients in a large hospital in the US reported 861 errors, 152 of which (18%) were involved antibiotics (Picone et al., 2008). In a Spanish analysis at a small hospital (200-bed), (6% n=173) MEs were stated for 2,696 hospitalisations over a two-year study, of which (20% n=34) involved antibiotics (Menéndez et al., 2008).

The majority of the above studies cited a common link between antibiotics and MEs, and the frequency with which these medicines are prescribed. In 2004, Winterstein et al. noted that the inclusion of transplantation, oncology and critical care units in studies, which frequently prescribe antibiotics, might have contributed to making them the medicine class most commonly correlated with MEs. In 2006, Ghaleb and colleagues stated that because sedatives and antibiotics are the most commonly prescribed medicines, this explains why they are the medicine classes most frequently linked with MEs.

Frequent use of a medicine might explain why it is subject to a greater risk. A medicine that is used infrequently might be correlated with fewer errors and would then appear to be less risky. However, when the potential effects from medications are taken into account (e.g. Insulin, Heparins, Chemotherapy and Factor VIII), a drug that is rarely

used, when associated with fewer errors might represent a higher-risk drug than a drug that is commonly used and associated with more errors.

The results of this study show that incidents of IPEs can be framed according to two categories: contamination related health and safety issues (51% n=188/372) and dose selection and preparation (49% n=183/372). The majority of the errors associated with contamination-related health and safety issues related to the treatment room not being clean and tidy before and during injectable drug preparation (12.3% n=46/372), nurses not following correct ANTT (10.4% n=39/372), aprons not being worn (9.9% n=37/372), preparing injectable medicines outside the treatment room (7.2% n=27/372), and gloves not being worn during preparation (6.9% n=26/372). A previous study also reported that contamination-related health and safety factors are a common problem. Beaney and Goode (2003) examined the risk of contamination in clinical areas, reporting that 35% of the plastic trays on the ward showed contamination with skin microorganisms and staphylococcus. This shows the risk of microbiological contamination is much higher when injectable medicine preparation takes place in an uncontrolled environment, such as a hospital ward.

By contrast, the pharmacy IV room has clean filtered air and staff wear protective clothing to avoid contaminating the medicines (Beaney and Goode, 2003). This has led the authors of several studies to suggest that all injectable medicines should be prepared in a pharmacy department (NHS North West, 1997; Beaney and Goode, 2003). The likelihood that admitted patients might encounter risk rises when injectable medicines are prepared in hospital wards, both in relation to medication errors (Taxis and Barber, 2003; Cousins et al., 2005) and regarding contamination with microbes, leading to

infection (Beaney and Black, 2012). Injectable medicines are intended to be prepared in high-quality cleanrooms in NHS Trust pharmacies (RPS, 2016), in accordance with defined national standards; and pharmacies are frequently assessed to confirm these standards are being preserved (Beaney, 2006). Indeed, standards in hospital wards commonly differ from those in the pharmacy cleanroom (Beaney and Goode, 2003; RPS, 2016), supporting the proposition that all injectable medicines should be delivered in a ready-to-use form, either by pharmaceutical companies or the pharmacy department. Unfortunately, our study did not assess whether microbiological contamination occurred as a result of the errors observed, as its aim was to investigate the incidence and types of IPEs in hospital clinical areas. Nevertheless, it can be stated that all hospitals should ensure policies and guidelines are available and used by staff, to ensure the proper preparation method is employed regardless of the working area.

The most common errors noted during dose selection and preparation were faulty labelling (12.3% n=46/372); not using a filter needle when specified (11.8% n=44/372); the drug not fully dissolving in the diluent (5.3% n=20/372); strongly shaking a drug causing foaming/bubbles (4.8% n=18/372), and absence of a second checker (3.7% n=14/372). The research findings revealed that faulty labelling was the most common type of error in this category at both hospitals. The findings from this research are comparable with previous findings. In 2005, Cousins and colleagues stated that 44% of the injectable medicines prepared in the UK Trust contained some type of labelling error, and that in 22% of incidents, the label was missing. Faulty labelling was also common in 20 hospital pharmacies in Wales and almost half of time, these were not prevented (James et al., 2011). There is several proposed explanation for these findings will be explored in next chapter.

Failure to use a filter needle was observed in 44 dose preparations across both sites of study during the observation periods. 11.8% of nurses did not use a filter needle to transfer the diluent from a glass ampoule into a syringe. Poor commitment to filter use and frequent inappropriate use in the study periods suggests this is a routine deviation from protocol engaged in by an important percentage of nurses. No previous injectable error studies have reported data regarding nurses' compliance with the use of a filter needle.

Thirty-eight errors were observed during the reconstitution phase and resulted from poor preparation technique. The majority of errors occurred when nurses failed to fully dissolve a powder during the reconstitution phase, or did not comply with mixing instructions stated in the product monograph or hospital guidelines; e.g. vigorously shaking teicoplanin, causing foaming and hard shaking Factor VIII, leading to the loss of some of the prescribed dose. A study by Taxis and Barber (2003) reported that most preparation errors were associated with multiple step preparations (14%, n= 50/345), as with drugs that required reconstitution with a solvent and the addition of a diluent. Two studies have also reported that faulty reconstitution, addition and mixing is a common problem (Hoppe-Tichy et al., 2002; Wirtz et al., 2003). McDowell et al. (2010) reported that the reconstitution phase in IV preparation was the most error-prone step, and that eliminating this step by using ready-to-use infusions would reduce the overall injectable medicines preparation error rate.

Almost all the preparations in the study periods were linked to at least one deviation from best practice. Lack of nursing commitment to some stages, e.g. involving wearing

apron/gloves and no second checker, were observed during the study period. The commitment by nurses to the stages in the present study was lower than in the few studies designed to investigate the prevalence of nurses' deviations from best practice while preparing and administering injectable doses. For example, an observational study by Ong and Subasyini (2013) stated that 74% of nurses were not committed to routinely wearing gloves when preparing injectable doses. Gill et al. (2012) reported that 83% of nurses check the name and expiry date of injectable medication during administration stage, our study showed that checking procedure are lacking during preparation. Previous studies have reported that the lack of a checking stage is a common practice among nurses, and may be considered a significant factor contributing to errors, particularly with injectable doses (Armitage and Knapman 2003, Westbrook et al. 2011, Gill et al. 2012, Keers et al. 2013). The systematic review by McDowell et al. (2010) stated that appropriate checking during injectable dose preparation reduced the error rate from 0.73 to 0.22.

Differences in nurses' level of commitment to checking procedure during injectable medication preparation was found in previous studies, to range from 50% (Westbrook et al., 2011) to 89.5% (Gill et al. 2012). In the present study, inadequate commitment to double-checking was reported (3.7% n=14/372) than in previous studies, while adequate commitment to double-checking was stated (96.2% n=358/372). The observer impression was that nurses' commitment to the two stages (wearing apron/gloves prior to the start of preparation, and double-checking of the final product) was lower towards the end of their shifts than at the start of their shifts. Nurses' commitment to wearing apron/gloves declined during a shift, even though Trust policy emphasises the importance of wearing apron/gloves before commencing preparation, as an aseptic

requirement for infection control (Nursing & Midwifery Council, 2015). This result may be associated with the length of shifts and nurses' tiredness at the end of their shift and will be explored in the next chapter.

An incompatibility with other previous studies that was noted involved the investigation of aseptic techniques (ANTT). The current findings reported that 10.4% (n=39/372) of observation, staff did not follow ANTT (i.e. not touching the sterile tip of a syringe, and not using apron and gloves). Microbiological assessment would be necessary to assess the significance of these deviations. There are currently insufficient specified instructions or policies regarding aseptic techniques. For example, the hospital medicine policy used on the wards notifies nurses to follow 'ANTT', with no further clarification. Instructing nurses about the clinical effects of these types of errors might reduce the number of associated IPEs. Moreover, further investigation is needed to study consequences of deviating from recommended ANTT techniques. Additionally, making a provision to the centralised intravenous additive service (CIVAS) or purchasing ready-to-use injectable medicines could usefully be studied to minimise preparation errors.

The severity of the mistakes was measured based on potential harm to the patient, and was measured by expert judgement on a validated linear scale, ranging from 0 to 10, where 0 equated to no harm and 10 to a mistake that would result in death (Dean and Barber, 1990). The severity of errors and the frequency of the error data were used to calculate consequence and likelihood scores, to find a risk score for each error analogous to that used by the National Patient Safety Agency (NPSA, 2008). Errors with extreme and high-risk scores will provide a focus for developing strategies to help prevent them from occurring again.

For all four wards included in this study, the majority of errors were assigned a moderate level of potential harm (Taxis and barber, 2003; Wirtz et al. 2003; Taxis and Barber, 2004). In total 13.1% (*n* = 49) of errors scored between 0.5 and 3.4 and were thus considered eligible to cause minor harm; 79.5% (*n* = 296 errors) scored between 3.5 and 7.4, and were thus considered to cause moderate harm; and 7.2% (*n* = 27 errors) scored between 7.5 and 9.4, and so were deemed to be capable of causing harm of major severity. None of the 372 errors had a mean score higher than 9.5, suggesting none would have proven fatal. Some errors with minor consequences for the patient, e.g. faulty labelling of an antibiotic, might represent a failure in the existing system of policy. Guidance and policies include not leaving the treatment room to prepare medicines, and an injectable medicines preparation guide should be initiated by the pharmacist checking the preparation room at ward level. The gross disregard for a clean/ uncluttered treatment room was a common factor on all four wards that the researcher (AA) observed. This may involve nursing culture, which will be discussed in detail in chapter six.

In the current study severity data and frequency data was used to calculate the risk score for the preparation errors, to provide a focus for developing risk reduction strategies. The results showed that data requiring action can be divided according to two levels: extreme risk and high risk. In the present study, the researcher has chosen to focus on extreme risk when developing risk reduction strategies for the four different wards.

The results of this study showed the errors could be graded as representing an extreme risk in approximately half (52.1% n=12/23 types of errors) of cases. The most frequent types of errors graded as representing an extreme risk were wrong diluent; gross

disregard for a clean/ uncluttered treatment room and faulty labelling. Characteristic types of errors were clarified at each study site. The variations in practice between them might have contributed to the errors discussed in the next chapter. Moreover, the resulting risk scores suggest different priorities need to be tackled to reduce the errors in each of the wards. For example, in surgical ward (S) risk reduction strategies should focus on ensuring that the nurses always keep the treatment room clean and tidy before and after preparing injectable medicines, and making sure that the wrong diluent is not given, especially if the drug has potential toxicity such as insulin (S38). Whereas, in medical ward (C) the risk strategies should focus on addressing problems during the reconstitution stage; for example C62 and C73 and the absence of a second checker (e.g. C74). In the surgical ward (H), risk strategies should prioritise avoiding a breach of ANTT (e.g. H209); faulty labelling (e.g. H250) and use of the filter needle for withdrawing the medicine from ampoules (e.g. H237). On the other hand, in medical ward (B), risk strategies should focus on ensuring injectable medicines are prepared in the treatment room only and that nurses follow NHS policies (e.g. B102).

As far as this author knows, this is the first study to employ severity data and frequency data to calculate a risk score for IPEs, to provide a focus for developing risk reduction strategies. The types of errors graded as extreme risk are of greatest concern, as they can have a direct effect on the patient's care management. However, it should be emphasised once again that there were no errors graded as catastrophic/fatal were witnessed during this study, in contrast to previous patient safety incident reports (NPSA, 2009). In addition, it is important to note that this study did not capture all the IPEs reported (Dean and Barber, 2001; Taxis and Barber, 2013; Wirtz et al. 2003; Crowley, 2006; Ameer, 2105). This includes incidents involving wrong route and administering of non-

prescribed medicine. The presence of the researcher in the preparation room might have helped to minimise some errors. However there is no concrete evidence proving this interpretation.

This study was subject to some limitations. When it was designed, it was anticipated that the observations would cover three shifts; however, due to the length of nurses' shifts, it was difficult for the observer to arrive at a morning shift and stay until after the night shift. Therefore, all observations were conducted from the middle of the morning shift to the end of the first half of the night shift to ensure adherence to the study objectives. The nurses were aware that their injectable preparation task was being observed and therefore all were consenting participants. This may have affected their performance, as they might not behave in the same way when not being observed. However, before the observations began, clear instructions were given to the nurses about working in their normal way, and they were familiarised with the significance of this research, so as to undertake the task on that basis.

Another limitation of the study was that the observation studies were carried out over a limited time frame: 10 days for each ward. However, this proved sufficient time to observe errors made during medicine preparation, and ten days is a common time frame for this kind of investigation to limit observer fatigue. Also, the sample size was sufficient to confirm an association between nurses' preparations and occurrence of errors (see section 5.8.1).

Another limitation of the study is that some selection bias with those nurses who agreed to participate and observed differing from those who did not (i.e. those nurses more

confident in their skills more likely to give consent –therefore leading to lower error rate than population rate). However, the effect of the selection bias may not be great in this study as all the nurses observed agreed to participate in the present study.

A final limitation of the study was that there was no mechanism to establish whether the nurses were aware they had made IPEs, or if they learnt from their mistakes.

Despite these limitations, this study produced valuable data, allowing conclusions to be drawn.

5.10 Conclusion

The observation method is valid for use with nurses on both surgical and medical wards. The observational approach to medication preparation practice revealed a high rate of IPEs in the hospital environment, consistent with other UK studies. The results of this study show no significant difference in the IPEs rate between four wards; there were however differences in the phase of the preparation process at which errors occurred. There were no differences between the severities of errors on the different wards; the majority of errors were ranked as being moderate to major. However, after accounting for error frequency, twelve types of errors were graded as posing extreme risk namely, two types of errors on surgical ward (S); three types of errors from medical ward (C), and nine types of errors from surgical ward (H) and medical ward (B). The chief errors witnessed were: gross disregard for clean/ uncluttered treatment room, faulty labelling, filter not used, breach of ANTT, wrong addition/mixing, unused gloves, and no double

check for the final product. Our findings indicate the significant role played by nurses in the safe preparation of injectable medicines.

These data therefore provides a significant tool for prioritising risk reduction strategies when preparing injectable medicines on the four wards, to enhance patient safety. In addition, the results from this study indicate a need to develop a set of safety measures to address key issues, such as the gross disregard for maintaining a clean/ uncluttered treatment room. In addition, the need to improve the systemic factors that cause IPEs, for example addressing the use of a filter needle when dealing with ampoules or offering ready-to-administer injections to minimise error potential. The findings of this study will contribute to the development of safety measures in the next section of this thesis.

Chapter Six

A Qualitative Study Investigating the Perspectives of Nurses Concerning the Factors Contributing to Injectable Medicine Preparation Errors in Hospital Wards

6.1 Introduction

Preparing injectable medicines is a fundamental skill required of many nurses. Sufficient clinical knowledge and adequate nursing skills are essential for ensuring a safe and high quality preparation practice. Furthermore, ensuring patient safety is a main role of nurses in clinical practice (Elliott and Liu, 2010). Appropriate preparation of injectable medicine accounts for a significant portion of a nurse's duties. Nurses spend more than a third of their time on activities associated with medicines (Keers et al., 2013), and it has been said that preparing injectable medicines is the most risky job a nurse undertakes (Beaney, 2010). Additionally, the nurse is the final individual who can confirm the injectable medicine has been correctly prescribed and prepared before it is administered (Davey et al., 2008; Beaney, 2010). Hence, nurses play a vital part in ensuring patient safety by avoiding harmful errors (Rothschild et al., 2006). In the absence of effective safeguards to avoid injectable medication preparation errors (IPEs), patients (and nurses) can be at a high risk during the medication preparation phase (Beaney, 2010). Hence, understanding the nature and causes of IPEs is important to develop more efficient defensive barriers and strategies to prevent errors during the preparation stage (Taxis and Barber, 2003; Wirtz et al., 2003; Taxis and Barber, 2004; Cousins et al., 2005; Westbrook et al., 2011; Keers et al., 2013).

The purpose of injectable medication preparation is to ensure that the correct drug and formulation is prepared at the correct time, in the correct dose, via the correct route, and administered to the correct patient (National Patient Safety Agency, 2007, Beaney, 2010; Royal College of Nursing, 2016; The Nursing and Midwifery Council, 2016). All UK hospitals are required to have an injectable medications standard policy that must contain injectable medicine preparation procedures that are in line with the Nursing and

Midwifery Council (NMC) code of conduct and Standards for Infusion Therapy (NPSA, 2007; Nursing and Midwifery Council 2016).

Healthcare staff who are involved in preparing injectable medicines in UK hospitals should have completed essential training and demonstrated the competencies required by the NHS Trust in relation to injectable medicines. Furthermore, a high level of training is required for some specific groups of injectable medicines (e.g. preparation of IV doses and chemotherapy drugs) (NMC, 2016).

Injectable medications must only be prepared according to clear and accurate written prescriptions provided by an authorised prescriber (Royal College of Nursing, 2016; NMC, 2016).

A small number of studies have investigated the causes of errors in the preparation of injectable medicines. Three studies (Taxis and Barber, 2003; Taxis and Barber, 2004; Crowley, 2006) focused on the causes of injectable medicine errors in UK and German hospitals, whereas other studies have placed greater focus on administration errors (Hartley and Dhillon, 1998; Bruce and Wong, 2001; Wirtz et al., 2003; Cousins et al., 2005). All studies used direct observation to investigate IV drug errors. Two studies (Taxis and Barber, 2003; Taxis and Barber, 2004) collected additional data through informal conversations with the nurses being observed, and then applied human error theory as a framework to analyse and categorise incidents in UK and German hospitals, respectively. One UK study (Taxis and Barber, 2003) reported complex or unclear design of equipment, such as unclear or complicated presentation of vials, and preparation procedures. Other less common factors found to contribute to IPEs in injectable doses involved unauthorised medication, and unclear prescriptions (Taxis and

Barber, 2003; Taxis and Barber, 2004); preparation of the wrong medicine; unacceptable cleaning technique; failure to follow aseptic non touch technique (ANTT); and expired medication, or unknown expiry date (Crowley, 2006; Ameer, 2015). Lack of knowledge about the preparation of injectable doses, including how to use infusion equipment, incorrect preparation technique (e.g. not using a filter needle; gross disregard for clean/aseptic technique during injectable medication preparation), and unclear procedures, instructions/guidelines, and manufacturer leaflets were other common causes of injectable errors (Taxis and Barber, 2003; Taxis and Barber, 2004). Taxis and Barber (2004) reported that, in a German hospital, nurses did not have adequate knowledge to safely prepare injectable medications, and that nurses were not evaluated appropriately on injectable drug preparation. In a UK hospital, lack of training, which focused mainly on the reconstitution stage (failing to fully reconstitute a product during preparation, or follow to the mixing instructions) also contributed to a lack of knowledge, and most nurses were not aware of the potential risk of such a practice (reconstitution process) (Taxis and Barber, 2003; Crowley, 2006; Ameer, 2015). Furthermore, in their study of the UK and Germany, Taxis and Barber (2003) reported that the lack of involvement of pharmacists during injectable preparation, and of a separate room or dedicated area for injectable drug preparation on hospital wards, were the main causes of error in injectable medicine preparation.

In terms of working environment, a lack of qualified nurses, insufficient skill mix, poor communication between nurses, and lack of staff, combined with the common factors of multitasking and distraction/interruption, have also been found to lead to errors in injectable preparation (Bruce and Wong, 2001; Taxis and Barber, 2003; Taxis and Barber, 2004; Crowley, 2006; Keers et al, 2015).

6.2 Methods to determine the causes of IPEs

Several investigation approaches have been utilised to collect data on the causes of IPEs, including quantitative self-completion questionnaires, qualitative interviews, focus groups, and direct observation (Osborne et al., 1999; Crowley, 2006; Ulanimo et al., 2007, Cohen and Shastay, 2008; Jones and Treiber, 2010; Ameer, 2015). A limited number of nurses used daily notebooks (i.e. a book in which nurses record details and incidents relating to errors in preparing injectable) (Ameer, 2015). Limited investigates have employed a mixed approach, although Crowley (2006) conducted a focus group followed by face-to-face interviews and Ameer (2015) collected data using three different methods: incidents reports, questionnaires, and semi-structured interviews with staff who had been involved in medication errors. Some investigative studies reported data corresponding to Reason's (1990) categorisation of active failures to determine the main cause of IPEs (Taxis and Barber, 2003; Taxis and Barber 2004; Crowley, 2006; Ozkan et al., 2011; Ameer, 2015). These studies mainly reported slips, lapses, mistakes, and violations. While there were some differences between the studies in terms of the approaches used, the most common contributing factors classified in the studies were similar. However, studies varied in the level of detail they provided. For example, studies which relied on interviews (with or without observation), focus groups, or self-report methods enabling free text responses were able to provide detailed information about the different causes of IPEs. In some cases, the studies related the causal factors to specific IPEs (e.g., incorrect dose); however, others relied on structured methods, such as short answer surveys/questionnaires (Tang et al., 2007; Jones and Treiber, 2010), and others used direct observation methods alone (Tissot et al., 2003) - these provided less detailed information.

In 1954, Flanagan was used the critical incident technique as a method to investigate and analyse causes of incidents that led to an adverse event. This qualitative and retrospective method requires the collection of data about behaviours from the staff involved in relevant incidents in the form of a written statement, interviews, and questionnaires. The critical incident technique is considered to be a valid method of collecting and analysing data on adverse event (Vincent, 2003). Nevertheless, a key weakness of this method is that the collected information relies on participants' memories, which can be influenced by hindsight bias (Flanagan, 1954; Keers et al., 2013). As such, the observational technique used by Tissot et al. (2003) may be more valid and reliable approach to collecting data about the causes of MEs, as it maintains a distance from the opinions of individuals directly involved in the errors, assuming that there is no influence of researcher opinion (Keers et al., 2013). In addition, using an observational method, the researcher can classify deviations from standard procedure that the staff missed. But, a weakness of research using direct observation only, for example that by Tissot et al. (2003), is that the researcher may be incapable to explore the causes that led to an individual's error. Hence, a number of investigations have merged observational approaches with interviews (Crowley, 2006; Chua et al., 2009; Ozkan et al., 2011; Ameer, 2015) or informal conversations with the nurses involved (Taxis and Barber 2003; Taxis and Barber 2004) to establish error causation. The key strength of such studies is that collecting data using two methods can help to link the causes of mistakes that the researcher would be incapable of noticing alone, with those causes that would not be known by the individual who made the error (Keers et al., 2013). Furthermore, this mixed method approach can resolve contradictions between actions that the staff report they have undertaken, and those that they actually undertake in practice (Mays and Pope, 1995; Keers et al., 2013).

In investigations that conducted self-completed questionnaires, although some included an already prepared list of contributory factors for participants to choose from (Deans, 2005; Tang et al., 2007), others only used open-ended questions (Jones and Treiber, 2010). Ready prepared lists can be considered a weakness, as the list of factors contributing to IPEs provided to nurses may not include sufficiently detailed information, or all likely causes.

In conclusion, numerous studies have investigated the causes of medication errors in general, and a few with a focus on IPEs. Various approaches have been used by studies to collect data on this issue. While these studies differed in their approaches, hospital settings, drug distribution systems, and the description of errors studied, factors such as the quality of prescriptions, distraction and interruption, lack of staff, workload, length and type of shift, and lack of nurse training and knowledge were reported in almost all studies. Some contributing factors differed depending on the study setting and computer system used in the hospitals.

6.3 Significance of the research

A few studies, particularly in the UK, have focused on the causes of IPEs, and studied the views and opinions of nurses via qualitative interviews to gain insight into nurses' understanding of the issue. Moreover, numerous modifications have recently been implemented in the UK hospitals. These modifications include increasing the shift lengths to 12 hours, and running automated dispensing cupboards on hospital wards. Furthermore, the NHS Trust has recently employed numerous nurses, especially within surgical and medical wards, thus, at the time of this study, there were many junior and

inexperienced nurses working in the NHS Trust. These modifications in environment and staffing may have an influence on medication safety, particularly in regard to medication preparation.

This chapter employs interviews and questionnaires to examine the underlying causes of a number of errors reported in the observational study, by gathering views of the nurses involved. It also establishes nurses' opinions on how such errors can be minimised, in order to develop preventative strategies.

The analysis in the present study is more robust and more clearly linked with human error theory than previous research. Earlier studies addressing injectable medicine preparation errors have focused on quantifying the problem (Wirtz et al., 2003; Taxis and Barber; 2003; Cousins et al., 2005; Crowley, 2006; Dehmel et al., 2011). Yet, in order to effectively reduce injectable drug preparation errors, a deeper understanding of how and why errors occur is required (Leape, 1994). To that end, the NPSA has adopted a systems approach to safety, within which applying a human error or human factors approach to understanding and analysing error incidence is appropriate (NPSA, 2003). In this context, human factors are defined as: "An applied science of system design that assesses human strength and compensates for human limitation" (Schneider, 2002, p. 1156). The analysis of the current study focuses on active failures that led to injectable medicine preparation errors, and also further explores the local task-based, team-based, and individual factors, as well as working environment, and organisational factors present when the error occurred and which might have contributed to causing the error.

6.4 Aims and Objectives

The aim of this investigation is suggestions ways to reduce the IPEs in hospital wards. The objectives are the following points:

- Determine the causes of errors observed during the preparation of injectable medicines from the hospital wards by nurses.
- Develop strategies for reducing the risk of such errors reoccurring.

6.5 Methodology and study design

6.5.1 Overview

In this study, a combination of interviews and questionnaires were used because in the pharmacy aseptic units the study did not find many staff happy to do an interview, so the study required a second way of collecting data to try to get more information. There are numerous different techniques that can be utilised to collect qualitative data; however, the three main approaches are interviews, focus groups, and questionnaires (Arhinful et al., 1996; Creswell, 2013; Trochim et al., 2015) (see Section 2.7). The present study applied a qualitative face-to-face semi-structured interview and self-completed questionnaire. The self-complete questionnaire technique is cheaper than other approaches, and the survey can potentially be distributed to large numbers of participants at different sites (Creswell, 2103). Furthermore, it can preserve anonymity, enabling the participants to feel relaxed and able to provide honest responses regarding workplace factors (Constantinos et al., 2011). Self-complete questionnaires must be well designed and clear to the participants; thus questions must be simple and easy to understand, as no interviewer will be available to assist the participants (Phellas et al.,

2011). Self-complete questionnaires can include three types of questions: (1) open-ended questions; (2) closed-ended questions; and (3) a mixture of closed-ended and open-ended questions (Kane, 2004). The present study used a questionnaire consisting of a mix of closed- and open-ended questions (Appendix 17). As shown in Table 6.1, Creswell (2013) has summarised the main advantages and disadvantages of mixing closed- and open-ended questions in a questionnaire. The use of this method in the present study enabled a greater understanding of the views of nurses concerning the factors contributing to IPEs.

In addition, qualitative interviews were used to collect data, as they combine structure with flexibility, which enables topics to be presented and discussed in the most appropriate order (see Section 2.7). Moreover, the nature of interviews allows data to be generated through communication between the interviewer and interviewee. The ability of the interviewer to utilise different investigations, prompts, and other techniques to elicit in-depth answers and fully explore the issue under study is another feature of interviews (Creswell, 2013). Semi-structured interviews consist of open-ended questions that relate to the research topic under investigation. While these questions are pre-defined, they still offer opportunities for both the interviewer and interviewee to discuss particular topics in further detail (Ritchie and Lewis, 2003). The use of semi-structured interviews and self-completed questionnaires in the present study allowed the researcher to collect more robust data and maintain a focus on the views and opinions of nurses concerning the factors contributing to IPEs.

Table 6.1: Advantages and disadvantages of the mixture of close- and open-ended questions approach (Adapted from Creswell, 2013).

	Advantage	Disadvantage
Self-completion questionnaire close- and open-ended questions	Inexpensive. This means they can provide large amounts of research data for relatively low costs.	Time consuming to collect the data. It takes longer for the respondent to complete open questions. This is a problem as a smaller sample size may be obtained.
	The data can be quickly obtained as closed questions are easy to answer (usually just ticking a box).	Time consuming to analyse the data. It takes longer for the researcher to analyse qualitative data as they have to read the answers and try to put them into categories by coding, which is often subjective and difficult.
	The questions are standardised. All respondents are asked exactly the same questions in the same order. This means a questionnaire can be replicated easily to check for reliability. Therefore, a second researcher can use the questionnaire to check that the results are consistent.	
	Allow individuals to express what they think in their own words.	
	Used for complex questions that cannot be answered in a few simple categories but require more detail and discussion.	

6.5.2 Development of the questionnaire

Developing the questionnaire was a significant part of the research study. Targeted responses from participants can be acquired only if a questionnaire is structured well, taking into account important factors such as the reliability and validity of the information obtained. Hague (2006) has provided guidelines outlining seven phases of the questionnaire design process, which are the following: (1) determine what data is required; (2) build a significant list of questions; (3) improve the question terminology; (4) develop the response format; (5) place the questions into a suitable order; (6) finalise the design of the questionnaire; (7) pre-test and review the questionnaire.

For the present study, a mixture of closed- and open-ended questions were included in the questionnaire design, in order to meet the study objectives (Appendix 17). All questions were formulated after studying results obtained from the aseptic study and reviewing published literature. Furthermore, previously published studies (Vincent et al., 2000; Woloshynowych et al., 2005) were referred to when formulating the questions. The focus of the questions included in the questionnaire was on exploring the perceptions of the injectable medicines preparation teams regarding the factors that contribute to a specific IPEs observed, and how to prevent these errors. Completing the questionnaire required approximately ten minutes. The questionnaire contained three main parts, as follows:

- **Part One:** Questions about the error observed and the circumstances that the nurse believed lead to the error.
- **Part Two:** Questions about the factors contributing to the error, and how to reduce the risk of this error occurring again.
- **Part Three:** Demographics: questions requesting information about the participant's current job grade, contract type, area of work, years of experience in the current trust, employment status, and number of injectable medicines prepared each day.

6.5.3 Reliability and validity

Reliability refers to the level to which data, measures, and processes are consistent and repeatable. In the current study, the questions were subject to an internal review by the supervisory team (Dr. Julie Letchford; Dr. Lynette James) to ensure the feasibility and reasonability of the questionnaire items. To ensure the reliability, the questionnaire was

piloted among nursing staff (n=5) at the Royal United Hospital in Bath. In this pilot study, participants indicated a good understanding of the questions.

6.5.4 Development of the interview schedule

A semi-structured, face-to-face interview model was developed in order to guide the interviews so that the researcher was able to collect significant data regarding the factors contributing to medication preparation errors based on the framework of factors influencing clinical practice developed by Vincent et al. (2000) (see Section 4.4.2). The interview schedule was reviewed by Dr. Lynette James, a Consultant Pharmacist - Acute Care and Medication Safety (All Wales) in Cardiff and Vale University Health Board (University Hospital of Wales). A simulation of the interview was conducted at the University of Bath in April 2016, with supervisors Dr. Julie Letchford and Dr. Matthew Jones, resulting in the final interview schedule (Appendix 18).

The interview schedule was divided into three main parts (see Appendix 18). In the first part, participants were asked to provide brief information about the circumstances that led to the specific error that they were responsible for, and were asked to describe the steps they took when preparing the product concerned. The second part focused on the perceptions of the participant regarding different factors contributing to the specific IPEs observed, based on the following classifications: task environment; error-producing conditions; individual factors; team factors; patient factors; and organisational factors (Vincent et al., 2000). The third part consisted of one general question asking participants how, in practice, they avoid these contributing factors. In each part of the interview, additional brief questions were asked to elicit further

explanation and justifications where required. Furthermore, questions raised by the participant were discussed and participants asked for any explanations needed.

6.5.5 Study setting

The present study was conducted in a range of hospital wards at two UK hospitals (see Section 5.5.2). The two hospital trusts provide a full range of hospital services for the local community, as well as specialist services for many medical and surgery specialisms including cancer, cardiothoracic surgery, women's and children's services, kidney care, and orthopaedics. Registered nurses are responsible for preparing all injectable medicines before administering them to patients. In addition, the pharmacy department prepares some high-risk medicines, such as chemotherapy drugs, which are available ‘ready to use’ from the pharmacy unit.

6.5.6 Study participants

All nurses were informed about the study and invited to participate before recruitment began; this was intended to increase awareness about the study and also to provide an opportunity for prospective participants to ask any questions or request further information about the study. This was achieved using copies of the study protocol and a participant information leaflet. Furthermore, information about the study was sent by ward managers via group emails to all nurses to inform them about the study and to invite them to participate. This invitation email provided brief information about the study, including the goal, approvals obtained, eligible participants, what participation would involve, and what to do if they were willing to take part. In addition, a copy of the invitation letter, study protocol, and participant information leaflet were attached to

the email. Qualitative studies typically rely on small samples, because they are intended to collect detailed data, though they are relatively time consuming (Tuckett, 2004; Richards, 2009). Depending on the research objectives, it is generally accepted that between 9 to 12 participants is sufficient for this method (Dean et al., 2002; Guest et al., 2013; Hennink et al., 2017), and was deemed to be adequate for the present qualitative study. All the nurses who had made a medication error were first invited for interview and then asked to complete a questionnaire. At the first site (pharmacy environment), the interview offer was made on a voluntary basis, but this resulted in a limited number of results and so at the second site, nurses were offered a financial incentive to participate in the interviews and complete the questionnaire. In both cases nurses who did not wish to be interviewed were still invited to complete the questionnaire; those who agreed to be interviewed and completed a questionnaire discussed their questionnaire responses in the interview. Those who were willing to take part in the study were provided with a participant information leaflet and consent form (see Appendix 14) and were required to provide their written informed consent (see Appendix 15) prior to being interviewed. Nurses' participation in the interviews and/or questionnaire was entirely voluntary and participants were able to withdraw from the study at any point up to the date of the study report, which was stated as 9th January 2017, without giving any reason. During the interviews, no upsetting, embarrassing, or sensitive subjects were discussed. Furthermore, nurses were free to refuse to answer any question they were asked during the interview. Hence, it was unlikely that any nurses would encounter any discomfort or harm during the interviews. In addition, the interviews were confidential and any personal information detected during the course of the research was anonymised by the researcher. The researcher (AA) clarified to nurses that information used for the study would not be associated with specific nurses.

At the end of the interview, the contact details of study team members were provided in all research documents and study communication (emails) in case nurses had any questions or desired any further information.

6.5.7 Ethical approval

Ethical approval for this study was obtained in accordance with the Research Ethics Procedure of the University of Bath's (see Section 5.6.4).

6.5.8 Data collection

Interviews and questionnaires with nurses were conducted between September and November 2016. All interviews and questionnaire completion took place in a quiet room on the ward on which the nurses worked. Nursing staff who made an error while being observed by the researcher were invited to an interview first then complete a questionnaire within 48 hours of the error's documentation. A semi-structured, face-to-face interview model was conducted, using a topic guide. At the beginning of each interview, the investigator provided general and brief information about the study and the nature of the questions that would be asked. The participant was asked to verbally confirm that they had read the information leaflet and that they had read and signed the consent form. Each interview lasted approximately 10 to 15 minutes. With the consent of participants, interviews were audio-recorded and transcribed verbatim. A questionnaire was also given to the relevant nurse after each interview, which took approximately 10 minutes to complete it. Respondents were asked to return their completed questionnaires to the researcher, or to an agreed location in their hospital ward within 48 hours of the occurrence of the error.

On receipt of the completed questionnaires, the nurses received a £5 gift voucher of their choice, and a £10 gift voucher upon completion of the interview. The vouchers only given at site two of the study, based on experience of poor uptake of interviews at site one. All data collected from the interviews and questionnaires was anonymised prior to data analysis to prevent the disclosure of information in any research report that could be linked to individual participants.

6.5.9 Data storage

To guarantee privacy and security of all study data, electronic data files were saved on a password locked and encrypted USB drive. All study data relating to the final interview transcripts, questionnaires, consent forms, and all USB drives that were used to store electronic files were stored in a locked filing cabinet the University of Bath. Audio recordings were destroyed at the end of the study. Each participant was given a reference number, which was used during the study and stored separately from their contact details. Only members of the study team had access to this data.

6.5.10 Data analysis

All anonymised transcribed interviews and questionnaires were subjected to thematic analysis (Gale et al., 2013; Vaismoradi et al., 2013) (see Sections 2.7.2 & 2.7.3). Thematic analysis is a qualitative descriptive method of data analysis, and one, which is used often, used in qualitative research of nursing practices (Vaismoradi et al., 2013). The use of this form of qualitative descriptive analysis was deemed appropriate for the current investigation, as it requires a relatively low level of interpretation, in contrast to grounded theory, where higher level of interpretive complexity is needed (Vaismoradi

et al., 2013). Framework analysis is commonly used to thematically analyse semi-structured interview transcripts and completed questionnaires (Gale et al., 2013).

Interview transcripts and questionnaires were analysed manually (see Section 2.7.4), and validated by the supervisors (JL; MJ; LJ) who checked the key researcher's coding and confirmed results; any discrepancies were discussed and resolved.

6.6 Results

6.6.1 Participants' demographic data for questionnaires and interviews data

1) Questionnaires data

The researcher distributed 62 questionnaires to hospital nurses in relation to 62 injectable preparation errors committed on four wards at two participating sites. Fifty completed questionnaires were collected. Fifteen questionnaires were distributed on the surgical ward (S); 12 on the medical ward (C); 21 on the second surgical ward (H); and 14 on the second medical ward (B). In total, 50 completed questionnaires were returned, containing information regarding 50 injectable preparation errors. Sixteen junior nurses (surgical ward (S): n=8, medical ward (C): n=8), five senior nurses (surgical ward (S): n=3, medical ward (C): n=2), 26 junior nurses (surgical ward (H): n=13, medical ward (B): n=13), and three senior nurses (surgical ward (H): n=2, medical ward (B): n=1) completed questionnaires; two errors were committed by one nurse on the medical ward (C).

Nurses' demographic characteristics are shown in Table 6.2, and a summary of the observed error associated with each questionnaire returned from the four wards in Table 6.3. The number of participants from the surgical ward (S) (n=11) was similar to that from the medical ward (C) (n=10), and the number of questionnaire responses from the surgical ward (H) (n=17) was similar to those from the medical ward (C) (n=12). The mean length of participants' experience as registered nurses was 9.7 years (range: 6 months –31 years). Their total years of hospital experience ranged from 1 to 33 years. Most participants were full-time employees and had permanent contracts (86%), though some (14%) were part-time employees or had either a bank or an agency staff contract. The average number of IV doses prepared each day was nine (range: 1 dose - 20 doses).

Table 6.2. Questionnaire respondents' (n = 50) demographic data.

Characteristics	Surgical ward (S) (*n*=11)	Medical ward (C) (*n*=10)	Surgical ward (H) (*n*=17)	Medical ward (B) (*n*=12)
Gender				
Woman	11 (100 %)	3 (30%)	15 (88%)	5 (42%)
Man	0 (0%)	7(70%)	2 (12%)	7 (58%)
Hospital employment				
Full-time	9 (82%)	9 (90%)	17 (100%)	12 (100%)
Part-time	2 (18%)	1 (11%)	0 (0%)	0 (0%)
Contract type				
Permanent	10 (91%)	8 (80%)	17 (100%)	12 (100%)
Bank staff	0 (0%)	2 (20%)	0 (0%)	0 (0%)
Agency staff	1 (9%)	0 (0%)	0 (0%)	0 (0%)
Agenda for change band				
Band 5	8 (73%)	8 (80%)	15 (88%)	11 (92%)
Band 6	3 (17%)	2 (20%)	2 (12%)	1 (8%)
Years of post-registration experience				
<1	1 (9%)	0 (0%)	7 (41%)	0 (0%)
1–10	8 (73%)	8 (80%)	6 (35%)	10 (84%)
10–20	0 (0%)	0 (0%)	2 (12%)	1 (8%)
20–30	1 (9%)	2 (20%)	2 (12%)	1 (8%)
>30	1 (9%)	0 (0%)	0 (0%)	0 (0%)
Average number of doses prepared each day				
<5	1 (9%)	0 (0%)	0 (0%)	0 (0%)
5–10	8 (73%)	9 (90%)	11 (65%)	7 (58%)
10–20	2(18%)	1 (10%)	6 (35%)	5 (42%)

Table 6.3: A summary of the observed error related to each questionnaire returned from the four different hospital wards (n=50)

Ref	Gender	Job title	Type of error and description	Ward	Risk score
S7	Female	Senior nurse	Gross disregard for clean/ uncluttered treatment room.	Surgical (S)	Extreme risk
S1	Female	Junior nurse	Unused apron: A plastic apron was not worn during preparation.	Surgical (S)	High risk
S4	Female	Junior nurse	Unused apron: A plastic apron was not worn during preparation.	Surgical (S)	High risk
S19	Female	Junior nurse	No double check: a second nurse did not check the dose prepared by the first nurse.	Surgical (S)	High risk
S23	Female	Senior nurse	Wrong dose: Leakage from ampoule /vial / syringe resulted in the dose being reduced by more than 10%	Surgical (S)	High risk
S34	Female	Senior nurse	Wrong dose: Leakage from ampoule /vial / syringe resulted in the dose being reduced by more than 10%	Surgical (S)	High risk
S24	Female	Junior nurse	Omitted medicine: Dose not prepared, omission not documented.	Surgical (S)	High risk
S28	Female	Junior nurse	Breach of ANTT: Deficient in performing infection control after break in ANTT (not used a plastic tray during preparation).	Surgical (S)	High risk
S29	Female	Junior nurse	Unused apron and gloves: A plastic apron and gloves were not worn during preparation.	Surgical (S)	High risk
S35	Female	Junior nurse	Wrong medicine selected: Co-amoxiclav 1.2g instead of amoxicillin 1 g.	Surgical (S)	High risk
S43	Female	Junior nurse	Faulty labelling: Physician changed dose after being made up. Additional 200 mg added to infusion but label not changed.	Surgical (S)	High risk
C50	Male	Junior nurse	No double check: a second nurse did not check the dose prepared by the first nurse.	Medical (C)	Extreme risk
C51	Male	Senior nurse	No double check: a second nurse did not check the dose prepared by the first nurse.	Medical (C)	Extreme risk
C62	Male	Junior nurse	Incorrect addition or mixing: drug was strongly shaken, causing foam/bubbles.	Medical (C)	Extreme risk
C63	Male	Junior nurse	Incorrect addition or mixing: drug was strongly shaken, causing foam/bubbles.	Medical (C)	Extreme risk
C64	Male	Junior nurse	Incorrect addition or mixing: drug was strongly shaken, causing foam/bubbles.	Medical (C)	Extreme risk
C65[★]	Female	Junior nurse	Gross disregard for clean/uncluttered treatment room.	Medical (C)	Extreme risk
C65	Female	Junior nurse	No double check: a second nurse did not check the dose prepared by the first nurse.	Medical (C)	Extreme risk
C22	Female	Senior nurse	Incorrect expiry date: the final product expired: out of date drug delivered to ward due to error in logging expiry date in fridge record.	Medical (C)	High risk
C30	Female	Junior nurse	Incorrect expiry date: the final product expired: out of date drug delivered to ward due to error in logging expiry date in fridge record.	Medical (C)	High risk
C59	Female	Junior nurse	Wrong medicine: a 1.2g dose of the antibiotic co-amoxiclav was prepared as an I.V. bolus injection instead of 1 g of amoxicillin.	Medical (C)	High risk
H183[★]	Female	Junior nurse	Deficient in performing infection control after break in ANTT: Staff nurse not using a plastic tray to prepare IV medications.	Surgical (H)	Extreme risk
H183	Female	Junior nurse	Unused apron/gloves: A plastic apron/gloves were not worn during preparation	Surgical (H)	Extreme risk
H188	Male	Senior nurse	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Surgical (H)	Extreme risk

[▯]Two errors within one drug observation

Continued Table 6.3

Ref	Gender	Job title	Type of error	Ward	Risk score
H189	Female	Junior nurse	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Surgical (H)	Extreme risk
H190	Female	Junior nurse	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Surgical (H)	Extreme risk
H195	Male	Junior nurse	Unused apron/gloves: A plastic apron/gloves were not worn during preparation	Surgical (H)	Extreme risk
H207	Female	Junior nurse	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Surgical (H)	Extreme risk
H219	Female	Junior nurse	Unused apron/gloves: A plastic apron/gloves were not worn during preparation	Surgical (H)	Extreme risk
H221	Female	Junior nurse	Unused apron/gloves: A plastic apron/gloves were not worn during preparation.	Surgical (H)	Extreme risk
H225	Female	Junior nurse	Filter needle not used whilst making product packaged in a glass ampoule.	Medical (H)	Extreme risk
H237	Female	Junior nurse	Filter needle not used whilst making product packaged in a glass ampoule.	Medical (H)	Extreme risk
H240	Female	Junior nurse	Filter needle not used whilst making product packaged in a glass ampoule.	Medical (H)	Extreme risk
H243	Female	Junior nurse	Filter needle not used whilst making product packaged in a glass ampoule.	Medical (H)	Extreme risk
H247	Female	Junior nurse	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Medical (H)	Extreme risk
H251	Female	Junior nurse	Unused apron/gloves: A plastic apron/gloves were not worn during preparation.	Surgical (H)	Extreme risk
H246	Female	Junior nurse	Wrong dose: leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10% .	Medical (H)	High risk
H249	Female	Senior nurse	Unused apron: A plastic apron was not worn during preparation.	Surgical (H)	High risk
B86	Male	Junior nurse	Preparing product outside treatment room in unsuitable location such as nurse reception	Medical (B)	Extreme risk
B96	Female	Junior nurse	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Medical (B)	Extreme risk
B101	Female	Junior nurse	Incorrect additions or mixing: drug was strongly shaken, causing foam/bubbles.	Medical (B)	Extreme risk
B103	Male	Junior nurse	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Medical (B)	Extreme risk
B118	Male	Junior nurse	Preparing product outside treatment room in unsuitable location such as nurse reception	Medical (B)	Extreme risk
B120	Male	Junior nurse	Gross disregard for clean/ uncluttered treatment room.	Medical (B)	Extreme risk
B126	Male	Junior nurse	Unused apron/gloves: A plastic apron/gloves were not worn during preparation.	Surgical (B)	Extreme risk
B180	Female	Junior nurse	Preparing product outside treatment room in unsuitable location such as nurse reception.	Medical (B)	Extreme risk
B249	Female	Senior nurse	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Medical (B)	Extreme risk
B89	Male	Junior nurse	Unused apron: A plastic apron was not worn during preparation.	Medical (B)	High risk
B90	Male	Junior nurse	Unused apron: A plastic apron was not worn during preparation.	Medical (B)	High risk
B153	Female	Junior nurse	Omitted medicine: dose not prepared, omission not documented.	Surgical (B)	High risk

It can be noted from Table 6.3 that questionnaires were obtained for a variety of different errors previously categorised as extreme risk (64%, n=32/50) or high risk (36%, n=18/50). A summary of the observed error graded as extreme risk from the four wards in Table 6.4.

Table 6.4: A summary of the observed error graded as extreme risk from the four different hospital wards (n=32).

Ward	Number of errors graded as extreme risk	Types of errors graded as extreme risk	Number of questionnaires associated with extreme risk errors
S	9	Messy room (n=7)	1
		Wrong diluent (n=2)	None
C	26	Air bubbles (n=9)	3
		No double check (n=8)	3
		Messy room (n=9)	1
H	114	Faulty labelling (n = 26)	5
		Gloves not used (n = 16)	5
		Filter needle not used (n = 21)	4
		Breach of ANTT (n = 16)	1
		Messy room (n=17)	None
		Undissolved powder left in vial (n = 9)	None
		Inappropriate location of medicine preparation (n = 6)	None
		Incorrect diluent (n=2)	None
		Calculation error (n=1)	None
B	121	Inappropriate location of medicine preparation (n = 20)	3
		Faulty labelling (n = 19)	3
		Messy room (n=17)	1
		Gloves not used (n = 9)	1
		Air bubbles (n=5)	1
		Filter needle not used (n = 20)	None
		Breach of ANTT (n = 18)	None
		Rubber septum not wiped (n = 8)	None
		Undissolved powder left in vial (n = 0)	None

It can be illustrated from Table 6.4 that the current study has questionnaire data for a good number of different types of error previously graded as extreme risk. This data can be used to help design error reducing strategies for the majority of extreme risk errors, which may also impact on some of the other errors identified. The participants ticked boxes to indicate which factors they considered to have contributed to the error (i.e. error producing conditions and latent failures), and then completed free text responses to describe the errors in more detail and propose barriers and defences against their recurrence.

2) Interview Data

The researcher conducted 12 interviews with staff in relation to 12 injectable preparation errors that occurred on two wards at one site. A summary of interviewees' is presented in Table 6.5. Seven interviews were conducted in the surgical ward (H), and five in the medical ward (B). Seven junior nurses (medical ward (B) n=2, surgical ward (H) n=5) and five senior nurses (medical ward (B) n=3, surgical ward (H) n=2) were interviewed; two of the errors were made by the same individual in the surgical ward (H). Interview transcripts were coded drawing on Human Error Theory.

Table 6.5: A summary of interviewees conducted on surgical ward (S) and medical ward (H) (n=12)

Ref	Gender	Job title	Type of error	Ward	Risk score
H183[1]	Female	Junior nurse	1. Unused aprons/gloves: A plastic apron/gloves were not worn during preparation. 2. Breach of ANTT: Deficient in performing infection control after break in ANTT (not used a plastic tray during preparation).	Surgical (H)	Extreme risk
H187	Female	Senior nurse	Faulty labelling: Nurse prepared IV antibiotic drug (Tazocin 4.5g), placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Surgical (H)	Extreme risk
H225	Female	Junior nurse	Filter needle not used: whilst making product packaged in a glass ampoule (Cyclizine 50mg).	Surgical (H)	Extreme risk
H226	Female	Senior nurse	Filter needle not used: whilst making product packaged in a glass ampoule (Cyclizine 50mg and morphine sulphate).	Surgical (H)	Extreme risk
H259	Female	Junior nurse	Calculation error: Incorrect dose of drug due to wrong calculation of volume needed: prepared 8.6 ml instead of 11.6 ml dose needed.	Surgical (H)	Extreme risk
H245	Female	Junior nurse	Wrong dose: Leakage from syringe resulted in the dose being reduced by more than 10%	Surgical (H)	High risk
B86	Male	Senior nurse	Inappropriate location of medicine preparation: Preparing product outside treatment room in unsuitable location such as nurse reception	Medical (B)	Extreme risk
B92	Female	Senior nurse	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	Medical (B)	Extreme risk
B106	Female	Senior nurse	Faulty labelling: Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	Medical (B)	Extreme risk
B144	Female	Junior nurse	Unused aprons/gloves: A plastic apron/gloves were not worn during preparation.	Medical (B)	Extreme risk
B148	Male	Junior nurse	Wrong medicine selected: co-amoxiclav 1.2 g in100 ml instead of amoxicillin 1 g in 100 ml.	Medical (B)	High risk

[1] Two errors within one drug observation.

In total, 114 errors classified as presenting an extreme risk were detected in the surgical ward H (see Table 6.5). Interview data was obtained for six of these errors. These were filter needle not used (n=2); apron/gloves not used (n=1); faulty labelling (n=1); calculation error (n=1); and, breach of ANTT (n=1). For ward B there were 121 errors classified as extreme risk (see Table 6.7). Interview data was obtained for four of these errors. These were faulty labelling (n=1); inappropriate location of medicine preparation (n=1); apron/gloves not used (n=1); breach of ANTT (n=1).

This data can be used to develop some error reducing strategies for the majority of extreme risk errors, which may also relate to some of other errors identified. Unfortunately, it was not possible to interview participants working on wards S and C; because the pharmacy staff were very busy during the current study however, the questionnaires completed by nurses on these wards do give some insight into the causes of errors in these settings consider how to avoid them reoccurring in the future.

6.6.3 Active failures for Causes of IPEs from questionnaires and interviews

In Human Error Theory, active failures are defined as unsafe acts that have an immediate adverse consequence (Vincent et al., 1998). In this study, 50 active failures were observed whilst coding open text questionnaire responses: 25 knowledge- or rule-based mistakes associated with a lack of education or training or poor practice; 12 violations that ignored polices; 11 lapses; and, 2 slips. Interview data were obtained for twelve active failures, classified as six knowledge/rule-based mistakes, four lapses, one slip, and one violation that ignored polices. Range of Knowledge- or rule-based mistakes and poor practice were reported by participants. The underlying causes are summarising in Table 6.6.

Table 6.6: Causes of knowledge- or rule-based mistakes and poor practice made at four hospital wards in two sites study.

Type of error	Number of questionnaires	Number of interviews	Example quote
Faulty labelling	7	1	"Dose was changed by F1 after being made up. Additional 200mg added to infusion but label not changed before leaving treatment room. Not actual error - dose correct but label still said old dose." [S43] **(From questionnaire).**
Incorrect addition or mixing	5	None	"Preparation was initially withdrawn up with bubbles in the syringe. It was the first time that I had to prepare this blood product. I was corrected by a colleague more familiar with the drug." [C62] **(From questionnaire).**
Not wearing an apron or gloves during injectable preparation	3	1	"I wasn't aware that we had to wear gloves or an apron. I thought it was just your own preference if you wanted to wear gloves- you know." [H183] **(From interview).**
Wrong dose	3	1	"I didn't realise you weren't meant to put [two syringes into one] into one so …but that's probably a mistake on my part." [H245] **(From interview).**
Breach ANTT	2	1	"Incomplete knowledge and still learning as newly qualified. I put the syringe down and the needle attached [onto a] surface to ask for a second signature." [S28] **(From questionnaire).**
Incorrect expiry date	2	None	"Chemo expiry date. It was not a mistake as it was spotted and reached pre going the chemo to the patient." [C22] **(From questionnaire).**
Failing to use a filter needle	1	1	"I used a green needle to filter up cyclizine instead of the pink filter needle [lack of knowledge about pink needles] that was available." [H226] **(From interview).**
Unclean or cluttered treatment room	1	None	"This was a usual amount of clutter for this environment. This not a mistake." [C65] **(From questionnaire).**
Incorrect calculation	None	1	"Umm, so I was asked to prepare an aminophylline intravenous infusion- umm, which I had never done before, and the nurses on the ward had never prepared that because it is not a respiratory ward it is a surgical ward so I was unfamiliar with the medication and I did not manage to do the calculation correctly [H259] **(From interview).**
Preparing product outside treatment room	1	None	"Not a mistake - patient has Hickman line so drugs need to be prepared inside room to decrease infection." [B180] **(From questionnaire).**

Several of violations came from deliberately ignoring the policies were stated by participants. The underlying causes are summarising in Table 6.7.

Table 6.7: Causes of violations came from deliberately ignoring the policies made at four hospital wards in two sites

Type of error	Number of questionnaires	Number of interviews	Example quote
Failing to use a filter needle	3	None	"I didn't use filter needle for withdrawing IV drugs." [H243] **(From questionnaire).**
Preparing product outside treatment room	2	1	"We can prepare IV medication because we don't have any closed room in this ward to prepare IV medication we have only small area which is all the other wards they do it in treatment room but in this ward because of a high workload umm…. we can prepare IV medication in the entrance of the ward, is located in front of the HDU department." [B86]**(From interview).**
Not wearing an apron or gloves during injectable preparation	2	None	"I didn't wear an apron and gloves when I was drawing up a saline flush." [H219] **(From questionnaire).**
Unclean or cluttered treatment room	2	None	"Work space was untidy. To tidy up messes that are not ours." [S7] **(From questionnaire).**
No double check	2	None	"I should have left the treatment room to find someone to perform a second check." [C50] **(From questionnaire).**
Faulty labelling	1	None	"I did not label a bolus of Tazocin." [H189] **(From questionnaire).**

Some of lapses (forgetting) were reported by participants. The underlying causes are summarising in Table 6.8.

Table 6.8: Causes of lapses (forgetting) made at four hospital wards in two sites

Type of error	Number of questionnaires	Number of interviews	Example quote
Forgetting to wear an apron or gloves during injectable preparation	7	1	"Started drawing up the antibiotic finished drawing up the antibiotic and then realised I'd forgotten gloves and apron." (B144).] **(From interview**
Dose delayed or omitted medicine	2	None	"I forgot IV drug dissolving in treatment room." [S24] **(From questionnaire).**
Forgetting to label IV bolus	1	1	""It slipped my mind since I have known that we're meant to label IV bolus…but obviously this one just slipped through the net." [H187] **(From interview**
Forgetting to use filter needle	None	1	"I didn't put a filter needle on as I was drawing it up I used an ordinary needle umm having just forgotten." [H225]**(From interview**
Breach ANTT	None	1	"So I might forget was supposed to clean the needle with alcohol wipes after needle touched the gloves or change the needle, so someone might forget to." [B92] **(From interview**
No double check	1	None	"Nurses are busy, and sometimes it is very difficult to find a person able to do a second check. If you have an increased volume of work, you can forget." [S19] **(From questionnaire).**

The slip involved selecting the wrong medicine from the shelves to prepare the final product was reported by participants. The underlying causes are summarising in Table 6.9.

Table 6.9: Causes of slip made at four hospital wards in two sites

Type of error	Number of questionnaires	Number of interviews	Example quote
Wrong medicine	2	1	"Instead of picking amoxicillin I picked co-amoxiclav" [B148] **(From interview** "Had co-amoxiclav in my head but realised it was meant to be amoxicillin." [S35] **(From questionnaire).**

6.6.4 Error-producing conditions (EPCs) for IPEs

1) Questionnaires data

In Human Error Theory, error-producing conditions are defined as situations that increase the probability of an error occurring (Vincent et al., 1998). Nurses were asked to select all the error-producing conditions present at the time of the mistake, from a pre-defined list. Five main themes and 33 codes for error-producing conditions were identified. The error-producing conditions identified from the questionnaire data are presented in Table 6.10. The most common error producing conditions were environmental factors related to high workload and a congested environment; and individual factors related to distractions, interruptions and haste. The least common causes of errors included: failure to follow policy, protocol, or procedure; failure to use ANTT; insufficient equipment (e.g., plastic tray/gloves); failure of equipment (e.g., drug preparation guidelines); inadequate verbal communication with colleagues; lack of support from colleagues; lack of supervision from senior staff; and, working alone.

Table 6.10: Error-producing conditions that contributed to injectable medicine preparation errors on participating wards

Theme	Code	Surgical ward (S) (*n* = 11)	Medical ward (C) (*n* = 10)	Surgical ward (H) (*n* = 17)	Medical ward (B) (*n* = 12)	Total (*n* = 50)
Environmental factors	High workload	7 (64%)	9 (90%)	9 (53%)	8 (67%)	33 (86%)
	Congested environment (inadequate space)	7 (64%)	4 (40%)	5 (29%)	5 (42%)	21(42%)
	Staff shortage	3 (27%)	3 (30%)	3 (18%)	4 (33%)	13 (26%)
	Poor layout of work environment	3 (27%)	0 (0%)	6 (35%)	3 (25%)	12 (24%)
	Noise	6 (55%)	0 (0%)	2 (12%)	2 (17%)	10 (20%)
	Insufficient rest breaks	1 (9%)	3 (30%)	2 (12%)	1 (8%)	7 (14%)
	Preparing multiple injections at the same time	0 (0%)	0 (0%)	3 (18%)	0 (0%)	3 (4%)
Individual factors	Distraction or interruption	8 (73%)	5 (50%)	5 (29%)	3 (25%)	21 (42%)
	Haste	8 (73%)	1 (10%)	4 (24%)	1 (8%)	14 (28%)
	Unfamiliar with policies or protocols	0 (0%)	3 (30%)	4 (24%)	1 (8%)	8 (16%)
	Lack of knowledge	2 (18%)	3 (10%)	2 (12%)	0 (0%)	7 (14%)
	Lack of experience	1 (9%)	3 (30%)	2 (12%)	0 (0%)	6 (12%)
	Stress	2 (18%)	0 (0%)	3 (18%)	1 (8%)	6 (12%)
	Fatigue	2 (18%)	3 (30%)	0 (0%)	0 (0%)	5 (10%)
	Inattention or absent-mindedness	2 (18%)	0 (0%)	1 (6%)	1 (8%)	4 (8%)
	Unfamiliar with environment	0 (0%)	0 (0%)	1 (6%)	1 (8%)	2 (4%)
Rule-based factors	Misunderstanding policy / protocol / procedure	0 (0%)	0 (0%)	5 (29%)	0 (0%)	5 (10%)
	Failure to use ANTT	2 (18%)	0 (0%)	1 (6%)	0 (0%)	3 (6%)
	Failure to follow policy, protocol, or procedure	1 (9%)	0 (0%)	1 (6%)	1 (8%)	3 (6%)
	Use of wrong policy or protocol	0 (0%)	0 (0%)	0 (0%)	1 (8%)	1 (2%)
Medicine-, equipment-, and material-related factors	Poor labelling	0 (0%)	2 (20%)	4 (24%)	0 (0%)	6 (12%)
	Lack of equipment (e.g. label for IV bolus, needle or syringe)	0 (0%)	0 (0%)	5 (29%)	0 (0%)	5 (10%)
	Unfamiliarity with medicine	0 (0%)	3 (30%)	1 (6%)	0 (0%)	4 (8%)
	Failure of equipment (e.g., syringe/ guidelines)	2 (18%)	0 (0%)	1 (6%)	0 (0%)	3 (6%)
	Complexity of IV preparation	0 (0%)	3 (30%)	0 (0%)	0 (0%)	3 (6%)
	Inappropriate equipment (e.g. plastic tray/label)	0 (0%)	0 (0%)	2 (12%)	0 (0%)	2 (4%)
	Unavailability of drug/diluent	0 (0%)	0 (0%)	1 (6%)	0 (0%)	1 (2%)
Team-related factors	Inadequate verbal communication with colleagues	1 (9%)	1 (10%)	2 (12%)	0 (0%)	4 (8%)
	Inadequate verbal communication between ward and pharmacy	0 (0%)	2 (20%)	0 (0%)	0 (0%)	2 (4%)
	Lack of support from colleagues	1 (9%)	0 (0%)	1 (6%)	0 (0%)	2 (4%)
	Lack of supervision from senior staff	1 (9%)	0 (0%)	0 (0%)	0 (0%)	1 (2%)
	Poor team work	0 (0%)	0 (0%)	1 (6%)	0 (0%)	1 (2%)
	Working alone	1 (9%)	0 (0%)	0 (0%)	0 (0%)	1 (2%)

Various error-producing conditions could also be identified from the analysis of free-text responses. These contributory factors related to environmental factors, individual factors, mental stressors, task factors and patient factors.

I. Environmental factors

Environmental factors considered to contribute to errors occurring related to high workload and short staffing.

- ***Workload***

Participants suggested that errors correlated with high workload included an untidy workplace, forgetting to wear gloves or apron and forgetting to perform a double check, which were reported to happen mainly during busy times. This could result from the culture of the hospital ward and nurses, working under pressure to prepare injectable medicines and do other jobs besides drug preparation at the same moment. Typical examples are given below:

> "Work space untidy, we don't have enough time due to workload to tidy up." [S7]
>
> "High workload made by mind not to use apron." [B90]
>
> "High workload to request second signature of IV antibiotics as patient awaiting dose." [S28]

Factors contributing to high workload included short staffing (n=4), other clinical demands (n=6), and a congested working environment [(n=4) which resulted from an inadequate working area in which to prepare medication]. Typical examples are given below:

> "Short staffing increases workload for other staff." [H219]
>
> "Area cluttered due to patient clinical demands." [C65]

> "Sometimes there are too many medications on the desk. Sometimes there are too many nurses preparing injectable in the same small space." [B86]

High workload was often linked with distraction, particularly during busy times during the day (e.g. drugs round). Participants identified that heavy workloads and distraction by other staff was a significant issue impacting their concentration levels during the preparation of injectable drugs and as a result, might lead to errors. Typical examples are given below:

> "Very busy ward. Many healthcare professionals coming and going and leaving notes / medical equipment out and not put away afterwards." [B120]

> "Too many staff members around nursing station at once. Shortage of doctors today so they are more rushed and busy." [B120

> "Distracted from task by colleagues." [H221]

- ***Short of staffing***

Five nurses across the two sites identified staffing levels as a significant factor leading to mistakes. Staffing issues included staff being moved to another ward, which consequently raised the workload. For example:

> "Lack of staffing. Staff moved to another ward in morning." [C62]

II. Individual factors

- ***Lack of knowledge, skills and experience of nurses***

Individual factors considered to contribute to errors occurring centred on a lack of knowledge, skills, and experience. Inadequate knowledge and experience regarding specific medicines was particularly well documented amongst junior nurses. Several nurses related these inadequacies to the lack of training they received when they joined the Trust. Typical examples are given below:

"Staff nurse thought it was sufficient enough to wash hand before and after preparing IV drugs." [H183]

"Lack of knowledge on the trust policy regarding labelling of IV Tazocin." [H190]

III. Mental stressors

- ***Distraction***

Several nurses identified that distractions were an important factor which affected their concentration whilst preparing injectable medicines and that this could lead to mistakes. In addition, time constraints resulting from high workload lead them to prepare injectable drugs in haste and as a result, caused nurses to make mistakes. For examples:

"Lots of distraction." [B89]

"Presence of colleagues asking questions whilst preparing medications." [H221]

"Because there are computers near the place where we prepare injectable and the doctors or others are using the space as well." [B86]

"Due to time constraints to give medications on time did not label syringe." [H189]

"Many of the patients are all due IV antibiotics at the same time this put a lot of pressure on nurses to work quickly, so patients receive their medications on time." [H195]

Two of the nurses reported that pressure to prepare drugs and do other jobs at the same time was an important factor that contributed to injectable preparation errors. For examples:

"Staff not available to tidy as pressure to do own jobs." [B120]

"If you have more pressure, you have to run more." [B153]

- ***Other mental stressors***

Hunger, and stress were identified by one nurse as a factor contributing to errors.

> "Several situations contribute lead to mistake happening (hungry, stress)." [H251]

IV. Task factors

- ***Unavailable medication***

An unavailable medicine was reported by one nurse as being related to a preparation error of a complex dose of a SC anticoagulant.

> "There was not a dose for the amount prescribed. Not suitable injection." [H246]

Numerous participants reported that various other task factors also contributed to errors. These included a lack of filter needles, a lack of appropriate labels especially for an IV antibiotic bolus and the absence of clean plastic trays. Typical examples are given below:

> "No filter needle available on the ward." [H237]
>
> "No labels specifically for bolus. Have to use patient label printer which is not at work station." [H247]
>
> "As stated not using the plastic trays, e.g. dirty trays and not enough trays." [H183]

V. Patient factors

- ***Patient clinically demand***

Patient-related issues were also reported to contribute to errors. One nurse stated that patients with poor clinical conditions often experienced drug preparation errors because of the high number of drugs prepared for them. Continuous distraction by an unwell patient was also revealed by one nurse working in a ward environment.

> "Distracted by unwell patient so unable to complete task." [S24]

2) Interviews data

A total of five main themes and eighty-five codes of error-producing conditions were identified in this research study; the error-producing conditions reviewed during the interviews are shown in Figure 6.1.

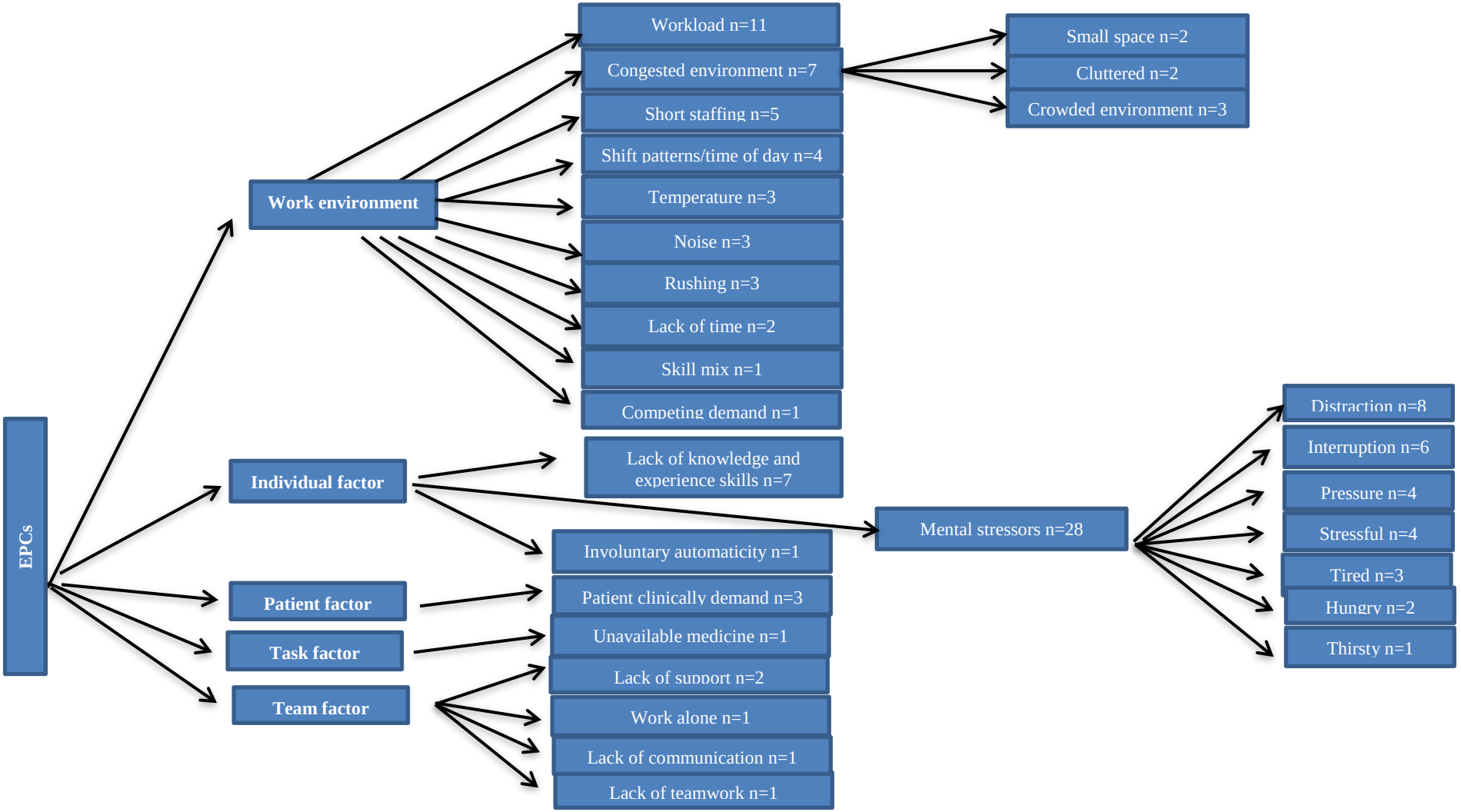


Figure 6.1: Themes and codes for error-producing conditions contributing to injectable medicine preparation.

I. *Work Environment*

- ***Workload***

Issues with workload that contributed to the incidence of injectable preparation errors were regularly reported during interviews using phrases such as *"busy*", "*busy workload*", "*always busy*", "*very busy*", "*busy environment*", "*got a lot going on*" and *"loads of IVs"*. The majority of nurses stated that a high workload was a significant contributor to injectable preparation errors. For examples:

> "If you've got eight patients on IV doses and you've got to do that within an hour it does get quite difficult to [do] each one properly so the heavy workload definitely has a factor of it as well." [B92]

> "The ward was very busy it was at the time of the evening drug round so there's a lot going on with lots of injections and IVs to consider yeah." [H245]

Some of the interviewees mentioned that their heavy workload led them to rush through medication tasks and consequently, caused them to make errors more easily. Typical examples are given below:

> "Haste I think is one of them. […] It was busy, you need – obviously, I wanted to do it correctly but I had other things to do as well, so it needed- this sounds wrong- I wanted to do it as fast as I could." [H245]

> "If you're rushing to do five or six in a short period of time then you might not be as aseptic [B92]

High workload was attributed to short staffing by a number of the nurses interviewed. However two nurses attributed this to the patient's clinical demand rather than staffing levels (see patient factors p.306). Typical examples are given below:

> "I also believe that it's down to time. There's a very high workload and not many staff." [H225]

> "I think how busy the ward is - I think there should be more staff on it at any one time." [H226]

> "Sometimes you have to help. If there is not enough nurses then you do someone else's teams' IVs as well so that would definitely affect it." [B92]

Workload was frequently linked with competing demand, especially during busy times of the day (e.g. in the morning and evening). Interviewees stated that heavy workloads and lack of time for drug preparation made it difficult sometimes to give all the drugs on time, causing timing issues. For examples:

> "It was [the error] during my morning drug round, [not] my lunchtime drug round, [but] this morning, and there is always a lot to do around that time because you have got IVs and all the other drugs to do." [H226]
>
> "A ward full, we have eight patients are in ours. Maybe we have six IVs at the same time. All of the rest of the patients and this six patients have more drugs to be done at the same time." [B106]
>
> "I had a patient that was having chest pains at the same time as a new patient being brought in to me who was rather sick and was needing antiemetic's quite quickly so I was trying to get a million and one things done at the same time." [H225]

- ***Congested environment***

Other issues identified related to the small size of the treatment room and the fact that it is often cluttered and easily crowded. Typical examples are given below:

> "Where we have to draw up our IV is very very small. There's a computer desk where there is at least three chairs and there is also drug trolleys so it's a very small, tight area and there was at least two more nurses there who were also prepping for IVs." [H225]
>
> "It is a very congested area. There is enough room for maybe two nurses doing one drug but when you've got maybe more than three drug charts in total and you separate it that takes up the whole table so if you have another nurse that comes over doing drugs or you've got a doctor coming over to talk to you that's making things complicated." [H183]

- ***Environmental conditions***

Nurses also reported that noise levels on the ward and high temperatures could lead to errors.

> "I think the worst thing is the noise because you are doing one thing and you can only do this thing in silence at 6 o clock in the morning. It's the only one moment that you're going to have silence to do antibiotics in this drug round. All the rest you are going to have a lot of noise, the families asking for information, this is the worst thing I think." [B106]

> "It's always very hot here so people get can get quite flustered and stressed, then you end up really time cutting by not being as sterile as you should be or that's usually the case." [B92]

II. *Short staffing*

Numerous nurses from the two wards identified staffing levels as a significant factor leading to mistakes. Staffing issues included an insufficient number of staff (which consequently raised the workload) and the skill mix of nurses during a shift. Typical examples are given below:

> "There is a staffing issue desperately [going] on within the NHS and I think that obviously helps these mistakes occur more frequently." [H226]

> "There was one of me, eight patients, and no healthcare assistant so I had to wash, toilet, see to personal care, dinners as well as doing my job on top of that so it was very stressful morning. Although I did have help from other members of the ward, they weren't there constantly. Like I should have had a healthcare assistant on the long day so I feel that yeah the staffing wasn't sufficient enough." [B187]

III. *Shift patterns / time of day*

Four of nurses interviewed indicated that shift patterns were a primary contributing factor to injectable preparation errors. Some interviewees from different wards mentioned that lunchtime or evening drugs rounds when staff were busy or the end of shift were linked with stress, which might affect their concentration as they prepared drugs. One of the nurses also related that the general stress associated with the end of shifts results from the multi-tasking nature of the job (i.e. duties given for nurses besides medicine preparation). For examples:

> "I believe it was around 6 o'clock in the evening when which is when the evening drug round happens and you have all your patients that you need to give their evening medications then if they've got 6 o' clock IVs you need to give them as well before it gets to hand over time because it's the last part of the shift it's always very busy because you have a lot to do because you need to complete your notes and complete everything you haven't done that shift." [B245]

> "It was more difficult to do the calculation because of it being so late on in the day." [H259]

IV. ***Individual factors***

- ***Lack of knowledge, skills and experience of nurses***

Many of the nurses indicated that individual factors were an important aspect in preparation errors. Specific individual factors included a lack of knowledge, skills, and experience. Many of the nurses related these inadequacies to the lack of training they received when they joined the Trust for example one nurse was unaware you could not add two medicines to one syringe.

> "Well I wasn't aware that you couldn't add two medications into one syringe so that was part of the mistake I suppose …When I spoke to my senior staff they said that it's not the ideal thing to do. I still don't really understand why that is an issue." [H245]

Some nurses were unaware of the importance of using filter needle or labelling IV bolus.

> "I've never really had much training on them or read the policy about it so I just kind of followed what I knew and what I'd been taught when joining the Trust." [H225]

> "If you have clear that you are going to give this drug in this moment with your vial with you, with the drug chart with you, double checked, is not clear for us maybe that you have to label it." [B106]

One participant was unaware of a correct ANTT during injectable medicines preparation.

> "I wasn't aware of the policy you had to wear gloves in all the years training I have always just gelled or washed my hands." [H183]

Other individual factors reported by the nurses in connection with preparation errors included inexperience in specialist drugs and unfamiliarity with the task. Typical example is given below:

> "Umm I…. felt that I could do the calculation I wasn't too worried about the mathematics just being the first time doing something always feels uncomfortable in whatever it is. I feel now if I was to do it again I would feel a lot more comfortable but I think you are always going to have the first time of doing anything and it doesn't mean you shouldn't do it just because it feels a bit scary at first. I think it is difficult not being experienced in a particular specialist drug." [H259]

Another possible factor was defined by one of the interviewees as an involuntary automaticity when preparing injectable medicines, which may lead to non-adherence to some of preparation process. For example:

> "I have done it so long without gloves you know thinking that my hand washing was enough, sterile enough to do it you know." [H183]

V. ***Mental stressors***

- ***Interruption and distraction***

Several interviewees stated that distractions and interruptions were significant factors affecting their concentration levels during their preparation of injectable medicines and as a result, this could lead to mistakes. For example:

> "We have only [one] open area to prepare the medication and the consequence [that] can happen while preparing it [is] the nurse can be distracted by different team members." [B86]

In addition, pressure resulting from the distraction and interruption within the ward during preparation for the final product was reported to increase stress and sometimes make it difficult to give all the patients' drugs on time. Typical example is given below:

> "That made me a bit more [stressed] and yeah that was the main reason." [B148]

While some nurses stated that interruptions can happen at any time and in all areas, others explained that in busy areas and during busy times, such as during the drug round, interruptions are more frequent, such as when other nurses ask for help checking their own medicines. For example:

> "A lot of interruptions because it's at a time where people need their IVs checking." [H245]

Different sources of distractions were recorded, although the primary cause of interruption, as stated by most interviewees, was patient families, who may ask questions in the middle of their own drug rounds or request help. For example:

> "The family all can interrupt the service and the main thing is the interruption." [B86]

Other sources of distraction identified by nurses included other nurses, health care professionals, and, primarily, doctors asking questions during ward rounds. Typical examples are given below:

> "There is constantly people asking you questions and talking to you whilst you're preparing so that can cause you to be distracted." [B92]
>
> "I think the worst thing is the distraction. At the same time that you are doing the drug, doctors start coming to you and say 'don't forget to do this thing', [the machines are] bleeping all the time, the IV you put to other patient is bleeping because they have finished ..." [B106]

- ***Other mental stressors***

Tiredness, hunger, and thirst were identified by the nurses as factors contributing to errors, primarily when linked with feeling overworked and receiving inadequate breaks during shifts. For examples:

> "Yes potentially I am tired, I have [a] very busy workload today, umm so lack of time would also be a factor." [H225]

> "We're human. If you haven't [had] any breaks […] it's going to contribute to fails. If you are unwell, you are going to be more [likely] to [make] mistakes if you are tired." [B106]
> "Umm, probably hungry and tired, yeah." [H183]

VI. ***Patient factor***

- ***Clinically demanding patients***

The acuity and clinical condition of some patients was identified by the nurses as a possible cause of injectable preparation errors. In this study, the condition of the patients was a common factor mentioned in interviews. Additionally, one of interviewees explained that a patient's phobia of needles was believed to be a source of higher risk for incidents of medicine errors. For examples:

> "My patient is afraid of needles and I didn't think it was fair to inject her twice so I added the amount from the syringes into one syringe with a subcutaneous needle to give that way." [H245]

> "I had a patient that was having chest pains at the same time as a new patient being brought in to me who was rather sick and was needing antiemetic's quite quickly, so I was trying to get a million and one things done at the same time. I knew that my patient needed this medication quite quickly to help resolve his nausea so I just did what I would normally do and used the green needle." [H226]

VII. *Task factor*

- ***Unavailable medication***

Unavailable medicine was mentioned by one of the interviewees as related to a higher risk of error. For example:

> "I didn't have the correct doses on my trolley. It's very simple straight to the point medicine but it's when you get a dose which is 75mgs, yes it was 75 so you have the injections in 20s 40s 80s 100s and 120s so there was nothing appropriate for a 75 because the 80 couldn't seem to draw it down that's why I put it all into one syringe because you can then accurately measure the amount you are taking in." [H245]

VIII. *Team factors*

Several team factors were classified by the nurses as possible causes of injectable preparation errors. Lack of support was the most common factor mentioned.

> "I think that I guess I could have had more support." [H259]

> "I was down a healthcare assistant so I had eight patients all to myself with no help with personal care or their hygiene." [H225]

A lack of teamwork could also contribute to errors. For example, one nurse explained that the plastic trays are not clean because of the doctors.

> "The doctors do tend to leave everything in the trays blood everywhere you know so, you have got to make sure you clean them you know. I always clean them with the alcohol because they can you know." [H183]

Additionally, working alone and miscommunication with staff was reported by one of the nurses as resulting in a higher risk of medication errors.

> "I think it is difficult not being experienced in a particular specialist drug and I think it would be helpful to be able to communicate with sort of senior nurse who had prepared the infusion many times before." [H259]

6.6.5 Latent conditions for IPEs

1) Questionnaire data

In Human Error Theory, latent conditions stem from flawed decisions often taken by people not directly involved in the workplace (e.g. management) (Vincent et al., 1998). As Table 6.12 shows, there were three themes and 12 codes of latent conditions that contributed to the occurrence of injectable medicine preparation errors. The latent condition that most commonly contributed to the occurrence of errors was local-work related and concerned the design of the treatment room, typically in relation to its size, and a lack of equipment and materials; this was evident on all four wards. The most common management-related latent condition was pressure to complete a task; again this was common to all wards. The most common weakness in the system defence was non-existent protocol or policy and difficulty with using policy or protocol; this was common in two clinical areas (C & H).

Table 6.12: Latent conditions cited as contributing to injectable medicine preparation errors

Theme	Code	Surgical ward (S) (*n* = 11)	Medical ward (C) (*n* = 10)	Surgical ward (H) (*n* = 17)	Medical ward (B) (*n* = 12)	Total (*n* = 50)
Local work- and task-related conditions	Poor design (e.g. small size or location of treatment room)	7 (64%)	4 (40%)	5 (29%)	6 (50%)	22(44%)
Weakness in the system defence	Lack of equipment and material	0 (0%)	0 (0%)	8 (53%)	0 (0%)	8 (16%)
	Non-existent protocol or policy	0 (0%)	2 (20%)	2 (12%)	0 (0%)	4 (8%)
	Difficulty with using policy or protocol	0 (9%)	3 (30%)	1 (6%)	0 (0%)	4 (8%)
	Unsuitable equipment (e.g. plastic tray/label)	0 (0%)	0 (0%)	2 (12%)	0 (0%)	2 (4%)
	Failure of equipment (e.g., syringe)	2 (18%)	0 (0%)	0 (0%)	0 (0%)	2 (4%)
	Lack of information source (e.g. drug book)	0 (0%)	0 (0%)	1 (6%)	0 (0%)	1 (2%)
	Unavailability of drug	0 (0%)	0 (0%)	1 (6%)	0 (0%)	1 (2%)
Management-related factors	Pressure to complete tasks	4 (36%)	7 (70%)	7 (41%)	4 (33%)	22(44%)
	Protocol design	0 (0%)	0 (0%)	3 (18%)	3 (25%)	6 (12%)
	Failure to enforce policy/ protocol	0 (0%)	0 (0%)	3 (18%)	1(8%)	4 (8%)
	Insufficient training for task	0 (0%)	3 (30%)	0 (0%)	1(8%)	4 (8%)

Several management related factors and weaknesses in the system defences were specific to each ward, suggesting that respondents can distinguish between different latent conditions in different environments. Analysis of the free-text responses identified further examples of latent conditions, related to work pressure and local practice-standards:

a) Local work-related conditions

Several latent conditions were identified as contributing to injectable preparation errors. Three nurses considered that heavy workload and staff shortages were significant factors which led to mistakes.

> "Busy day and staff needed." [H225]
>
> "Insufficient staff: sometimes we (nurses) need to stop preparing injectable and help a patient." [B86]

One of the participants stated that low staff number will raise workload for other nurses in the shift.

> "Short staffing increases workload for other staff." [H219]

Another common issue linked to the local work and task conditions that were revealed by nurses included a lack of equipment (out of stock) inside the IV treatment room.

> "We don't have any filter needles in the ward." [H243]
>
> "Lack of appropriate labels to use on syringes." [H189]

b) Weakness in the system defence

Many participants from two wards reported that the poor design or poor layout of the work environment within the ward was a significant factor leading to errors.

> "Limited space to prepare, need expediency when preparing medications." [H221]

One nurse reported that another issue pertaining to a weakness in the system, was the culture of accepting practices, which may not be in line with strict policy. For example, one nurse indicated a need for more practical guidance on IV preparation. Because this detailed guidance is lacking, nurses learn from each other. This includes learning poor practice, such as deviations from procedures, which may then become accepted.

> "If nurses don't focus up on mistakes then such things as not wearing aprons when preparing IV antibiotics is commenced these mistakes will continue and other nurses will continue with that culture." [H195]

c) Management factors

The two main organisational issues identified by the nurses were absents or insufficient training for nurses themselves concerning IV preparation. Several participants expressed the opinion that the training programme as well as the practical training provided by the NHS Trust was inadequate, including the training that the nurses undertake in IV preparation. Nurses indicated that errors often reflect a conflict between the policy and the actual content of the training programme. For instance, some nurses knew that the policy stated that IV boluses had to be labelled and they should use a filter needle for IV drugs, but this was not included in the training that he/she had recently received. Participants followed the techniques taught in training but violated the policy in doing so.

> "It's a practise on the ward that IV Tazocin 4.5g is administered to the patient without labelling." [B103]
>
> "I question it is a mistake not to wear an apron to draw up IV drugs. When I did my IV training we were not told to do so." [H249]
>
> "We don't routinely use filters, it was not mentioned at preparation training." [H240]
>
> "So no knowledge led to this mistake - not knowing the trust policy on IV Tazocin preparation led to me preparing the IV antibiotics and not labelling the medication which in the hospital policy states this should be done." [H190]

Another participant added that it is usual practice to shake a vial, for she and the other members of her cohort had been trained to do this.

> "This practice is not viewed as a mistake in our work environment, because it's not usual practice to not shake the vial. We are trained to shake the vial. Yes, there were bubbles, but this is not a mistake." [C65]

One of the participants believed that work pressure may lead to the IV treatment room becoming cluttered and unclean.

> "Area may have been uncleaned due to work pressure. However, area is always cluttered." [C65]

2) Interviews data

There were three main themes and 37 codes or sub codes of latent conditions identified in this study, which contributed to injectable preparation errors. They are shown in Figure 6.2.

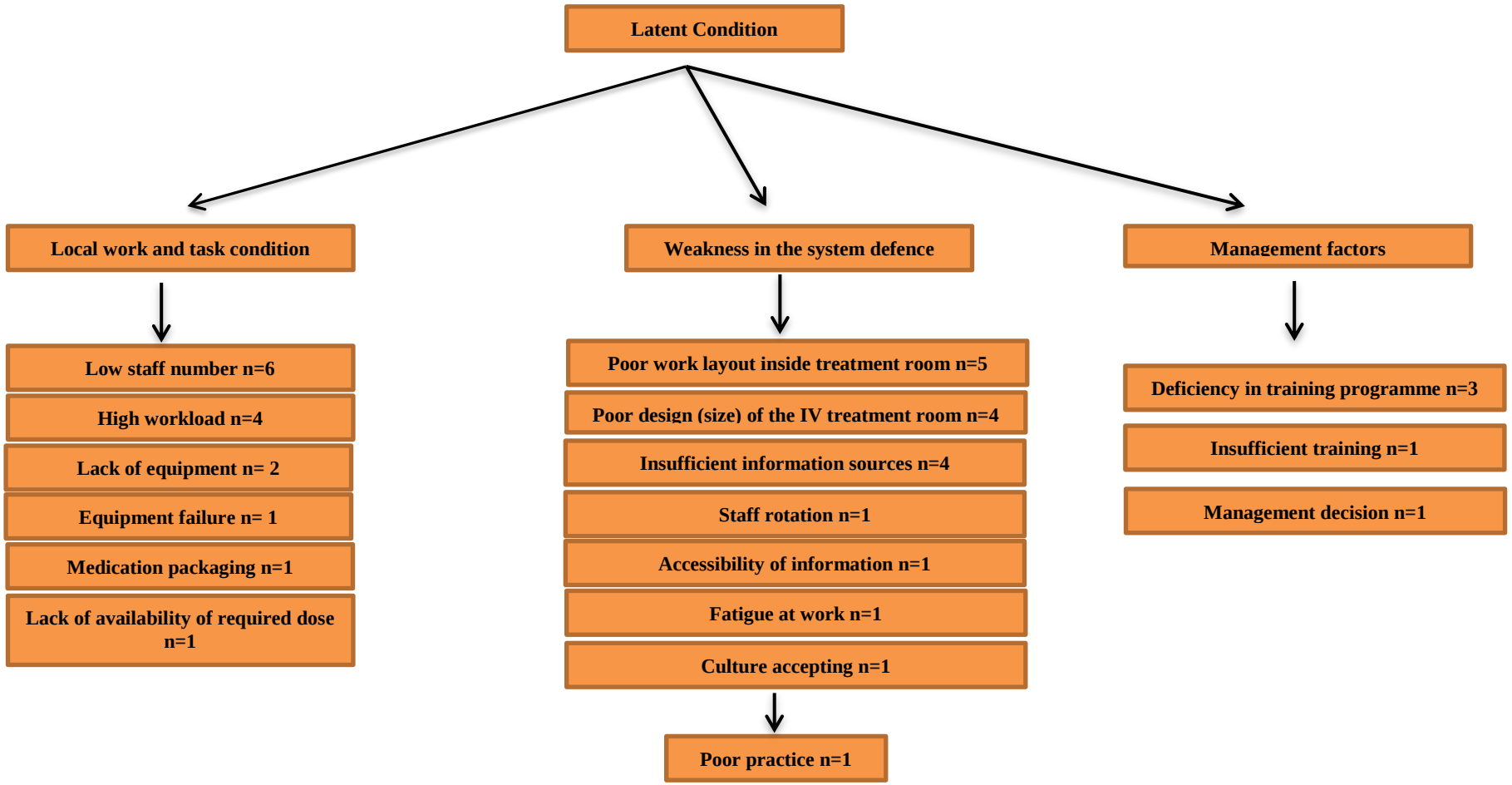


Figure 6.2: Themes and codes for latent conditions contributing to injectable medicines preparation

a) Local work and task conditions

Numerous latent conditions were classified as contributing to injectable preparation errors. Some interviewees considered that the high workload (n=4), together with low staff numbers (n=6), contributed to the errors. Additionally, a senior nurse reported that a lack of staff will increase workload and thus, could delay some of the injectable medicines. Typical examples are given below:

> "So it was very stressful morning. Although I did have help from other members of the ward, they weren't there constantly; like, I should have had a healthcare assistant on the long day so I feel that, yeah, the staffing wasn't sufficient enough." [H225]

> "As per the management, the number is good. I think we are one of the wards with the, the most sufficient staff, so we can't really blame. But if you need to go with the policies, sometimes we think we need many more staff to prepare the medication for all the patients on time." [B86]

Other factors linked to the local work and task conditions that were revealed by interviewees included a lack of equipment and lack of availability of required devices inside the treatment room. Typical examples are given below:

> "I would say lack of trays, you know, you can never find enough trays." [H183]

> "We don't actually have a drug label that will fit on a bolus because we have the infusion labels that we fill in but they are too big for a bolus." [H187]

> "Not having in a correct dosage syringe. There was nothing appropriate for a 75 because the 80 couldn't seem to draw it down." [H245]

b) Weakness in the system defence

The layout and geography of the ward as well as the size or location of the associated treatment room was raised by many interviewees as a significant factor leading to errors. Typical examples are given below:

> "We don't have much space to keep antibiotics for this big ward so that is one thing. And it is in alphabetical order so it looks a similar colour and a similar

> font. The preparation area is small and the cupboards [are too] small to accommodate enough antibiotics." [B148]
>
> "All of our needles even are all in one place and they are not particularly well signed so maybe if I'd seen a sign saying filter needle I would have thought, ahh yes, I need to use a filter needle rather than- I just picked up the one that I would normally use." [H226]
>
> "The apron and gloves are on the other side of the corridor, it's maybe a bad place." [H183]
>
> "We don't have any closed room in this ward to prepare IV medication, we have only [a] small area." [B86]

Several nurses attributed insufficient information about some drugs and procedure to increase risk of medication incidents. This includes the failure to provide adequate information and lack of instruction for preparing injectable medicines. For examples:

> "I did look in the IV book, and it said nothing about using a filter needle." [H225]
>
> "In the IV book it doesn't say anywhere about labelling bolus." [H187]

One interviewee argued that difficulty in accessing medication guidelines or procedures from the site's online resource can contribute to injectable medicine preparation errors.

> "They are all on our online site, however, they take a long time to find. They're not particularly easy to find." [H245]

The effects of staff rotation (moving staff to cover other wards) were also classified as a potential source of error, because it produces a possible lack of ownership: A requirement for nurses to be on the ward at a specific time meant that other staff members were sometimes given the responsibility of completing the process of preparing the injectable medicine.

> "Unfortunately one of our staff got taken down to X and Y to help … but you do need extra staff to help …when you have got lots of IVs you know because you can get behind with schedule." [H183]

Tiredness at work was reported as another important contribution factor for causing errors, as this leads to loss of concentration.

> "It definitely took [me] longer than it would have done if I wasn't tired." [H259]

Another issue pertaining to a weakness in the system was the culture of accepting practices, which may not be in line with strict policy. For example, one nurse indicated a need for more guidance on IV preparation. Because detailed guidance is lacking, nurses learn from each other. However, nurses may learn poor practices from each other, such as deviations from procedures, which may become accepted.

> "I wouldn't stop and think, 'oh you should be wearing gloves when you are doing that' because we do it so often without gloves, we don't stop and say to each other." [H183]

c) Management factors

The main organisational issue classified by the nurses is a deficiency in the injectable preparation-training programme provided to nurses. Nurses indicated that errors often reflect a conflict between the policy and the actual content of the training programme. For instance, interviewees knew that the policy stated that IV boluses had to be labelled and they should use a filter needle for IV drugs, but this was not included in the training received. Interviewees followed the techniques taught in training but violated the policy in doing so.

> "When we were taught in our IV policy training when we first started I remember being given green needles and orange needles but not the pink needles to draw up when we were practising in the learning and resource." [H225]
> "Throughout all of our training, we haven't been told that bolus needed to be labelled." [H187]

A senior nurse explained that nurses prepared IVs in what they considered to be an area authorised by the manager and the head of nursing as an acceptable area. However, this

practice conflicted with the hospital policy, and it proved difficult to confirm whether this practice is indeed accepted by the organisation.

> "The manager and the head of nursing and the team are accepted in this ward that we can prepare IV medications in the entrance of the ward, located in front of the HDU department." [B86]

6.6.6 Suggested barriers and defence for Causes of IPEs from questionnaires and interviews

As a result, several strategies were suggested by participants to reduce the risk of errors during the preparation of injectable medicines. The underling barriers and defence are summarising in Table 6.13.

Table 6.13: Barriers and defence suggested by participants from four hospital wards in two sites study.

Themes	Categories	Number of Questionnaires	Number of interviews	Example quote
Management Decisions	Training	7	4	"Re-train staff as hospital policy states to refresh them on the risk of not wearing gloves/aprons when preparing IV antibiotics." [H195] **(From questionnaire).** "Make training available, once you start doing something all the time then nurses follow in suit so it's just making everyone aware that filter needles are there to be used and that we should be using them." [H226] **(From interview).**
	Staffing	7	4	"I think having extra staff would ease the pressure on everyone else a bit." [H245] **(From interview).**
	Better supervision	5	1	"If it was your first time doing it, you could maybe find a senior nurse and show her your calculation, Ideally, you would show your calculations to someone that had a lot of experience in preparing that infusion." [H259] **(From interview).** "It should be clarified with our team leader if we need to wear aprons to draw up IV medications." [H249] **(From questionnaire).**
	Communication	1	1	"Incorrect expiry date from pharmacy. Sometimes chemo delayed by doctors due to patients being unwell. This can cause a problem with patient's chemotherapy by having incorrect expiry date. Pharmacy should check expiry date for chemo. Better communication between doctors, nurses, and pharmacists." [C30] **(From questionnaire).**

Themes	Categories	Number of Questionnaires	Number of interviews	Example quote
Environmental protection	Design or layout of IV Treatment room	7	8	"Area not cleaned due to open window. Treatment room with no window, closed area." [C65] **(From questionnaire).** "Ok I believe if we have a bit more controlled preparation area, where we are not distracted." [B148]**(From interview).** "Bigger space to prepare IV medication or spilt in two as the ward is big and make that space only to prepare drugs 'no computers there'." [B86] **(From questionnaire).** "If the sink and gloves were in the middle, separating us from the doctors and the computers that might help." [B144] **(From interview).**
	Medicines, equipment's and materials	9	5	"Enoxaparin in a vial just in case it's not a standardised dose. If they did it like that then that potentially would avoid the confusion." [H245] **(From interview).** "With label we have nothing for syringes. Not for syringe. We have to fix it to the syringe. This is more work- this is more work because you have to write properly to avoid that when you fix it you don't lose information sometimes it's uncomfortable. Maybe with another kind of label, a smaller that fits better to the syringe." [B106] **(From interview).** "By supplying filter needles to the ward area." [H243]**(From questionnaire).** "Ensure trays are clean and used when preparing IV medication. Provide us with enough trays." [H183]**(From questionnaire).**
	Information sources (Policies/ Guidelines	None	3	"Clarifying this point of the policy with the staff and maybe explaining why this is necessary… why it is not enough if you have your syringe in your hand your vial in your other hand and the drug chart with you, why it's necessary to have a label with this kind of thing... why it is not enough with all the precautions that we made to be safe for a patient." [B106] **(From interview).** "Could be some policies handed out regarding these filters needles." [H226]**(From interview).**

Continued 6.13

Themes	Categories	Number of Questionnaires	Number of interviews	Example quote
Environmental protection	Local work	3	4	"Signals that remind you don't forget to wear aprons and gloves."[H251] **(From questionnaire).** "In packaging, we have, well, most of the medication [is] the same colour. Amoxicillin and amoxiclav is most similar in font as well so maybe in a different font and colour coding may help." [B148](**From interview).** "Ensuring we encourage staff to wear aprons and report mistakes when noticed." [H195] (**From questionnaire).** "Make sure everyone has their breaks and has time to have a drink and have something [to] eat so they're not forgetful"B92] **(From interview).** "More signs around … which go through the steps that you should do to be aseptic. Just more visible signs to keep updating people and reminding them." [B92]**(From interview).** "Should be … a 'Stop think' sign; before you do this, drug please be aware you must wear gloves and use a tray. I think it should be like that right in front of you."[H183](**From interview).** "If there was better labelling on the needles then it would be another reminder to use a filter needle."[H225]] **(From interview).**

The results of the current study shows that quantitative and qualitative data can be used to better understand the underlying causes of errors, and the potential barriers that can be put in place to reduce the incidence of injectable preparation errors.

6.7 Discussion

A qualitative face-to-face semi-structured interview and self-complete questionnaire study was conducted to explore the views, knowledge, and experiences of nurses on four hospital wards regarding the contributory factors associated with IPEs in the hospitals, and the strategies that can be used to reduce errors during preparation. Although similar studies have been conducted on preparation and administration of injectable medicines in general, this is the first study to investigate these issues specifically for injectable preparation. Furthermore, in this study, Reason's (1990) organisational accident causation model (Vincent et al., 1998) was used to analyse the causes of IPEs.

The nurses who participated in this study had been observed making a specific error while preparing injectable medication and were selected in order to expand the current understanding of factors influencing injectable medicine preparation in hospital wards, and of how incidents threatening patient safety arise. While previous studies have been conducted on the causes of medication errors, most of these studies did not investigate the causes of errors as the main purpose of the study, or did study the causes of observed errors but using a self-report document that provided limited information and detail about the topic (Ashcroft and Cooke 2006, Alrwisan et al. 2011, Cousins et al. 2012).

The questionnaire and interview data was divided into four main themes: (1) active failures; (2) error producing conditions and factors related to the individual nurses, the task, shift patterns, environment (interruption and distraction), patient, team, or management, all of which were identified as factors contributing to IPEs; (3) latent conditions; (4) barriers and defence. Any stage or process within the injectable medicine preparation procedure can give rise to errors. IPEs can arise from the incorrect choice

of medicine, incorrect dose, incorrect calculation, incorrect volume of diluent, wrong route of administration, or faulty labelling. For example lack of familiarity with the NHS Trust's guidelines and policies, the outcome of the use of abbreviations or poor handwriting on the prescription, inadequate knowledge about the medicine or policies, or misjudgements of potential harm (Taxis and Barber, 2003; Taxis and Barber, 2004; Crowley, 2006; Ameer, 2105).

Interesting similarities in the causes of IPEs were identified at the two hospitals used in this study. Similar types of slips, lapses, violations, and knowledge or rule-based mistakes were observed in both hospitals. Lack of knowledge and skills, such as blood product knowledge, amongst nurses, especially bank agency and junior nurses who may have less knowledge and experience, were cited in the questionnaires and interviews as factors contributing to errors during injectable medicine preparation. Lack of knowledge and skills have been cited as a cause of error in some published studies (Taxis and Barber, 2003; Taxis and Barber, 2004; Crowley, 2006), and in other studies that used Human Error Theory, rule-based mistakes have been found to be strongly associated with nurses' knowledge and experience (Westbrook et al, 2011; Keers et al., 2013). In 2007, Tang and colleagues reported that approximately 30% of nurses associated their mistakes with being new and having limited experience. Taxis and Barber (2003) studied errors related to IV doses; they observed nurses preparing and administering IVs in two UK hospitals (n=113) and reported that lack of experience and knowledge amongst nurses caused 80% of observed errors. Nurses' knowledge and rule-based mistakes frequently involve a lack of knowledge about the medicine itself, protocols, guidelines, policies and procedures of injectable medicine preparation, and also unfamiliarity with the area and equipment used.

Some investigations have attributed the lack of knowledge amongst nurses to university programmes and the teaching of better technical and pharmaceutical knowledge. The findings from numerous studies of nurse education point to a lack of sufficient pharmacological knowledge amongst nurses, as well as inadequate on-going teaching at hospitals (Crowley, 2006; Brady et al., 2009; Avery et al., 2012; Ameer, 2015). Furthermore, a lack of experience was associated with new staff. According to some studies, nurses specified that mistakes mainly happened in the early times of their nursing profession (Taxis and Barber, 2004; Crowley, 2006; Jones & Treiber, 2010; Ghaleb et al., 2010).

In 1995, Reason reported that errors caused by insufficient individual knowledge could be managed by increasing the number of training programmes available. Similarly, numerous studies have suggested that comprehensive training, especially for new nurses, is needed to overcome the effects of nurses' lack of knowledge on injectable medicine preparation safety (Taxis and Barber, 2004; Prot et al., 2005; Crowley, 2006; Tang et al., 2007; Brady et al., 2009; Ozkan et al., 2011; Avery et al., 2012; Ameer, 2015). Hence, overcoming insufficient training and inadequate knowledge is reflected at organisational responsibility, and not an individual factor only (Taxis and Barber, 2004; Crowley, 2006; Ozkan et al., 2011, Ameer, 2015).

In the present study, nurses also highlighted the necessity for training, and placed the responsibility of their training on the organisation. In addition, they believed that the education and training delivered by the NHS Trust was inadequate for them to prepare injectable medicines safely. This was further highlighted when participants described the on-going training provided to them, and the inadequate evaluation of their injectable medicine preparation skills. Therefore, the 'lack of knowledge and experience of nurses'

factor indicates that providing sufficient training, especially for new staff, by increasing their training period would be one strategy for meeting nurses' requirements and reducing IPEs.

There is much evidence for the influence of nurses' training and staffing levels on patient safety outcomes overall, though limited studies reporting on medication errors (McGillis Hall et al., 2004; Ball, 2010). Within one year, the National Patient Safety Agency (NPSA) stated that 35,000 patient safety incidents in England and Wales were caused by staffing issues due to lack of trained staff or lack of experience, and approximately 25% of these incidents were associated with severe harm (NPSA, 2009). In 2010, the Royal College of Nursing (RCN) published a report entitled "Guidance on Safe Nurse Staffing Levels in the UK", which reviewed various evidence for a relationship between lack of nursing staff and patient safety in hospitals. The report showed that an increased number of registered nurses on the staff was related to lower rates of adverse patient events and mortality (Ball, 2010).

The questionnaire and interview participants in the present study identified the lack of or inadequate training and evaluation provided by the NHS Trust as another factor. For example, participants highlighted the need for additional training on the practical side of injectable medicine preparation, where they currently learn from each other. In this situation, nurses might learn poor practices from each other, for example violations of policies and guidelines (Taxis and Barber, 2004, Crowley, 2006, Ameer, 2015). Hence, it is essential to ensure that nurses receive the training they need by increasing the training provided to them, especially for new graduate nurses. Increasing nurses' skills and knowledge in this way would improve patient safety and minimise risks. This can also be achieved by re-evaluating the competency exam that nurses must undertake

before they are permitted to prepare injectable drugs. On-going learning and education sessions for nurses must also be provided to guarantee that nurses' knowledge of injectable medicines, such as blood products, is up to date. A ward nurse manager who was interviewed also highlighted the importance of re-evaluating nurses' competence at preparing injectable medicines at frequent intervals to ensure their competence to carry out injectable medicine duties. In addition, it is necessary to assess the training methods implemented in the NHS Trusts and evaluate their impact on nurses' skills and knowledge.

Participants specified that they are more likely to make errors under stress and pressure, especially at the end of shift. Since long shifts are common practice in several hospitals, measuring the influence of pressure and stress at the end of shift on the incidence of IPEs is important in order to assess the risk of this problem. While some studies have focused on this relationship, to date most of these studies have relied on self-reported data on errors made by nurses. To the best of the researcher's knowledge, as yet there has been no quantitative research studying this correlation via observational studies. Observational investigations are considered the ideal method for collecting data about IPEs. Hence, further study using the direct observation technique is required to adequately measure the impact of stress and pressure amongst nurses at the end of shift on IPEs.

Pharmacological form was also identified as a significant contributor to IPEs by one of the nurses in the present study, especially during a complex injectable preparation. Several causes were found to contribute to this issue, although nurses' experience, knowledge and workload inside the wards were common factors mentioned by the

interviewees. Latent failures contributed to this issue included lack of training, which meant nurses were preparing the injectable medicines under stress.

A further issue that was identified was the skills and knowledge of individual nurses, which was cited as a common cause of IPEs involving nurses' calculation skills. In spite of nurses' calculation skills being a major aspect of nursing efficiency (Nursing and Midwifery Council, 2012), some previous studies have also reported that major deficiencies in both mathematical and conceptual skills amongst nurses may affect their capability to calculate medication doses correctly in practice (Wright, 2007; Fleming et al., 2014). A study by McMullan and colleagues (2010) reported that 91% of student nurses and 88% of registered nurses failed to pass a medication calculation test. This has led to investigators suggesting additional education on conceptual drug calculation skills and mathematical (Fleming et al., 2014) as a part of medicines education via nursing courses and on-going education programmes (McMullan et al., 2010; Fleming et al., 2014). In terms of the role played by nurses' calculation skills in medication errors, numerous previous studies have cited this as one of the factors contributing to errors (Gladstone, 1995; Taxis and Barber, 2004; Deans, 2005; Crowley, 2006; Chua et al., 2009; Avery et al., 2012; Ameer, 2015). However, a study conducted by Wright (2010) to determine whether there was an association between medication errors and nurses' poor calculation skills found a lack of evidence to support a relationship between the two, which indicates a need for further investigation into calculation errors in practice. In the current study, one participant who highlighted nurses' poor calculation skills as a potential factor leading to IPEs explained that this factor is even more significant when preparing doses for respiratory infections patients, which may require difficult calculations. This is comparable to the results of other studies, which have

found that the likelihood of making errors due to incorrect dosage calculations of dose is higher for complex medications (Brady et al., 2009, Ozkan et al., 2011).

Different practical issues can arise during the reconstitution, mixing and addition stages of injectable medicine preparation. In 2005, the Royal College of Nursing (RCN) IV Therapy Forum published national practice standards that require organisations to have a protocol for reconstituting, which should be developed alongside the pharmacy. This document was utilised in the wards of the present study, however information about those medications where specific errors are common would greatly help the development of such a protocol. Adding/mixing errors namely (air bubbles) were one of the main types of injectable error classified in studies of injectable medicines, and general studies of medical and surgical wards, where injectable medicines are usually used (Schneider et al., 1998; Taxis and Barber, 2003b; Tissot et al., 2003; Wirtz et al., 2003; Cousins et al., 2005; Crowley, 2006; Ameer, 2015).

The reconstitution stage of preparation is time consuming, particularly if the powder is difficult to dissolve and close attention is required where medicines are oversensitive to foaming, as there is a risk of withdrawing an incomplete dose, for example Teicoplanin, Factor VIII, Tazocin, and Gentamicin (Crowley, 2006; NPSA, 2007; Royal Collage of Nursing, 2016; NMC, 2016). The difficulties specified by the participants in the present study were comparable to the previous studies (Schulman et al., 1998; Crowley, 2006; Ameer, 2015). The guidelines also require ward managers to highlight those medications that the nurse may not reconstitute.

The main issues mentioned by the participants in relation to the work environment were high workload, congested environment, staff shortage, interruption and distraction, staff skill mix, and shift patterns. These issues have also been identified in other studies (Beso et al., 2005; Crowley, 2006; James et al., 2008; James et al., 2011; Avery, 2012, Ameer, 2015). High workload was mentioned by most of the participants in the present study as a significant contributor to IPEs, primarily in reference to the time of preparing the therapeutic doses. This is a similar finding to those of other studies on factors contributing to IPEs, which have also highlighted workload as one of the most common factors (Gladstone, 1995; Taxis and Barber, 2004; Deans 2005, Crowley, 2006; Chua et al. 2009; Avery et al., 2012; Ameer, 2015). Compared with other studies, the results of the present study also reported that high workload was primarily caused by lack of staff which in turn is associated to management decisions with regard to employment. Some participants related this to the number of injectable medications needing to be prepared for patients, and others to the patients' conditions rather than to insufficient staffing. Tissot and colleagues described heavy workload for nurses as the numbers of patients each nurse (Tissot et al, 2003). The nurse to patient ratio is usually used to measure workload in order to study the correlation between nurse workload and patient outcomes (Aiken et al, 2002). However, this mode of assessment has some weaknesses, as high workload has been found to be multivariate and can be influenced by numerous factors affecting the nurse to patient ratio, such as the patients' health situation, the skill mix of the nurses, and time of shift (Montgomery, 2007). As such, Reason (1990) recommends that workload should be measured at the management level. In addition, Taxis and Barber (2003) have also reported that increased workload combined with distractions and interruptions led to mistakes in their study of the causes of injectable medicine preparation errors.

Participants in the present study stated that high workload-related mistakes included incorrect dose, incorrect diluent, incorrect medicine, breach of the 'aseptic non touch technique' (ANTT), and medicine omission; all of these were described as occurring primarily during busy times, for example at the drugs round. This could be due to the nature of nursing multitasking, and the need to work under stress/pressure to prepare injectable medicines and complete other tasks at the same time. Multitasking at the same time as preparing injectable medicines is a time saving commonly used by staff to control heavy workload (Taxis and Barber, 2003; Brady et al., 2009).

Other published studies further indicate that high workload also contributes to other types of mistakes. For example in an observational study, Crowley (2006) identified that heavy workload contributed to all types of IPEs, though especially errors in aseptic technique and re-use of single dose containers. Furthermore, Ameer (2015) stated that, in situations of stress and time pressures caused by high workload, nurses were more likely to make calculation errors. Furthermore, investigations that have stated data regarding the cause of violations during injectable medicine preparation have reported that such violations by nurses could be caused by increased workload (Taxis and Barber, 2003; Keers et al., 2013, Ameer, 2015). A prime example of these types of violations was nurse non-compliance with injectable medicine preparation polices. Crowley (2006) confirmed that stress, time pressures, and a heavy workload led to nurses not following the standard policies and protocols of injectable medicine preparation. In a recent study, nurses' compliance with injectable medication preparation practice policies was found to be influenced by patient health situation and high workload (Ameer, 2015). It was further reported that high workload, in addition to other factors, affected nurses' compliance with the procedures of checking and double-checking medications (Ameer, 2015). This is comparable to the findings of the present study, in

which nurses have stated that the causes of inappropriate checking or non-commitment with the checking process, specifically the failure to double-check, were mostly the result of high workload.

The number of nurses working also has an influence on the rate of IPEs, as reduced nursing staff means an increased number of preparations per nurse, and so increases workload will increase the chance for making errors (Crowley, 2006). Staff shortage has been found to increase mistakes by creating a busy work environment, impeding proper process and procedures, preventing nurses from preparing injectable medicines on time, and leading to decreased attention to detail (Taxis and Barber 2004; Crowley, 2006; Ameer, 2015). Additionally, when staff shortages are combined with a high workload and increased patient acuity (patients who are very sick), this can lead to increased levels of fatigue and pressure or stress amongst nurses, posing additional and increasing risks to patients (Crowley, 2006). Research that has studied the influence of nursing staff levels on the rate of medication errors has found that the rate of IPEs is minimised by increasing the number and experience of staff. In 2004, McGillis Hall and colleagues studied the influence of various nurse staffing strategies on patient outcomes, including medication errors, and found that a low number of professional nurses on the staff was linked with a higher proportion of medication errors occurring on the units under study (McGillis Hall et al., 2004). Similarly, Beyea and colleagues reported that 40% of 206 medication errors were the result of new nurses (17%); heavy workloads (15%) and staff shortages (8%) (Beyea et al, 2003). Tissot et al. (2003) carried out direct observation to collect data on the risk factors related to injectable medicine administration errors, and found that the risk of making a mistake was three times higher in nurses caring for more than five patients when compared to nurses with less than five patients. In addition, Ball and colleague (2009) surveyed 9,000 nurses in the UK, and more than 52% stated that

they experienced a high workload when providing treatment. Those who reported that they were very busy were working in an environment where there were nine patients per nurse; by contrast, those who stated that their workload was not very high were caring for six patients (Ball and Pike, 2009). The National Institute for Health and Care Excellence (NICE) advice on safe staffing levels for nursing states that there is no standard nurse-to-patient ratio for all wards that can guarantee safe patient care, and that the safe level depends on the individual requirements of the wards. Nevertheless, the advice makes an evidence-based suggestion for safe nurse staffing levels to meet both nurse and patient requirements (NICE, 2014).

Inappropriate workspace, which were mentioned by the majority of participants, have also been referenced in several past studies as factors that negatively affect nurses' concentration, and as such contribute to IPEs (Taxis and Barber, 2004; Pape et al., 2005; Wrench and Allen, 2006; Crowley, 2006; Ameer, 2015). Several published literature in the UK and other European countries have identified the need of a solely IV treatment room to prepare injectable medicines as an issue contributing to mistakes, requiring staff to prepare injectable medicines in less than perfect situations (Crowley, 2006; Ameer, 2015). In summary, clinical areas had no solely IV treatment room; hence, nurses used nursing stations and patients bedsides for this task (Tissot et al., 2003; Taxis et al., 2004; Crowley, 2006; Ameer, 2015). Zavery et al. (2005) investigated the injectable preparation rooms on 71 wards in two UK hospitals, and reported that 80% wards had unclean and cluttered IV preparation rooms. This highlights the lack of understanding of the significance of design to patient safety within the NHS (Department of Health and the Design Council, 2006). At present, there are ideas about how to resolve this issue within the improved NHS hospital plan, which sets out the need for a solely, clean and uncluttered IV treatment room for injectable drugs preparation, with adequate

storage room that is isolated from physicians, patients and usual causes of environmental contamination (Smith and Watkins, 2016). The results of the current study, confirmed by the previous studies, focus the important of comprehensively assessing the injectable drugs preparation procedure, as management and environmental factor can impact on patient safety. Adequate attention and appropriate priority should be awarded to overcome these issues, and it is essential that the aforementioned factors are considered in the design and planning of new hospital wards.

The most common task-related factors reported by the participants at both sites were a lack of filter needles and a lack of and inappropriate labels in the IV treatment room, especially for IV antibiotic boluses. Poor commitment with filter or label use, and common inappropriate use in wards suggested that this is a routine deviation engaged in by a large percentage of nurses. Various causes were found to contribute to this practice. Nurses' confidence in their experience and knowledge were common factors mentioned by participants. EPCs that contributed to such a practice included insufficient staff and a high workload, which led to nurses preparing medication task under stress or pressure. These results are comparable with those of published literature, where problems about non-use of a filter needle and faulty labelling during injectable drug preparation have been often stated (Taxis and Barber, 2004; Crowley, 2006; Keers et al, 2013; Ameer, 2015), although incomplete information/knowledge has been provided about the sources of such practice.

Unclean or the absence of clean plastic trays was reported as another task-related factor leading to a congested environment in the IV treatment room. This factor can be directly linked with other factors cited by some participants, for example the design of the IV treatment room. An open area should be provided in the IV treatment room, making it

easy for staff to enter the IV treatment room, take the plastic tray and return it dirty or put it in the wrong place – this was reported on all of the wards. The significant influence of poor quality plastic trays indicates that the quality of injectable medicine preparation also depends on the performance of other healthcare professionals (Keers et al., 2013).

Numerous studies have highlighted interruption and distraction as major factors contributing to general medication errors in hospitals in the UK, Europe, and the USA (Gladstone, 1995; Meurier and Vincent, 1997; Osborne et al., 1999; Hand and Barber, 2000; Pape, 2001; Tissot et al. 2003; Taxis and Barber, 2003; Mayo and Duncan, 2004; Deans, 2005; Pape et al. 2005; Crowley, 2006; Tang et al. 2007; Jones and Treiber 2010; Ozkan et al. 2011; Gill et al. 2012; Ameer, 2015). However, little information has been published about the types, rate, and sources of interruptions, or the correlation between distractions and interruptions and error in practice (Raban and Westbrook, 2014). In 2004, O'Dowd investigated distractions and interruptions on medicine rounds, and reported that nurses were interrupted and/or disturbed on average more than six times each round, and a maximum more than twenty-five distraction/interruptions per round were reported. Furthermore, the participants in the study expressed that there should be no distractions or interruptions, as being removed from the task at hand could be unsafe. In addition, Biron et al. (2009) reviewed 23 studies on the types and rate of distraction and interruption in nursing work environments, and their potential contribution to injectable medicine administration errors. The authors reported that nurses themselves were the most common cause of distractions/interruptions, however, some were caused by system failures, for example lack of medicine or equipment. However, in the present study, participants indicated healthcare professionals were the main cause of distractions/interruptions, though they also mentioned other causes, for example other nurses and other patients. A large number of published literatures that classified the

contribution of distraction and interruption to mistakes were either qualitative or based on incident reports that might indicate a weakness in the form of under-reporting. An Australian study used the direct observation approach to control the influence of distraction and interruption on injectable medicine administration errors in hospitals (Westbrook et al., 2010). The authors relied on a sample of ninety-eight nurses preparing and administering more than 4,000 medicines, and identified an important relationship between the rate and severity of injectable medicine administration errors and interruptions to nurses during administration. The authors found that interruptions were reported in more than 50% of administrations and that every interruption was linked with a 13% increase in mistakes. The number of errors increased from 25% in administrations with no interruptions to 39% in administrations with three interruptions. The severity of the errors also increased with an increased number of interruptions. Where there was no interruption, the likelihood of a major error was 3%; with four interruptions this risk almost doubled to 5%.

Numerous interventions have been used in various studies to reduce distractions and interruptions during the preparation of injectable medications and measure their effect on IPE rate; however, Raban et al. (2014) examined the efficiency of these interventions in reducing rates of distraction and interruption, and related medication errors, and found that there was little indication of their efficiency in this regard. To reduce the occurrence of distractions and interruptions, their natures should first be identified; hence, more direct observation techniques on distraction and interruption during the preparation of injectable medicines is needed to control preventable distractions and interruptions. Furthermore, the way in which nurses manage distractions/interruptions in practice is another strategy requiring further study (Biron et al, 2009). Therefore, more support information regarding the distraction and interruption strategies applied by staff to

reduce their occurrence is vital, as well as the used of disguised observation to better measure the efficiency of any strategies (Crowley, 2006; Raban and Westbrook, 2014; Ameer, 2015).

The findings of the current study indicated that some of nurses believed that skill mix and inappropriate staff contributed to the occurrence of mistakes. Participants believed that, agency, bank and new staff they were untrained to prepare injectable drugs or inexperienced with the area, and so required close supervision. These results are similar to those of other studies that have stated inappropriate staff and skill mix as a cause of IPEs, and consistent with what was reported by the participants in the present study, were factors mentioned by many other studies (Taxis and Barber 2003; Taxis and Barber 2004; Deans, 2005, Crowley, 2006; Chua et al., 2009; Avery et al., 2012; Keers, 2013; Ameer, 2015). Staff skill mix, in other words the proportion of inexperienced to experienced staff within the staff team, has been already stated to impact the safety of injectable drug preparation. In 2012, Frith and colleagues studied the correlation between staff skill mix and medication mistakes in eleven hospitals. The authors stated an important correlation between the ratio of experienced staff in the ward and the occurrence of medication mistakes, whereby the number of medication mistakes reduced when the number of experienced staff increased, and when the number of inexperienced staff decreased.

Shift patterns, specifically in relation to lunchtime or evening medicine rounds, and those at the end of a shift, were also cited as a factor contributing to errors in the present study. Some of the participants stated that there was increased incidence of mistakes during the lunchtime or evening medicine rounds. However, previous studies indicate that this may have been due to the increased number of doses being prepared during the

day, or the higher frequency of error detection during the day shift (Ruggiero, 2003; Crowley, 2006; Geiger-Brown et al., 2012; Ameer, 2015). Participants specified that the risk of mistakes increased at the end of shift, and linked this with stress affecting their concentration as they prepared drugs, particularly when combined with hunger and not taking enough breaks. As far as this author knows, that working twelve hours is usual occupation for hospital nurses thru both day and night shifts, exhaustion become more of a problem in the end of the shift, as the nurses have to prepare the doses of injectable drugs before they leave, which is when their exhaustion, and pressure, are expected to be at their highest. The correlation between the end of shift and increased levels of exhaustion, and stress or pressure between staff has been proven in the literature, particularly when merged with insufficient breaks and shift rotations (Crowley, 2006; Winwood et al, 2006, Stimpfel et al, 2012; Dall'Ora, 2015; Ameer, 2015). Rogers and colleagues (2004) highlighted that the probability of making a mistake tripled when nurses reached the end of their shift. A study by Scott et al. (2006) including more than 500 critical care nurses investigated the influence of shift patterns and time of day on hospital nurses' wakefulness and the occurrence of medication errors. The results further supported the correlation between end of shift, reduced wakefulness amongst nurses, and a larger number of medication errors. The authors showed that the risk of medication errors doubled when nurses reached the end of their shift. Consequently, in 2011, the Joint Commission published a notification to all hospitals requiring them to pay more attention to the risks of exhaustion between hospital nurses caused by extended shifts, and to formulate plans to manage this issue (Joint Commission, 2011).

In the present study, few numbers of patient-related factors were highlighted. Participants considered that patients with complex clinical states were at higher risk of IPEs due to either their capability to deteriorate quickly, or because of the number of injectable medicines prescribed for them. Comparable findings were reported by various other studies. For example, Tang and colleagues found that patients with poor clinical situation usually encountered errors during injectable drug preparation (Tang et al, 2007). A literature review also found that patient acuity affected IPEs, either due to the complexity of those patients' prescriptions (Benner et al., 2002; Crowley, 2006; Tang et al., 2007; Ameer, 2015), or due to the increased workload of nurses, mostly due to the additional intensive care that is needed or the high number of injectable medicines needing to be prepared (Jones and Treiber, 2010). A number of studies have related patient acuity with an increased rate of distractions and interruptions, high workloads, and high levels of stress or pressure between nurses (Crowley, 2006; Keers et al., 2013; Ameer, 2015).

In accordance with several previous studies, miscommunication issues between nurses or with other healthcare professionals (e.g., physicians) were reported by one of nurses in the present study as common factors contributing to mistakes (Taxis and Barber 2004; Crowley, 2006; 2008; Ameer, 2015). In general, the communication problem raised by participant, such as lack of communication between the preparation team and pharmacy department during the shift, led to frequent omissions and expiry date of injectable medicines. Regarding communication issues with pharmacy department, the main problem nurse stated was related to incorrect expiry date of chemotherapy medicine from pharmacy, and she/he suggested that better communication between the doctor who prescribes the medicine, the pharmacy department, and the ward can reduce the

risk of errors. Several studies of medicine safety have shown that the most significant IPEs result from miscommunication between healthcare professionals (McBride-Henry and Foureur, 2007). Hence, any interventions and strategies to enhance medication safety must consider the need to improve communication within the nursing team and amongst healthcare professionals. In the present study, some recommendation by nurse was presented; for example, increasing number of senior nurses inside the IV treatment room may assist to resolve communication problems relating to the importance of injectable preparation. Unsuccessful communication between healthcare professionals contributes to increase the rate of medication errors in hospital wards (Balas et al., 2004; Ameer, 2105).

The findings of this study have revealed that many individual, environmental, and organisational factors can contribute to injectable medication errors. The key factors identified include the complexity of some injectable preparations, insufficient training, and lack of access to the information required in order to safely prepare the injectable medicines on hospital wards. The complexity of some injectable preparations, such as aminophylline doses, which require complex calculations, have been mentioned as contributing to mistakes involving incorrect dose preparations and use of the incorrect preparation technique. The results of the present study support those of previous studies in terms of nurses' lack of adequate training on preparing injectable medicines, although only a few studies have focused on the factors contributing to errors in injectable medication preparation (Taxis and Barber, 2003; Taxis and Barber, 2004; Crowley, 2006). Participants attributed responsibility for training insufficiency and inadequate evaluation to the managers, and reported that the NHS Trusts intend to review the training provided to nurses continuously. Taxis and Barber (2003) stated that clinical pharmacists on wards can play an important part in classifying and focusing nurse

training requirements. Furthermore, two of the participants in this study have cited the performance of ampoules and the complex design of some drugs, such as enoxaparin sodium, as issues linked to manufacturers. Some strategies for minimising mistakes in injectable drugs preparation were recommended; one was to implement a Centralised Intravenous Additives Service (CIVAS), however there was no importance evidence of this action being taken (Taxis and Barber, 2003; Crowley, 2006; Ameer, 2015). Moreover, the participants in the current study suggested that nurses would benefit from refresher sessions, and that all nurses should be required to demonstrate their competence in injectable medicine preparation. Previous studies have also supported continuous training in injectable medicine preparation, in accordance with other compulsory training programmes (Nicholas and Agius, 2005; Crowley, 2006; Ameer, 2015).

In summary, there were some factors are common, others are more specific to the ward in which participants worked having an impact on the factors reported to contribute to IPEs. Participants from surgical wards stated that distractions and interruptions were more of a challenge when they came from the nursing team than from patients, as patients in surgical wards are mostly very unwell, although very unwell patients were stated to be at higher risk of mistakes due to their inability to communicate. Furthermore, when reviewing their workloads, participants working on surgical wards related their high workload to patient acuity rather than fewer staff, as participants from medical wards did. This may be due to the different nurse-patient ratio in surgical wards compared to medical wards, as each nurse in surgical ward was responsible for just three to four patients, whereas in medical wards this may be seven or eight.

Finally, the staff were in some wards denial on medication errors that had occurred, this differed between wards. For example, participants from the surgical wards did not consider this to be an issue, and stated that they received routine feedback via ward supervisors. In contrast, participants from medical wards believed learning from known mistakes was impeded due to the absence of feedback. This may be because senior nurses and ward managers in areas such as surgical wards were more active in keeping their staff updated with information about identified mistakes. Nevertheless, almost all nurses who participated in the present study reported that receiving feedback is important and that more feedback on errors would be useful.

A summary of the errors categorised as posing an extreme risk led to the development of risk reduction strategies for each ward, as summarised in Tables 6.14, 6.15, 6.16, and 6.17. These were developed from interview and questionnaire data and previous studies (Breckenridge, 1976; Hadaway, 2001; Jones, 2003; Taxis and Barber, 2003; ISMP, 2004; RCN, 2005; Alldred, 2006; Crowley, 2006; Brady et al., 2009; Avery et al., 2012; Ameer, 2015). Tables 6.14, 6.15, 6.16 and 6.17 show that individual, EPC, and latent factors can contribute to injectable preparation errors in the hospital environment.

The main factors recognised in the surgical ward (S) were difficulties related to the design and layout of the treatment room. Several participants mentioned difficulty working in the IV treatment room as a result of its small size, and interruption and distraction by other nurses, which led to gross disregard for maintaining a clean and uncluttered treatment room and the selection of an incorrect diluent for some injectable medicines (i.e. S7; S83). One of the participants suggested that having a quieter treatment room might help nurses to avoid errors. The outcomes of the present study supported the results of previous studies in terms of interruption and distraction during

the preparation of injectable drugs, by the nursing team or others, although only few studies have specifically investigated the factors contributing to mistakes related to injectable drug preparation in hospital wards (Taxis and Barber, 2003; Crowley, 2006).

The main factors in the medical ward (C) related to nurses' lack of knowledge or experience regarding the complexity of some injectable preparations requiring complex adding and/or mixing, with one participant mentioning specifically a lack of knowledge or experience of the blood product, i.e. Factor VIII doses (C62). The observed error in this case was strongly shaking the medicine, which caused foaming and bubbles. As specified above, participants acknowledged lack of knowledge and experience as a factor, and that the NHS Trust should ensure that its training is followed before start work in IV treatment room, and follow this up with adequate training.

The main factors on the surgical ward (H) were related to high workload and the critical health situation of patients on that ward. Several participants highlighted the difficulties of working on that ward as a result of patients' clinical demands, and the requirement for extra nurses to minimise the reoccurrence of IPEs. One participant mentioned patients' phobia of needles as contributing to IPEs, due to the incorrect preparation technique that can result (i.e. using one syringe rather than two syringes), resulting in too low a dose (H245). This participant further reported that high workload and patients' clinical demands led to a lack of breaks, and recommended that managers assign specific break times to all nurses, to be taken regardless of the amount of work needing to be completed.

The main factors documented in the medical ward (B) related to a lack of knowledge of NHS Trust policy regarding some of the injectable medicines and low staffing levels on the ward. Some participants explained that they did not know that they should label IV antibiotics bolus, wear an apron and gloves, and prepare all injectable medicines in the IV treatment room (e.g. B86; B92; B144).

The participants further reported that absence of regular training and education sessions, and suggested that the NHS Trust should ensure annual training and regular sessions either within or outside the Trust. One participant clarified that the lack of signs or posters illustrating the ANTT procedures in the IV preparation room was one of the reasons for the increased risk during the preparation of injectable medicines.

6.8 Limitation

The present study has a number of limitations. The first limitation was one that is true of all qualitative studies specifically that the outcomes of the study may not be generalisable (Johnson and Christensen, 2003). This is because of the study sample may not be representative, particularly due to the relatively small sample size included in qualitative studies. However, because two research methods were used (questionnaires and interviews), the sample size was adequate for achieving the aims of this study. In addition, there are significant similarities in the outcomes of the present study and previous studies that used either qualitative methods or different methodologies to categorise factors contributing to IPEs (Taxis and Barber 2004; Pape et al., 2005; Wrench and Allen, 2006; Crowley, 2006; Ameer, 2015).

The second limitation of this study is that it was conducted in only two types of ward, surgical and medical wards. Hence, nurses' opinions may not be generalisable to other types of ward, such as the Intensive Care Unit. Nevertheless, as numerous nurses had worked in other wards previously, they may have varied experience and opinions that reduce this limitation.

The third limitation of this study is that all interviews were conducted with nurses from only two wards, Surgical H and Medical B, and no nurses from the other wards (Surgical S and Medical C) were interviewed. This was the case due to issues around taking nurses away from their clinical responsibilities, fear of discussing a sensitive topic, and lack of nurse confidence. If nurses had been individually paid for participating in the interview, this may have motivated more nurses to participate in the study such as (Surgical H and Medical B). In spite of the fact nurses from the other wards (Surgical S and Medical C) were informed of the study, none volunteered to participate. Their participation may have improved the results of this study. In addition, the interviews were conducted with nurses who had made errors in injectable medicine preparation, which may have made them afraid to participate in the study, even though it was clarified that all personal information would be kept confidential and not made available to anyone outside of the study.

6.9 Future work

A number of participants acknowledged the issue of miscommunication between nursing teams, especially the expiry date of chemotherapy, which they said contributed to IPEs. Errors due to miscommunication included an expiry date, whereby it was unclear, due to lack of documentation, when a dose had been delivered by pharmacy department, or whether a dose had been delivered without being checked. Documentation issues could feasibly be enhanced by introducing an electronic preparation system, which has already been implemented in some wards of international hospitals (e.g. in Saudi Arabia). Further research could measure whether an electronic preparation system would reduce the number of documentation errors and minimise miscommunication problems.

From the statements received from the participants, some issues arose over the design/size and layout of the IV treatment room, Hence, the IV preparation process should take place in a solitary area. Consideration should also be given to studying this issue. It could be helpful to put some of these issues (open IV treatment room or small size) to a panel of healthcare professionals, for example focus groups to ascertain the ideal design / size / layout of a treatment room. This would enable different recommendations to be gathered and studied. The panel might not always identify issues or explanations that are relevant outside of their own professional area or expertise, however, their views and opinions may enable particular limitations to be addressed.

Another factor contributing to IPEs identified in study, and others, is the heavy workload and limited staff on wards, with a large number of agency or bank nurses working. Agency or bank nurses may have inadequate knowledge and training, and some may not be permitted to prepare and administer injectable medicines. Numerous studies have shown the harmful impact of nurses' heavy workload and low staffing levels on medication safety. These studies have also found that an increased number of staff, especially senior staff, leads to improved patient outcomes and minimises medication errors (Taxis and Barber 2004; Cousins et al., 2005; Pape et al., 2005; Wrench and Allen, 2006; Crowley, 2006; Avery et al., 2012; Ameer, 2015). Hence, staffing levels should be taken into account by nurse supervisors and institutional management. More studies using more robust methods are required to study whether there is an ideal staffing level for different wards, taking into account the patients' clinical demands (i.e. patient acuity) and shift patterns. Further work is also required to investigate the correlation between the ratio of experienced nurses (registered nurses) within a team and the proportion of IPEs that occur. Patients' clinical demands might also be included in such an analysis.

Good work flow and good strategy when completing the injectable medicine preparation procedure with clear delegation of responsibility for each member of the nursing staff is important to improve safety during preparation. The ward manager must thus consider how to enhance the work flow and work strategy. NHS Lothian has published a workbook entitled Intravenous Therapy and Infusion Devices (NHS Lothian, 2012); this workbook illustrates how a good work flow and good strategy can make the injectable medicine preparation procedure safer. However, further work is also needed to optimise

work strategy according to incidence of IPEs. Good supervision should also be included in that relationship analysis.

As discussed in section 5.6.4, patient consent was not required for this study as it was approved as either service evaluation or audit. However, ethical standards for the conduct of research have increased over the years, so in the future it is possible that a similar study would require patient consent.

6.10 Conclusion

Numerous factors were found to have led to IPEs in the hospital environment; some of these were common to all four-hospital wards, though some were reported only on a specific ward. Several common factors were associated with the nurses themselves, and involved lack of knowledge or experience, lack of concentration, and forgetting to complete tasks. Common error producing conditions (i.e. work environment) associated with IPEs included gross disregard for maintaining a clean and uncluttered IV treatment room, interruptions and distractions, high workloads with few nurses, and lack of commitment or adherence to the NHS Trust guidelines and policy processes.

Lack of materials or equipment and the preparation of injectable medicines outside the IV treatment room (at the nursing station) were contributory factors reported in wards H and B. This issue was also raised in wards S and C, but less often, as the site had a closed treatment room, and provided filter needles and labels. By contrast, there were some other factors that may have increased the occurrence of IPEs in wards S and C,

for example breach of ANTT and insufficient staff education. Numerous strategies were suggested by the nurses to improve safety during injectable medicine preparation tasks. These included developing the nursing team through training and education, particularly of new nurses; and minimising staff stress by ensuring that nurses have sufficient breaks in a quiet relaxing room.

Reporting identified mistakes, and the outcomes of these mistakes, is a key strategy for minimising IPEs. Moreover, enhancing the work environment can help to improve patient safety, for example by facilitating good work flow and good strategy, enhancing communication, and preventing interruptions and distractions. In addition, creating commitment to guidelines and policies, and ensuring clear delegation of responsibility to each member of the nursing team are further significant factors.

Utilising electronic systems, for example an electronic preparation design and electronic incidents reports, is a valuable practical solution for minimising IPEs. Future studies should therefore study the impact of these risk reduction strategies on errors related to injectable preparation in hospital environments.

Table 6.14: Risk-reduction strategies for active failure, EPC, and latent failure to minimise the risk of IPEs in the surgical ward (S)

Type of error	Class of contribution factor	Cause of error	Strategies
Gross disregard for maintaining a clean/uncluttered treatment room S7	Active failure	Violation (i.e. deliberately ignoring policies)	1. Train and inform each nurse to ensure commitment to policy. 2. Signs to indicate that the IV treatment room must be always clean and tidy.
	EPC	Work environment (i.e. high workload)	Setting priorities of work for the nursing team.
	Latent failure	1. Management factor (i.e. poor supervision) 2. Weakness in the system (i.e. poor design of treatment room)	1. Enforce policies and alert staff to clean and tidy the space as they work. 2. Provide a better IV treatment room (i.e. adequate space, lighting, and good layout).

Table 6.15: Risk-reduction strategies for active failure, EPC, and latent failure to minimise the risk of IPEs in the medical ward (C).

Type of error	Class of contribution factor	Cause of error	Strategies
No double check C50andC51	Active failure	Violation (i.e. deliberately ignoring policies)	1. Train and inform each nurse to ensure commitment to policy.
	EPC	Work environment 1. High workload 2. Mental stressors (i.e. destruction/interruption) 3. Team factors (i.e. lone worker)	1. Setting priorities of work for the nursing team. 2. Designation of a quiet room without telephones for preparing and checking products. 3. Plan workforce to ensure adequate staff and skill mix, and assign staff specific responsibilities.
	Latent failure	Management factor (i.e. Poor distribution of work by supervisor)	Create good work flow and good plan/strategy of work, for example: 1. Ensure that two nurses always prepare injectable medicines together. 2. Request a second signature prior to mixing in order to ensure that two nurses check the final product.
No double check C65	Active failure	Lapse The second nurse forgets to check the dose prepared by the first nurse.	1. Independent accuracy check of prepared medicines performed by senior nurse or accredited checking nurses. 2. Posters specifying the need to double check products attached to walls in the checking area (i.e. reminding nurses to check products).
	EPC	Work environment 1. High workload 2. Inadequate staffing 3. Mental stressors (i.e. destruction/interruption)	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels. 3. Checking zone without telephones (quiet room) for preparing and checking products.
	Latent failure	Management factors (i.e. poor allocation of work by supervisor)	As for no double check (C50 and C51).

Continued Table 6.15

Type of error	Class of contribution factor	Cause of error	Strategies
Incorrect addition/ mixing C62andC63 andC64	Active failure	Knowledge- or rule-based mistakes (i.e. lack of education or training) and poor practice	A clear structure instructions on preparation / administration of blood product.
	EPC	Work environment 1. High workload 2. Inadequate staffing Individual factors 1. Lack of skills and knowledge	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels 1. Standardising nurse training and assessing competency of nurses to prepare injectable drugs; induction programmes for new nurses, including nurses who have transferred from a different hospital - should include a procedure for validating competency at each stage of the process of preparing injectable medicines; details of changes in procedures and errors should be disseminated to nurses to ensure they are up to date.
	Latent failure	Management factors (i.e. deficiencies in training, guidance, or education) Weakness in the system defence (i.e. lack of experienced nurses)	Ensuring nurses are familiar with standard operating procedures; standardising the training of nurses; development of validation procedures to ensure that new staff, and those transferring from different hospitals, are competent to work in the IV treatment room. Ensure more experienced nurses are working on the shift; better nurses should rotate on the shift.
Gross disregard for maintaining a clean/uncluttered treatment room C65	Active failure	Knowledge- or rule-based mistakes (i.e. poor practice)	1. Train and inform all nurses of the importance of keeping the IV treatment room always clean and tidy. 2. Signs indicate that the IV treatment room must be always clean and tidy.
	EPC	Work environment 1. High workload 2. Patients' clinical demands	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels.
		1. Management factors (i.e. pressure to complete tasks) 2. Weakness in the system defence (i.e. open window inside IV room)	1. Rotating nurses' duties may reduce the fatigue, stress and risk associated with prolonged task performance; improved workforce planning; prioritisation of workload with products made in advance if appropriate. 2. Designation of a quiet room without windows for preparing injectable medicines.

Table 6.16: Risk-reduction strategies for active failure, EPC and latent failure to minimise the risk of IPEs in the surgical ward (H).

Type of error	Class of contribution factor	Cause of error	Strategies
Apron/gloves not used H183 and H221 and H251	Active failure	Knowledge- or rule-based mistakes (i.e., lack of education or training) and poor practice	Train and inform each nurse to wear apron/gloves; signs to indicate that nurses must wear apron/gloves inside the IV treatment room.
	EPC	Work environment Individual factors 1. Lack of skills and knowledge 2. Involuntary automaticity	1. Standardising nurses' training and assessing nurses' adherence to wearing apron/gloves in the IV treatment room; induction programmes for new nurses; details of changes in policies/guidelines and mistakes should be circulated to nurses to guarantee they are up to date. 2. Enforce nurses' commitment to the policy, enable nurses to attend conferences, and display posters demonstrating the risk of injectable preparation errors.
	Latent failure	1. Management factors (i.e. deficiencies in training, guidance, or education) 2. Weakness in the system defence (i.e. poor design and poor work layout of the IV room)	1. Inform nurses it is a legal requirement to wear apron/gloves when preparing IV drugs; ensuring nurses are familiar with standard operating processes; standardising nurse training. 2. Ensure an appropriate designated room (big room) and separate the nurses from the doctors and computers; the gloves and aprons should be stored in an appropriate place inside the IV treatment room.
Apron/gloves not used H195 and H251	Active failure	Lapse (i.e. nurse forgotten to wear apron and gloves)	Signs/posters stating 'Don't forget to wear apron/gloves while preparing injectable medicines' attached to the walls in the IV treatment room (i.e. remind nurses to wear apron/gloves).
	EPC	Work environment 1. High workload	1. Setting priorities of work for the nursing team.
	Latent failure	Management factors (i.e. poor supervision)	Ward manager should observe staff that they are always wearing apron/gloves, especially in the medicines round.
Apron/gloves not used H219	Active failure	Violation (i.e. deliberately ignoring policies)	Train and inform each nurse to ensure commitment to policy.
	EPC	Work environment 1. Inadequate staffing	Workforce planning to determine adequate staffing levels.
	Latent failure	1. Weakness in system defence (i.e. deviation from guidance)	1. Detailed guidance on the practical side of IV preparation.

Continued Table 6.16

Type of error	Class of contribution factor	Cause of error	Strategies
Faulty labelling H188 and H190 and H207	Active failure	Knowledge- or rule-based mistakes (i.e. lack of education or training) and poor practice	Train and inform all nurses that injections should be labelled immediately after preparation.
	EPC	Work environment 1. High workload Individual factors 2. Lack of skills and knowledge	1. Setting priorities of work for the nursing team. 2. Standardising nurse training and assessing the competency of nurses to prepare injectable drugs; induction programmes for new nurses, including nurses who have transferred from a different hospital - should include a procedure for validating competency at the labelling stage of the process of preparing injectable medicines; details of changes in procedures and errors should be disseminated to nurses to ensure they are up to date.
	Latent failure	Management factors (i.e. deficiencies in training, guidance, or education)	Re-training and ensuring nurses are familiar with the trust policy on the standard operating procedures for labelling IV medications; contacting learning and resource departments for more information regarding training on IV Abs labelling.
Faulty labelling H187 and H247	Active failure	Lapse Nurse forgotten to label the IV antibiotics	Posters/signs explaining IV antibiotics labelling for products to be attached to walls in the IV treatment room (i.e. remind nurses to label IV antibiotics)
	EPC	Work environment Time constraints resulting from high workload (i.e. haste)	Improved work flow/work strategy; prioritisation of workload with products made in advance if appropriate.
	Latent failure	Local work and task conditions (i.e. lack of label or inappropriate label)	Provide labels at the IV treatment room so that labels are easily accessible label.
Faulty labelling H189	Active failure	Violation (i.e. deliberately ignoring policies)	1. Train and inform each nurses to commitment to the policy. 2. Signs indicate that the IV antibiotics must be always labelled.
	EPC	Work environment Mental stressors (i.e. pressure)	Rotating nursing staff duties may reduce pressure/stress and risk associated with prolonged task performance; improved workforce planning; prioritisation of workload with products made in advance if appropriate.
	Latent failure	1. Management factors (i.e. pressure to complete tasks resulting from inadequate staffing levels) 2. Weakness in system defence (i.e. inappropriate label for IV antibiotics)	1. Ensuring there are enough nurses on the shift and nurses are familiar with standard operating procedures. 2. Having easily accessible labels to use.

Continued Table 6.16

Type of error	Class of contribution factor	Cause of error	Strategies
Breach of ANTT Deficient in performing infection control after break in ANTT (plastic tray not used during preparation) H183	Active failure	Knowledge- or rule-based mistakes (i.e. poor practice)	1. Train and inform all nurses on the importance of following ANTT. 2. Signs/posters to show the correct ANTT technique inside IV treatment room.
	EPC	Work environment 1. High workload 2.Patients' clinical demands Teamwork 3. Lack of teamwork	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels. 3. Scheduling staff to undertake specific duties; encouraging healthcare professionals (i.e. doctors, nurses, technicians) to clean trays if they have completed their work.
	Latent failure	1. Local work and task conditions (i.e. lack of equipment or equipment failure) 2. Management factor (i.e. poor supervision)	1. Provide enough trays inside IV treatment room. 2. Ward managers should observe staff to see that they are cleaning the trays, especially the physicians.
Filter needle not used H226 and H240	Active failure	Knowledge- or rule-based mistakes (i.e. lack of education or training) and poor practice	1. Train and inform all nurses on the importance of using a filter needle.
	EPC	Work environment 1. High workload 2. Inadequate staffing	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels.
	Latent failure	Local work and task conditions (i.e. poor layout of cupboards)	Careful design of cupboards such that filter needles are separated or highlighted in different font colours or text styles; ensuring that the filter needle is available in IV treatment room.
Filter needle not used H237 and H243	Active failure	Violation (i.e. from deliberately ignoring the policies)	1. Educate and inform each nurse to ensure commitment to policy. 2. Signs to indicate that the ampoules must be withdrawn by using a filter needle.
	EPC	Work environment Mental stressors (i.e. pressure)	Rotating nursing staff duties may reduce the pressure, stress and risk associated with prolonged task performance; improved workforce planning; prioritisation of workload with products made in advance if appropriate.
	Latent failure	1. Management factors (i.e. deficiency in training, guidance, and education)	Re-training and ensuring nurses are familiar with the NHS Trust policy on the standard operating procedures for the filter needle of injectable drugs

Continued Table 6.16

Type of error	Class of contribution factor	Cause of error	Strategies
Filter needle not used H225	Active failure	Lapse Nurse forgotten to used filter needle	1. Train and inform all nurses on the importance of using a filter needle. 2. Signs/posters highlighting the filter needle on cupboards to remind staff to use a filter needle.
	EPC	Work environment 1. High workload 2. Inadequate staffing Individual factors 3. Lack of skills and knowledge Teamwork 4. Lack of teamwork	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels. 3. Standardising staff training and assessing the competency of nurses to prepare injectable medicines; induction programmes for new nurses, including nurses who have transferred from a different hospital - should include a procedure for validating competency at each stage of the process of preparing injectable medicines; details of changes in procedures and errors should be disseminated to nurses to ensure they are up to date. 4. Scheduling staff to undertake specific duties; encouraging nurses to support other nurses if they need help.
	Latent failure	1. Local work and task conditions (i.e. lack of equipment or equipment failure) 2. Weakness in the system defence (i.e. lack of information or resources) 3. Management factors (i.e. poor supervision)	1. Provide enough filter needles. 2. Ensuring that guidelines and information/resources of filter needle are always in the IV treatment room. 3. Ward manager should observe staff to ensure that they are using the filter needle during preparation.

Table 6.17: Risk-reduction strategies for active failure, EPC, and latent failure to minimise the risk of IPEs in the surgical ward (B).

Type of error	Class of contribution factor	Cause of error	Strategies
Inappropriate location of medicine preparation: Preparing product outside the treatment room in an unsuitable location, such as a nurse station B86 and B118	Active failure	Violation (i.e. deliberately ignoring policies)	1. Educate and inform each nurse to ensure commitment to the policy. 2. Signs to indicate that all injectable medicines must be prepared in the IV treatment room.
	EPC	Work environment 1. High workload related to staff shortage Individual factors 2. Lack of skills and knowledge	1. Setting priorities of work for the nursing team, and workforce planning to determine adequate staffing levels. 2. Standardising nurse training and assessing the competency of nurses to prepare injectable drugs; induction programmes for new nurses, including nurses who have transferred from a different hospital- should include a policy/guidelines for the process of preparing injectable medicines; details of changes in procedures and errors should be disseminated to nurses to ensure they are up to date.
	Latent failure	2. Management factors (i.e. deficiencies in training, guidance, or education)	2. Re-training and ensuring nurses are familiar with the NHS Trust policy on the standard operating procedures for IV medications
Inappropriate location of medicine preparation: Preparing product outside the treatment room in an unsuitable location, such as a nurse station B180	Active failure	Knowledge- or rule-based mistakes (i.e. poor practice)	1. Train and inform all nurses on the importance of preparing all injectable medicines in the IV treatment room.
	EPC	Work environment Time constraints resulting from high workload (i.e. fatigue/tiredness)	Improved workflow/work strategy; prioritisation of workload with products made in advance if appropriate.
	Latent failure	1. Local work and task conditions (i.e. lack of information and sources) 2. Management factor (i.e. poor supervision)	1. Ensuring that guidelines and information/resources are available in the IV treatment room. 2. Ward manager should observe staff to ensure that they are preparing all injectable medicines in the IV treatment room.

Continued Table 6.17

Type of error	Class of contribution factor	Cause of error	Strategies
Faulty labelling B96 and B103 and B106 and B249	Active failure	Knowledge- or rule-based mistakes (i.e. lack of education or training) and poor practice	Train and inform each nurse to ensure adherence to injection labelling; signs to indicate that nurses must label all injectable medicines inside the IV treatment room.
	EPC	Work environment Individual factors 1. Lack of skills and knowledge	1. Standardising nurse training and assessing the ability of nurses to label all injections; induction programmes for new nurses; details of changes in policies/guidelines and mistakes should be circulated to nurses to guarantee they are up to date. 2. Enforce nurses' commitment to the policy, enable nurses to attend conferences, and display posters demonstrating the risk of injectable preparation errors.
	Latent failure	1. Local work and task conditions (i.e. lack of label or inappropriate label) 2. Management factors (i.e. deficiencies in training, guidance, or education)	1, Provide labels for the IV treatment room and make labels easily accessible. 2. Ensure nurses are familiar with standard operating processes; standardise the training of nurses.
Apron/gloves not used B144	Active failure	Lapse (i.e. nurse forgotten to wear apron and gloves)	Signs/posters statin 'Don't forget to wear apron/gloves while preparing injectable medicines' to be attached to walls in IV treatment room (i.e. remind nurses to wear apron/gloves).
	EPC	Work environment 1. High workload 2. Inadequate staffing	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels.
	Latent failure	Management factor (i.e. poor supervision)	Ward manager should observe staff to ensure that they are always wearing apron/gloves, especially in the medicines round.
Apron/gloves not used B126	Active failure	Violation (i.e. deliberately ignoring policies)	Train and inform each nurse to ensure commitment to the policy.
	EPC	Work environment (i.e. high workload)	Setting priorities of work for the nursing team.
	Latent failure	Local work and task conditions (i.e. poor layout of IV room)	Careful design of IV treatment room such that gloves are in the middle of the IV room and away from the sink, doctors, and computers.

Continued Table 6.17

Type of error	Class of contribution factor	Cause of error	Strategies
Deficiency in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by the maker B92	Active failure	Lapse (i.e. nurse forgotten to change the needle, or swabbing with alcohol after a needle touched by the maker)	Signs/posters stating ANTT procedure for the preparation of injectable medicines attached to the walls in the IV treatment room. (I.e. remind nurses to follow ANTT).
	EPC	Work environment 1. High workload 2. Inadequate staffing	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels
	Latent failure	1. Local work and task conditions (i.e. Poor design of IV room) 2. Management factors (i.e. deficiencies in training, guidance, or education)	1. Appropriate space in the IV treatment room (i.e. bigger size and closed room). 2. Ensuring nurses are familiar with standard operating processes; standardising the training of nurses.
Incorrect addition/ mixing B101	Active failure	Knowledge- or rule-based mistakes (i.e. lack of education or training) and poor practice	Clearly structured instructions on the preparation/administration of antibiotics medicines.
	EPC	Work environment 1. High workload 2. Inadequate staffing Individual factors 1. Lack of skills and knowledge	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels. 1. Standardising nurses' training and assessing the competency of nurses to prepare injectable drugs; induction programmes for new nurses, including nurses who have transferred from a different hospital - should include a procedure for validating competency at each stage of the process of preparing injectable medicines; details of changes in procedures and errors should be disseminated to nurses to ensure they are up to date.
	Latent failure	Management factors (i.e. deficiencies in training, guidance, or education) Weakness in the system defence (i.e. lack of experienced nurses)	Ensuring nurses are familiar with standard operating procedures; standardising the training of nurses; development of validation procedures to ensure that new staff, and those transferring from different hospitals, are competent to work in the IV treatment room. Ensure more experienced nurses are working on the shift; better nurses should rotate on the shift.

Continued Table 6.17

Type of error	Class of contribution factor	Cause of error	Strategies
Gross disregard for clean/ uncluttered treatment room B120	Active failure	Knowledge- or rule-based mistakes (i.e. poor practice)	1. Train and inform all nurses on the importance of keeping the IV treatment room clean and tidy. 2. Signs to indicate that the IV treatment room must be always clean and tidy.
	EPC	Work environment 1. High workload 2. Individual factors	1. Setting priorities of work for the nursing team. 2. Workforce planning to determine adequate staffing levels.
		1. Management factors (i.e. pressure to complete tasks)	1. Rotating nurses' duties may reduce the fatigue, stress and risk associated with prolonged task performance; improved workforce planning; prioritisation of workload with products made in advance if appropriate.

Chapter Seven

General Discussion

7.1. Overview

The current study examined the safety of the preparation of injectable medicines in both a pharmacy and ward environment. Firstly, it outlined issues associated with patient safety and iatrogenic injury, i.e. an illness caused by a medication or healthcare. Several guidelines and policies, as well as specified quality and safety organisations, have been established by healthcare agencies and governments to enhance patient safety and healthcare. The key function of organisations (i.e. the NPSA; WHO Patient Safety Programme) is to investigate and evaluate errors, followed by the creation of plans and strategies to reduce such errors. For example, NPSA was created as a guide for a government programme enhancing patient safety and the quality of healthcare, by establishing a national reporting agency for medication errors and launching training programmes resulting from the investigation of these errors (DOH, 2001; NPSA, 2004). Over the previous five years, the main NPSA roles concerning the safety of patients have been transferred to the NHS Commissioning Board Special Health Authority to guarantee an improvement in patient safety and handle problems related to patient safety (NPSA, 2015).

Previous studies of IPEs within the pharmacy and hospital environment revealed the importance of these issues on a global basis. There are a number of fundamental variations in the terms defining IPEs; however the key component remains constant, i.e. that IPEs are associated with the preparation of injectable medications, deviating from the prescribed instructions or the standard procedures for preparation.

Injectable medicines are an important treatment for patients on hospital wards, but are reported as a key cause of errors (Crowley, 2006; Ghaleb et al., 2010; Vogenberg and

Benjamin, 2011; Cousins et al. 2012; NPSA, 2013; Ameer, 2105), despite the fact that many are preventable (Breckenridge, 1976; Bates et al. 1995; Barker et al., 2002; Taxis and Barber, 2004; Keers, 2013). Extensive investigation has been carried out globally to study errors correlated with the practice of medicine or its use within healthcare locations (Leape et al., 1991; Wilson et al., 1995; Vincent et al., 2001; Barker et al., 2002; Taxis and Barber, 2004; James et al., 2008; Morimoto et al., 2010; Poon et al., 2010; Cousins et al., 2012; Rodriguez-Gonzalez et al., 2012). The majority of medication errors take place during prescription, preparation and administration (Crowley, 2006; Ashcroft & Cooke, 2006; NPSA, 2009; Ameer, 2015). Most investigations into such errors have focussed on the prescription and administration phases, with only a limited examination of the preparation stage within a pharmacy and hospital environment. However, preparation errors are common in healthcare organisations, with up to 16,000 preparation errors resulting in patient harm or death being reported to the NPSA in 2009 (NPSA, 2009). This led to a recommendation that concerted efforts should be undertaken to improve the safety of injectable medicine preparations within both the pharmacy and hospital environment. It is therefore vital to identify how and why errors occur.

This thesis is one of the first UK empirical studies to actively investigate errors occurring within this complex domain by highlighting IPEs within a range of aseptic pharmacy processing units and hospital wards throughout the UK. Numerous approaches can be used to detect IPEs, each of which has its own strengths and limitations (see Section 2.3.2). Direct observation was the principle method chosen for this study because it is valid, reliable and effective for collecting data on medication errors (Taxis and Barber, 2001, 2003).

This thesis adopted quantitative and qualitative methods to investigate the incidence, types, severity and causes of IPEs in three pharmacy aseptic production units and four hospital wards. The project comprised three stages. Stage one employed direct observation to investigate the incidence and types of errors, which occurred during the preparation of injectable medicines within aseptic pharmacy unit and hospital clinical area. Stage two assessed the severity of IPEs using a validated method (Dean and Barber, 1999) and calculated a risk score for each error type using consequence and likelihood scores analogous to that used by the NPSA. In Stage Three, staff who made the errors completed questionnaires and semi-structured interviews to assess the causes of these errors and the underlying contributory factors. Data were analysed using a thematic analysis according to the Reason's (1990) model of human error and Vincent et al.'s (1998) framework for accidents in healthcare organisations (Reason, 1990; Vincent et al., 1998).

7.2 Main Findings

Chapter Three of this thesis investigated the incidence, types and severity of IPEs occurring in three different pharmacy aseptic units across the UK. Over a period of twelve weeks, 27 pharmacy employees were observed preparing 997 doses, and 46 internal IPEs were identified. Hence, the incidence of IPEs in this study was 4.6% of the doses observed. This is higher than levels reported in previous UK studies (Bateman and Donyai, 2010), although consistent with a US study (Flynn et al, 1997). One external error occurred at site A. Therefore, the incidence of external errors in this study was 0.09% of the all doses prepared, which is higher than the UK published literature (Bateman and Donyai, 2010). No significant difference was identified between the incidence of internal IPEs at units A, B and C (One away ANOVA, f = 0.1223, p. value

= 0.8891) (see section 3.9.2). The majority of errors (67%) related to cytotoxic products, which may relate to a high number of these products being made by pharmacy aseptic production units.

The IPEs were categorised by type as follows: (1) worksheet errors (52.1%); (2) errors made whilst preparing the final product (26%); (3) errors made during the setup of materials (19.5%); and (4) errors made during the labelling phase (2.1%). Two types of errors (wrong diluent and wrong dose) graded as extreme risk were associated with 10 IPEs. This concurred with the conclusions of the published literature of a need for strategies to prevent the reoccurrence of IPEs in a pharmacy environment. Nevertheless, both the present study and previous studies observed differences in practice and preparation requiring several strategies to ensure IPEs are completely minimised. Only a small number of strategies to reduce IPEs have been identified in the published literature and none were identified within the setting of the three different pharmacy aseptic units. Hence, in order to determine proof of an existing solution, it was important to classify strategies employed nationally for the practices observed in the three pharmacy aseptic units. Consequently, the fourth chapter designed to create strategies to use in the three different pharmacy aseptic units (large unit; small unit and unlicensed unit) to reduce IPEs. Interviews were conducted with nine staff involved in injectable preparation errors across the three participating sites. Interviews were conducted without apportioning blame, enabling staff to express their views openly so that the researcher (AA) could better understand the causes of errors and the underlying contributory factors. The published literature recognises the importance of staff views in understanding errors. This study produced nine overall main themes associated with active failures; EPCs; and latent conditions from the interview data. The themes identified were as follows: (1) slips; (2) lapses; (3) knowledge-based mistakes; (4) the

work environment; (5) individuals; (6) the task; (7) the team; (8) local working and task conditions; and (9) weakness within the defence system. This resulted in numbers of strategies to minimise the errors. On order to priorities these were: (1) improve the layout of storage area (2) the creation of a medicine worksheet; (3) quality improvement of the design of the pharmacy computer system; (4) staff training and knowledge; (5) improve access to guidelines/policies; (6) double checking. These interviews highlighted the difficulties in dealing with IPEs in practice, and demonstrated that a single strategy is insufficient to reduce IPEs in pharmacy aseptic units. When interviewees were asked to categorise defences and barriers for IPEs strategies, their answers could be categorised into factors relating to: (1) individuals; (2) the work environment; and (3) the organisation. This highlights the importance of building a safe work environment and a supportive management/organisation. However, the management and/or an organisation also needs to establish a more organised and appropriate practice for preparing injectable medicines. This evidence has not been revealed by previous studies. For example interviews revealed unsafe activities among management, including: (1) poor layout of the storage area with similar packaged medications located next to each other (2) heavy workload combined with a shortage of staff; (3) poor design of pharmacy computer systems; and (4) inadequate staffing levels. The investigation must therefore go beyond the active failure resulting in the IPE to investigate the related: (1) individual; (2) working environment; (3) team; (4) task; and (5) organisational factors. Human error theory (i.e. Reason's (1990) model of error causation) was used to identify the contributory factors of IPE. These were described by the participants as being primarily related to error producing conditions (EPCs), with the most common being continuous interruptions and distractions. In addition, risks to patients were increased by: (1) a heavy workload; (2) a shortage of

staff; (3) stress/pressure from colleagues or patients; and (4) the education and knowledge of staff.

This thesis also recognises the contributory factors relating to active failures, i.e. (1) selecting an incorrect strength of drug from the shelves to prepare the final product; (2) knowledge-based mistakes, i.e. due to failing to understand the correct number of doses for a paediatric patient; (3) a failure to attach a label to the worksheet; and (4) forgetting to sign the label.

The interviewees were also asked to suggest strategies required to minimise IPEs within their practice. This highlighted: (1) the need for routine training programmes; (2) the improvement of the double-checking system; (3) the improvement of the working environment through the designation of a quiet room; and (4) the separation on storage areas and shelves of drug having a similar appearance or name.

In general, the results of these interviews demonstrated the need for improvements to the system. Some modifications can prove challenging (i.e. planning the workforce), however the study identified the following safety strategies in order of priority to minimise IPEs in the three different pharmacy aseptic units: (1) separating similar packaged medicines on shelf; (2) standardising colour signs for medicines; (3) bar-code verification of medicine/diluent identify at accuracy check; (4) setting work priorities for pharmacy staff; (5) rotating the preparation team responsibilities; (6) enhancing the training programme; (7) careful design of pharmacy computer screens (i.e. programming alerts into computers for potential overdoses); and (8) improvements to double-checking procedures.

Chapter Five of this current study assessed the incidence, type and severity of IPEs in medical and surgical wards at two UK hospitals. Over eight weeks, 66 nurses were observed preparing 1148 doses, with 372 IPEs being noted. Therefore, the incidence of IPE in this study was 32.4% of the doses observed. To put these results in context, recent systematic reviews of studies using the same method have found an error rate of 35% in UK hospitals (McLeod et al., 2013), and 48% worldwide (Keers et al., 2103). There was no significant difference in the incidence of errors between medical and surgical wards (one way ANOVA, f = 0.8706, p. Value (P) = 0.5264).

IPEs were divided into: (1) contamination-related health and safety issues (50.5%); and (2) dose selection and preparation errors (49.4%) which correlated with those found in other UK and international studies (Wirtz et al. 2003; Taxis & Barber, 2003; Cousins et al., 2005; Crowley, 2006). Twelve types of error were graded as extreme risk, and these were associated with 270 IPEs. These findings led the researcher to investigate the causes of these errors and the underlying contributory factors through the completion of semi-structured interviews and self-completion questionnaires (see Chapter 6). Many studies have used a self-reporting database or questionnaire, accompanied by a chart review or direct observation, to establish the causes behind reported, documented or observed errors. As far as the current researcher is aware, three studies conducted in UK and German hospitals used interviews to identify nurses' perceptions of the contributing factors associated with IPEs (Taxis and Barber, 2003; Taxis and Barber, 2004; Crowley, 2006). The NHS has focused some of these issues, e.g. long shifts; electronic prescribing; and increased staffing of inexperienced nurses, in particular in surgical and medical wards. These changes may have improved the safety of medication preparation in the NHS, in conjunction with UK health organisations continuing to use more electronic medication systems.

The qualitative analysis resulted in twelve main themes arising from the questionnaire and interview data. These were: (1) knowledge/rule-based mistakes; (2) lapses; (3) slips; (4) violations; (5) work environment; (6) individuals; (7) patient; (8) task; (8) team; (9) local work- and task-related conditions; (10) weakness in the system defence; and (11) management-related factors. The most common EPCs contributing to preparation incidents in order of priority were: (1) mental stressors (e.g. distractions; interruptions and stress/fatigue at the end of shifts); (2) heavy workload (3) congested workspace; (4) lack of knowledge and experience skills; (5) shortage of staff; (6) Shift patterns/time of day; (7) lack of equipment (e.g. labels for IV bolus, and plastic trays, needles and syringes); (8) poor layout of the working environment (9) lack of familiarity with policies or protocols; (10) insufficient rest break; (11) patient clinically demanding; and (12) poor communication between nurses, or with physicians. Large numbers of these issues have been reported in published literatures as impacting on nurses' concentration and thus contributing to medication errors (Taxis & Barber, 2003; Crowley, 2006; Avery et al, 2012; Keers et al., 2013; Ameer, 2015; James et al, 2016). The nurses were asked to identify defences and barriers in order to help build error prevention strategies. This established the importance of a well-designated treatment room to prepare injectable medicines, along with clean, tidy, uncluttered and appropriate working spaces. These problems should be identified during the design of clinical areas within the hospital, thus enhancing the working environment by: (1) reducing distractions/interruptions; (2) increasing commitment; (3) alleviating staff pressure; and (4) increasing staffing levels.

Seven strategies were proposed to minimise errors on these hospital wards. These were (1) better designated area to prepare injectable medicines; (2) better distribution of work

on the ward; (3) better training for nurses; (4) improved access to guidelines/policies; (5) improved stock of medicine, equipment and materials; (6) improve double checking; and (7) proactive reporting of all errors. A key finding from questionnaires and interviews was a lack of training with injectable medicines among nurses undertaking injectable preparation. The participants reported major variances in training programmes provided at university and hospital levels. Training they get at university, as a student was seen as different to what they receive as a registered and qualified nurse. Moreover the participants stated that the training for injectable medicine preparation in one NHS Trust was delivered either infrequently or not at all. The participants reported that the official training programme at NHS Trust concentrated on very general aspects, with preparation skills subsequently gained by observing nurse members and during practical supervision. The National Patient Safety Agency (in assistance with Skills for Health) have established an efficiency guide outlining the skills required to prepare injectable medications, along with an evaluation guide (NPSA, 2006). Furthermore, the Royal College of Nursing standards for infusion therapy (2016) specified the skills needed by nurses involved in injectable medicines; however, there is no robust procedure to guarantee such skills. These should be employed by the NHS Trust to determine training programme requirements and create written guidelines and procedures and protocols for all phases of the injectable medicine process.

Finally, the results of this hospital study illustrate that injectable medicines graded as extreme-risk for preparation within hospital wards could be prioritised for preparation within pharmacy aseptic units (Breckenridge, 1979; Bateman & Donyai, 2010). Although mistakes can also happen within the pharmacy unit, so a robust double-checking system is an essential stage of the injectable medicines preparation procedure,

ensuring the noting (and thus the prevention) of potential errors. Pharmacy staff preparing aseptic injectable drugs can concentrate completely on the task of preparing the injectable dose, with fewer distractions and interruptions (Crowley, 2006; Beaney, 2010). There are also a number of further strategies to minimise IPEs from reoccurring. This study recommends the following safety strategies to minimise IPEs in hospital wards: (1) to improve the IV treatment room (i.e. closed IV station, temperature control and reduced interruption/distraction; (2) to improve the training programme (i.e. one-to-one training can enhance skills in the preparation of injectable medicines); (3) to implement regular training for nurses; (4) to enforce policies and alert staff of the need to follow the protocol and guidelines; (5) to ensure workforce planning to determine adequate staffing levels; (6) to organise the workplace (i.e. effective work flow and plans/strategies); (7) to ensure an independent check of the accuracy of prepared medicines by senior nurse or accredited checking nurses; (8) the provision of sufficient equipment and materials within IV treatment rooms (e.g. filter needle, labels and plastic trays; (9) the improvement of error reporting and learning from errors. This summary of findings demonstrates that the aims and objectives of this study have been achieved.

7.3 The Study's Contribution to Knowledge

Results from this study have contributed to our understanding of IPEs. A key contribution of the current study is the evidence of unidentified errors occurring in the preparation process, which has not been reported previously in UK studies of medication errors. This may in part be due to the fact that previous studies have often focused on injectable administration errors, although Crowley (2006) examined injectable preparation errors in general, but without any emphasis on those responsible for the error. The present observational study and follow-up interviews or questionnaire

surveys focussed on those making the errors, to provide an in-depth understanding of the causes of injectable preparation errors. Furthermore, the approach used for the observation study was developed from an existing method developed by Crowley (2006). The adoption of such an audit tool in three different aseptic pharmacy units and four hospital wards allowed for a detail comparison of findings both between, and across, study settings. Findings will assist in raising staff awareness and promoting patient safety. A further contribution to knowledge results from the qualitative analysis of error causes using Human Error Theory. Much of the published literature has focused on quantifying of the problem whereas this study has uncovered underlying factors contributing to an injectable medicine preparation error. These include local task factors; team factors; individual factors; the working environment; and organisational factors.

Finally, a significant contribution to knowledge made by this current study is that the severity of errors was assessed using an independent panel of healthcare professionals, used to determine consequence and likelihood scores and calculate a risk score analogous to that used by the National Patient Safety Agency (NPSA, 2009). As far as the current researcher is aware, this is the first study to employ this method. The advantage of this method is that it allows the researcher to focus on errors with the highest scores to develop risk reduction strategies and help prevent their reoccurrence.

This study was unique, because it covered two real environments: (1) pharmacy aseptic units and (2) hospital wards. The investigation of such a real working environment within this complex domain allowed for deep details of comparisons between pharmacy and ward environments. For example: (1) the overall error rate of IPEs in hospital wards was six times more than the aseptic units; (2) breach ANTT; unused apron/gloves were commonly occurred in hospital wards, on the other hand, those errors were not detected

in pharmacy units; (3) pharmacy units were better organised than the hospital wards.

Overall, this study confirmed: (1) the incidence and types of IPEs; (2) their severity; (3) factors associated with the causes of these errors; and (4) the views/opinions and experiences of the preparation team. This study formed preliminary conclusions regarding the extent to which IPEs are a real problem in the pharmacy and hospital environment and findings will assist with the development and implementation of procedures to reduce IPEs in three different aseptic pharmacy units and on two hospital wards. Comparisons made between pharmacy and hospital environments will assist with the development of safer systems.

7.4 Study Limitations

Specific research limitations were noted in each results chapter. More general limitations included a lack of published data or incident reports relating to the impact of IPEs on patients. This information would have proven beneficial in determining the clinical significance of the IPEs that occurred. Furthermore, the generalisability of findings could be influenced by the sample size i.e. the number of staff who participated in the studies and the limited numbers of participating sites. A further potential limitation is the accuracy of the main researcher (AA), who was the sole observer, responsible for recording the preparation processes in the narrow IV treatment room during busy periods. Nevertheless, after being double-checked by the researcher and evaluated again by the supervisors (JL; MJ; LJ) all recorded IPEs were considered valid. In addition, the complete details of each error included in this thesis have been assessed by panel of five healthcare professionals, who were consulted in order to provide additional validation of the results.

A major limitation of this type of study concerns the probability of the influence of the observer on the observed. However, no increase or decrease was identified in the rate of error within the two environments over consecutive observational days suggesting that there was no evidence of the 'Hawthorne Effect' in the current study.

7.5 Future Work

This work has developed risk reduction strategies which could be used in the three different pharmacy units and hospital wards to addressed errors with the highest risk scores. The highest risk scores reported incidents in the three different pharmacy aseptic units described in this thesis consisted of wrong diluent and wrong dose, with many of the drugs reported as being considered extreme risk. Hence, it is recommended that future research should be undertaken to further explore reasons for wrong diluent/wrong dose and to measure the efficiency of interventions. The participants classified poor design of computer software as a common problem contributing to wrong diluent /wrong dose. Computer system weaknesses can be improved by ensuring labels for sound-alike medicines are printed using different fonts and colours and short expiry dates are highlighted. Further research is required to assess whether these strategies can reduce the level of wrong diluent/wrong dose. The observational study described in the hospital environment should be expanded to include all hospital wards, staff grades and night shifts. It is important to measure the influence of nurses' fatigue on medication errors and deviations from practice across hospital wards and during night shifts. Moreover, this current study found that nurses described increased levels of work pressure and stress during their shifts, combined with inadequate breaks. Therefore, further research should be undertaken to investigate the relationship between

the numbers of breaks nurses are able to take during their shifts, accompanied by their recovery levels. This could suggest a minimum number of break periods during a shift to ensure adequate recovery and reduce the influence of long working hours on nurses, as well as the impact of fatigue and the needs of patients. In addition, this study did not investigate the Intensive Care Unit (ICU), despite this being one of the most important units in the hospital, managing patients in a critical condition. Future research is required to explore the causes, incidences, types and severity of IPEs in ICUs.

This current study did not explore the microbial contamination of the prepared injectable medicines. The most frequently reported incident (50.5%) in the hospital study described in this thesis consisted of issues related to contamination, as well as to health and safety, with many of the medicines considered to be extreme risk. Further work is therefore required to investigate the incidence, type, severity and causes of microbial contamination of injectable medicines prepared in the hospital environment.

Finally, this thesis demonstrated the existence of a relationship between the contributing factors to IPEs and has developed strategies for the identified contributing factors. Future work is needed to study, understand, implement and evaluate these strategies in the three different pharmacy units and the two hospital wards. After implementation is important to evaluate its impact and thus complete a cycle of learning (see figure 7.1).

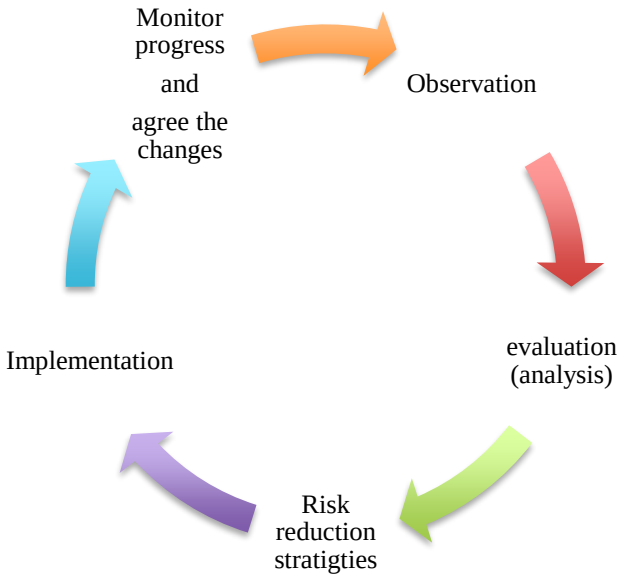


Figure 7.1: The cycle of learning

There are several barriers to implementing these strategies these may include financial constraints; staff resistance (i.e. not easy to change people behaviour); and technology issues (Nanji et al., 2009; Woods et al., 2012).

7.5 Recommendations from this research

This thesis makes a number of specific recommendations, focussing on current strategies, with the potential to assist the minimisation of IPEs in pharmacy and hospital environments, as outlined below. Reference numbers in brackets link recommendations back to the interview or questionnaire response to which they relate.

The Pharmacy Environment

I. Identify similar drugs that are look-alike or sound-alike and alert staff to their presence. Suggestions would include applying tall-man lettering; separating similar drugs on the same shelves and storage areas; colouring the fonts employed for pharmacy shelves, and using warning red label notes (PL1; PL12). This strategy will help to miminise the incidents and is compatible with published literature from a hospital in Wales, which suggested the separation of drugs of similar strength or colour-coded packaging (Crowley, 2006; James et al., 2008; ISMP, 2016).

II. Balance heavy workload within the pharmacy through prioritisation of work undertaken by pharmacy staff (PL11). Successful management can (as discussed above) minimise the incidence of errors during injectable preparation (Raddle, 1982, Limat et al, 2001).

III. Regulating staff training and measuring competency of staff to prepare injectable medicines (including induction programmes for new staff). These should include a process for validating competency at the each phase of the procedure of preparing injectable medicines and full details of modifications in guidelines or policies and errors should be publicised to staff to ensure they are up to date (PL1; PL12). This recommendation is stated by previous studies (Crowley, 2006; James et al., 2008, Bateman and Danyai, 2010, NPSA, 2012) which showed a need to determine a clear training programme for all pharmacy staff, in order to reduce injectable preparation errors for the aseptic unit.

The Hospital Environment

I. To provide a complete training programme for trainees and newly graduated nurses and on-going training for experienced staff. This should ensure they work under supervision until they gain a sufficient level of skill (H195; H226). Similarly, many studies have recommended that comprehensive training, mainly for new nurses, is required to overcome the effects of nurses' lack of knowledge on injectable medicine preparation safety (Taxis and Barber, 2004; Prot et al., 2005; Crowley, 2006; Tang et al., 2007; Brady et al., 2009; Ozkan et al., 2011; Ameer, 2015).

II. To review all medicines, equipment and materials stored in the IV treatment room to ensure all necessary items are available. Then, ensure supplies are regularly topped up (H245, B106, and H243). This recommendation is comparable with those of published literature, where problems about non-use of a filter needle and faulty labelling during injectable drug preparation have been often stated (Taxis and Barber, 2004; Crowley, 2006; Keers et al, 2013; Ameer, 2015).

III. To enhance the work environment in the ward by minimising interruptions and distractions in the IV treatment room, so minimising errors during the preparation of injectable medicines. Interruptions and distractions can be minimised by avoiding unnecessary conversation and unnecessary phone calls, as well as preventing unauthorised staff from entering the IV treatment room (B86; B148). This is comparable to the suggestions made by previous studies to designate IV treatment room, with no telephones, only for preparing and checking injectable medicines (O' Dowd, 2004, Raban and Westbrook, 2014, Ameer, 2015). In

addition, the participants in the present study reported that there should be no interruptions or distractions, as being removed from the task at hand could be unsafe.

IV. To balance the heavy workload in the ward by preventing staff shortages. This can be achieved through efficient organisation of breaks; annual leave; and cover for unpredictable events, for example staff who are sick (B92; H245). This recommendation compatible with various studies reported that an increased number of staff, leads to improved patient outcomes and minimises medication errors (Taxis and Barber 2004; Cousins et al., 2005; Pape et al., 2005; Wrench and Allen, 2006; Crowley, 2006; Avery et al., 2012; Ameer, 2015).

V. To improve safety by ensuring an effective flow of work during the preparation process of injectable medicines and clarifying the responsibilities of each member of the nursing staff (B144; H183; H249). The ward manager must thus consider how to enhance the workflow and work strategy to make the injectable medicine preparation procedure safer (NHS Lothian, 2012).

7.6 Research Output

Conference abstracts:

I. Almatroudi, A., Letchford, J., Jones, M. (2017). Assessment of the risk of injectable drug preparation errors observed in pharmacy aseptic units. Department of Pharmacy and Pharmacology. *International Journal of Pharmacy Practice*, 25 (Supplement 1), p.40.

II. James, K. L., Almatroudi, A., Forbes, N., Letchford, J. and Bateman, R. (2016). A qualitative evaluation of the causes of injectable preparation errors in the pharmacy environment. *International Journal of Pharmacy Practice*, 24 (Supplement 3), p.55.

Reports to research sites to inform them of the results and suggestions for improving their practice:

III. Almatroudi, A., Letchford, J., Jones, M. (2016). Observational study of injectable medicine preparation errors on two ward at Site I. Hospital I.

IV. Almatroudi, A., Letchford, J., Jones, M. (2017). Assessment of the severity of injectable medicine preparation errors previously observed on two wards at Site I. Hospital I.

V. Almatroudi, A., Letchford, J., Jones, M. (2017). Causes of injectable medicine preparation errors previously observed on two wards at Site I. Hospital I.

VI. Almatroudi, A., Letchford, J., Jones, M. (2017). Observational study of injectable medicine preparation errors on two wards at Site II. Hospital II.

VII. Almatroudi, A., Letchford, J., Jones, M. (2017). Assessment of the severity of injectable medicine preparation errors previously observed on two wards at Site II. Hospital II.

VIII. Almatroudi, A., Letchford, J., Jones, M. (2017). Causes of injectable medicine preparation errors previously observed on two wards at Site II. Hospital II.

IX. Almatroudi, A., James, K. L, Letchford, J. (2015). Investigation of errors in the preparation of injectable medicines in the pharmacy aseptic unit C. Pharmacy aseptic unit C.

7.7 Overall Conclusion

Preparation errors concerning injectable medicines are a common concern among staff and patients in both pharmacies and hospitals. Mistakes can result in dangerous outcomes for healthcare providers and, in particular, for the patient, and thus any mistake is unacceptable and avoidance strategies need to be put in place. This study aimed to identify preventable errors and propose strategies to reduce the risk of these errors recurring, thus minimising patient harm and enhancing safety. This investigation employed a mixed methods technique to investigate the incidence, types, and severity of injectable medicines preparation errors at three different pharmacy aseptic units and two hospital wards. The research also explored the causes of these errors and the underlying contributory factors. The observational study of medication preparation practice found a high rate of errors within both pharmacy and hospital environments. The overall results of the observation study are similar to those found in the published literature. Wrong diluent and wrong dose were the highest risk scores of injectable medicine preparation error for the three different pharmacy aseptic units. The highest risk scores of error for the preparation of common injectable medicines for both hospitals consisted of issues related to contamination and health and safety. A panel of five healthcare professionals confirmed that the injectable medicine preparation errors observed in pharmacy aseptic units and on hospital wards could be categorised as errors. After accounting for error frequency, two types of error were graded as posing extreme risk, and seven types of error were ranked as posing a high risk in the three different pharmacy aseptic units. Twelve types of errors were graded as posing extreme risk in four hospital wards. The majority of contributory factors on septic units and hospital wards were: (1) a lack of knowledge; (2) a lack of experience; (3) the presence of look- alike/sound-alike medicines; (4) heavy workload; (5) staff shortages; (6)

pressure/stress; (7) loss of concentration during work; (8) memory block; (8) hurrying through the preparation of injectable medicines with interruptions and distractions. The relative importance of these factors varies between units and wards. Further contributory factors in the pharmacy aseptic unit included prescription ambiguity, while in the hospital ward these consisted of the design of the IV treatment room and workflow. Safety during the preparation of injectable medicines can be improved by concentrating on staff development (i.e. training and education), focussing in particular on new members of staff. Furthermore, safety can be improved by minimising pressure on staff, ensuring that they have a quiet room and a sufficient number of breaks to promote relaxation times during shifts. Moreover, enhancing the work environment can increase patient safety in pharmacy and hospital environments, including: (1) ensuring an effective design of the IV treatment room; (2) enhancing communication between staff members; and (3) preventing interruptions and distractions for the IV preparation team. Additional essential factors include policy commitments and clear responsibilities being set out for each member of staff in the pharmacy and the wards. Further beneficial technical solutions for minimising injectable medicine preparation error include the implementation of electronic systems, i.e. electronic prescriptions and electronic reporting systems.

Further work is need to evaluate the feasibility of the recommended safety strategies and their application in practice. To the best knowledge of the current researcher, this is the first empirical study of its kind to actively investigate errors taking place during the real working environment within this complex domain.

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Appendices

Appendix 1

ETHICAL IMPLICATIONS OF RESEARCH ACTIVITY — **University of Bath**

This template must be completed for all research grant applications and should accompany the University's Research Proposal form (RS1) for approval by the Head of Department.
(Additional departmental information may be incorporated as appropriate, for example from an existing resources form).

Please note that this procedure is intended to help researchers consider ethical implications of research activity. Researchers are responsible for deciding, in conjunction with their departmental guidelines and professional disciplinary standards, whether a more extensive review is necessary.

To be completed by Principal Investigator/Staff member

Brief Title of Project	**Errors in the preparation of injectable medicines in the pharmacy environment**
Names of Principal/other Investigators	Abdulaziz Almatroudi

SECTION 1: COMPLETION FOR ALL RESEARCH

Are there ethical implications concerned with the following general issues? If yes, please provide details below	
1. Data storage (eg Confidentiality, availability, length of storage, etc)	Yes. See box on page 3.
2. Are you free to publish the results? eg Are there any restrictions raised by contractual issues?	Yes
3. Effect on/damage to the environment eg Hazardous waste may be produced; water or air might be polluted; injurious pathogens might be released; damage to ecological systems/habitats	NA

Specific Issues		
4. Does the research involve human participants in any way? (Please note if you are processing personal data you need to tick 'Yes')		Complete only Section 1
	Yes	Complete Sections 1 and 2
5. Does the research involve animals in any way?	No	Complete only Section 1
		Complete Sections 1 and 3

Demonstration of Ethical Considerations
Please outline the ethical issues which will need to be managed during the course of the activity

1) Focus groups with pharmacy staff
2) Observation of pharmacy staff preparing injectable medicines
3) Interviews with pharmacy staff on causes of errors and near-misses in the preparation of injectable medicines

Declarations
I confirm that the statements in Sections 1-3 describe the ethical issues that will need to be managed during the course of this research activity.

Principal Investigator	**Signature:** **Date:**
Second reader *(This will normally be a person external to the project team.)*	**Signature:** **Date:** 6/10/14
Head of Department	**Signature:** **Date:**

Please return this form to your Departmental Research Ethics Officer. (Issues will be monitored for incorporation into an annual departmental report to be submitted to the University Ethics Committee.)

Form EIRA1, Issue 3, 11/5/2010 Page 1 of 4

ETHICAL IMPLICATIONS OF RESEARCH ACTIVITY **University of Bath**

This template must be completed for all research grant applications and should accompany the University's Research Proposal form (RS1) for approval by the Head of Department.
(Additional departmental information may be incorporated as appropriate, for example from an existing resources form).

Please note that this procedure is intended to help researchers consider ethical implications of research activity. Researchers are responsible for deciding, in conjunction with their departmental guidelines and professional disciplinary standards, whether a more extensive review is necessary.

To be completed by Principal Investigator/Staff member

Brief Title of Project	**Errors in the preparation of injectable medicines in the Hospital Clinical Areas**
Names of Principal/other Investigators	**Julie Letchford**

SECTION 1: COMPLETION FOR ALL RESEARCH

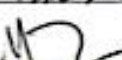
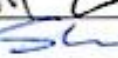
Are there ethical implications concerned with the following general issues? If yes, please provide details below	
1. Data storage (eg Confidentiality, availability, length of storage, etc)	Yes. See box on page 3.
2. Are you free to publish the results? eg Are there any restrictions raised by contractual issues?	Yes
3. Effect on/damage to the environment eg Hazardous waste may be produced; water or air might be polluted; injurious pathogens might be released; damage to ecological systems/habitats.	NA

Specific Issues		
4. Does the research involve human participants in any way? (Please note if you are processing personal data you need to tick 'Yes')		Complete only Section 1
	Yes	Complete Sections 1 and 2
5. Does the research involve animals in any way?	No	Complete only Section 1
		Complete Sections 1 and 3

Demonstration of Ethical Considerations
Please outline the ethical issues, which will need to be managed during the course of the activity.

1) Observation of nurses preparing injectable medicines.
2) Interviews with nurses on causes of internal errors in the preparation of injectable medicines.
3) Self-completion questionnaire to establish the causes of injectable medicine preparation errors in Hospital Clinical Areas.

Declarations
I confirm that the statements in Sections 1-3 describe the ethical issues that will need to be managed during the course of this research activity.

Principal Investigator	**Signature:**  **Date:** 4/12/2015
Second reader *(This will normally be a person external to the project team.)*	**Signature:**  **Date:** 4/12/15.
Head of Department	**Signature:**  **Date:** 4/12/15

Please return this form to your Departmental Research Ethics Officer. (Issues will be monitored for incorporation into an annual departmental report to be submitted to the University Ethics Committee.)

Appendix 2

Assessment of the severity of injectable drug preparation errors previously observed in pharmacy aseptic units and on hospital wards

1.0 Introduction

The preparation of injectable medicines is a complex, high-risk procedure, yet very little is known about preparation errors in UK hospitals. There is a need for investigations that can expand the current understanding of factors influencing injectable drug preparation in UK hospitals and how incidents that threaten patient safety arise.

In 2006, the UK National Reporting and Learning System (NRLS) received 9,000 reports of medication safety incidents related to injectable drugs. That year, injectable drugs accounted for 53% of patient mortality or harm due to medication errors (NPSA, 2006). In response, the UK NPSA published a report called 'Patient Safety Alert 20: Promoting the Safer Use of Injectable Medicines' (NPSA, 2007). In this context, an injectable preparation error is defined as "the preparation of an injectable medication that deviates from the prescription, manufacturer's guidelines, nationally or locally agreed-upon policy, procedure, or guidance, or generic standards for clean or aseptic preparation" (Crowley, 2006,). This study will adopt this same definition to enable a direct comparison of injectable drug preparation errors. By using Crowley's study in particular, this protocol can take advantage of that study's links with Patient Safety Alert 20 (Crowley, 2006).

An in depth assessment of errors can help to identify strategies to prevent similar errors happening in the future and thus improve patient safety. In response, this project will investigate the severity of injectable drug preparation errors recorded in pharmacy aseptic units and on hospital wards during previous observations.

This project focuses on internal errors, or near misses that occurred during the preparation of an injectable medicine. These were discovered during the work process before the medication had been delivered to the hospital bedside for patient use.

The median internal error rate recorded following observations at three different pharmacy aseptic units was 4.2%, which is higher than that (0.49%) reported in previous UK studies (Bateman & Donyai, 2010). This difference could be related to the methods used in their study. For example, Bateman and Donyai (2010) used incidence report details of internal errors from the UK National Aseptic Error Database. Also, self-reporting depends on staff knowledge that an error has happened, which can be affected by the staff being unaware of the reporting process or being hesitant to report errors for fear of being blamed. On the other hand, the result of median internal error rate in this research is consistent with a study by Flynn et al. (1997) in the US, which reported a median internal error rate of 5% in five US hospital pharmacies. The similar error rate may result from use of the same method (direct observation) in both sets of research.

A total of 46 internal errors were observed at three different pharmacy aseptic units; approximately 90% of these occurred during the preparation of chemotherapy medicines and monoclonal antibodies (MABs). Most errors occurred on the worksheet, the most common being failure to record the syringe volume. Errors were also commonly reported during set up and labelling; during set up of materials, the most common error was an incorrect quantity of syringes and during labelling, the most common error was incorrect batch number of starting materials. Errors were also recorded whilst preparing the product, which included wrong starting materials and wrong diluents. An observational study on clinical wards at two different hospitals will be performed shortly.

1.1 Aims

I. To confirm that the injectable drug preparation errors observed in pharmacy aseptic units and on hospital wards can be classified as errors.
II. To rank the severity of injectable drug preparation errors observed in pharmacy aseptic units and on hospital wards on a scale of 0-10.

Errors with the highest severity ranking will provide a focus for developing strategies to help prevent these types of mistakes from happening again.

2.0 Research Method

This project will employ a visual analogue scale to rank the severity of medication errors. This is simple to use and familiar to most healthcare professionals (Dean & Barber, 1999; Taxis & Barber,

2002). This method of assessing the potential of severity has been used previously by the General Medical Council for prescribing errors in primary care settings (Avery et al., 2012). It was initially developed by Dean and Barber (1999) specifically to assess the severity of medication errors without knowing the patient outcomes. This method of assessing the potential of severity was selected since it was found to be valid and credible (Taxis & Barber, 2002; Ameer, 2015). Dean and Barber (1999) suggested that, when the severity of medication errors is scored by each of four experienced healthcare professionals on a scale of 0 to 10, the mean score for each error can be used as a reliable index of severity. This was the first reliable, validated scoring method of assessing the severity of medication errors for which patient outcomes are not known. Their statistical analysis showed that, if any four reviewers from a panel of 30 experienced U.K. pharmacists, medical staff, and nursing staff were used; their mean scores would be generalisable to any other four reviewers selected from the same panel. Furthermore, the scoring method was valid because errors with known outcomes were included in the errors to be ranked, and the scores given for these medication errors reflected the severity of these outcomes.

This study will employ an independent panel technique to collect the opinions of healthcare professionals through two on-line questionnaires. The panel will comprise five experts: two physicians (a general physician and an oncologist), two pharmacists (a clinical pharmacist and an aseptic pharmacist), and one senior nurse. The research team will select the panel based on their area of clinical expertise. Each member will be invited to complete two questionnaires, one for observations previously reported as errors in pharmacy aseptic units (Questionnaire A; Appendix X) and the other for observations previously reported as errors on hospital wards (Questionnaire B; Appendix X). Each member of the panel will be given a description of the observation, and asked to agree or disagree that each observation was an error using definitions adapted from a previous study (Crowley 2006). An agreement of opinion among three of the five judges will be considered consensus (Ameer, 2015). Then, they will be asked to rank the severity of each injectable drug preparation error in terms of its potential to cause clinical patient harm on a scale of zero to ten: A mean score between 1 and 3 indicates a low level of harm, a score between 4 and 6 is a moderate level of harm, a score between 7 and 9 is severe harm, and a score of 10 indicates the potential for death. As all errors recorded previously did not reach the patient, the actual patient outcome of these errors is unknown. However, a small number of errors (approximately 10% if the total) with a known patient outcome will be included to validate the method in our hands. The panel members will not be aware of which these errors are.

Panel members will be invited to take part in the study by an email from the researcher. This is a well-established method for obtaining data on error severity (Dean & Baber, 1999; Taxis & Barber, 2002; Avery et al., 2012; Ameer, 2015). The email (Appendix Y) will introduce the purpose of this study, outline the overall aims and objectives and explain that the panel participants will be expected to do; this protocol and the questionnaires will be included, as attachments and contact details for the research team will be provided in case participants have any questions. As the hospital study is on-going, panel members will receive and complete the questionnaires A and B at different times. Each questionnaire is expected to take approximately two hours to complete and panel members who agree to take part will be expected to return their completed questionnaires to the researcher via email within two weeks. On receipt of each completed questionnaire, panel members will receive a £50 gift voucher of their choice (e.g. Amazon, Love2Shop, etc.). All questionnaire responses will be confidential to prevent the disclosure of information in any research report that could be linked to individual participants.

2.1 Data Analysis

The project will use a validated scale to assess the potential clinical harm of errors in preparing injectable medicines (Dean & Baber, 1999; Taxis & Barber, 2002; Avery et al., 2012). A coding framework will be developed for the severity questionnaire, and coded data will be entered into the Statistical Package for the Social Sciences (SPSS). Validation of errors will be based on the judgement that three out of five will be taken as consensus. The severity score will be based on the mean. The mean panel severity score will be calculated and used on an index of severity. If a panel member says an incident is not an error, it will be assumed that they would give it a severity score of zero. Furthermore, the panel members will have direct access to the findings of this study. The new error rate after the panel members have reviewed errors will be calculated as defined by Allan and Barker (1990), as summarised below:

- **Calculation used for new error rate (%):**

  The equation for this rate is: Number of types of new internal errors (incorrect in at least one way) × 100 / Number of observations

3.0 Ethical approval

Ethical approval for this research was obtained from the University of Bath's Research Ethics procedure.

3.1 Data storage

Raw data will be securely retained for five years before secure destruction. Analysed data will be anonymised.

4.0 Study funding

The author received an award from the government of Saudi Arabia to fund his doctoral study.

Contacts for further information

If you have any questions or concerns about the study, then please contact:

Dr. Julie Letchford	J.A.Letchford@bath.ac.uk	01225 38 6729
Dr. Matthew Jones	M.D.Jones@bath.ac.uk	01225 38 3829
Mr. Abdulaziz Almatroudi	aa687@bath.ac.uk	07972 03 7701

References

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Assessment of the severity of injectable drug preparation errors previously observed in pharmacy aseptic units and hospital clinical areas

Dear Healthcare Professional,

My name is Abdulaziz Almatroudi and I am a PhD candidate in the Department of Pharmacy at the University of Bath. I would like to invite you to complete an email questionnaire to assess the severity of some injectable drug preparation errors that occurred during a previous observational audit in pharmacy aseptic units and hospital wards, to help reduce the possibility of these errors from happening in the future. The specific aim of the severity questionnaire is to focus on the errors with the highest ranking and develop strategies to prevent these types of mistakes from happening again. I would be very grateful if you could volunteer to take part in this study, and to thank you for your time, you will be sent a £50 gift voucher of your choice (e.g. Amazon, Love2Shop. Etc.) Once you have completed the questionnaire.

If you decide to participate, please complete the attached questionnaire, which should not take longer than two hours, and return it by email to the researcher at (aa687@bath.ac.uk) within two weeks. Participation is entirely voluntary and the obtained data will be kept confidential.

The results of the study will be published or presented at meetings, but the data will be kept anonymous. Thank you very much for your cooperation and participation in this study.

If you have any queries, please contact:

Dr. Julie Letchford: J.A.Letchford@bath.ac.uk Tel 01225 386729
Dr. Matthew Jones: M.D.Jones@bath.ac.uk Tel 01225 383829
Mr. Abdulaziz Almatroudi (Researcher): aa687@bath.ac.uk Mobile [redacted]
Kind regards,
Abdulaziz Almatroudi

Questionnaire A: An assessment of the severity of injectable drug preparation errors previously observed in pharmacy aseptic units

This questionnaire requires you to make judgements about observations, previously recorded as errors in pharmacy aseptic units. Results will provide important data for my PhD thesis, which investigates injectable drug preparation errors. Specifically, it will enable the project team to focus on errors with the highest ranking, in order to put forward strategies to help prevent these types of mistakes from happening again. The tables on the following pages contain a description of each observation, previously recorded as an error. Please state whether you agree or disagree that each observation was an error using definitions adapted from a previous studies (Crowley 2006; Ghalab et al, 2010; NAERS, 2016), by clicking on the appropriate box. Then, rank the severity of each injectable drug preparation error in terms of its potential to cause clinical patient harm on a scale of zero to ten, by clicking on the appropriate box. A score of zero indicates no harm at all and a score of 10 indicates a potential for patient death. The questionnaire should take you less than two hours to complete. Once you have completed the questionnaire, please save the document and return the questionnaire to the researcher (aa687@bath.ac.uk) by email within two weeks. All data collected in this questionnaire will be will be analysed within the Department of Pharmacy and Pharmacology at the University of Bath. It will **treated confidentially and anonymised before publication**.

If you have any further queries, please contact:

Dr. Julie Letchford: J.A.Letchford@bath.ac.uk Tel 01225 386729
Dr. Matthew Jones: M.D.Jones@bath.ac.uk Tel 01225 383829
Mr. Abdulaziz Almatroudi (Researcher): aa687@bath.ac.uk Mobile [redacted]

Thank you for completing this questionnaire.

References:

Crowley C. (2006). Investigating intravenous medication preparation errors in hospital clinical areas. Doctoral thesis. Welsh School of Pharmacy, University of Wales, Cardiff.

Ghaleb, M. A., Barber, N., Franklin, B. D., & Wong, I. C. (2010). The incidence and nature of prescribing and medication administration errors in paediatric inpatients. Archives of Disease in Childhood, 95(2), 113–118.

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Ref: PL1	**Prescribed medicine:**	**Description of potential error**
Using the following error definition, do you consider this observation to be an error?		☐ Yes ☐ No
Please click the level of potential clinical patient harm	**Level of potential clinical patient harm** No harm ——— Death ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10	

Questionnaire B: An assessment of the severity of injectable drug preparation errors previously observed on hospital wards

This questionnaire requires you to make judgements about observations, previously recorded as errors on hospital wards. Results will provide important data for my PhD thesis, which investigates injectable drug preparation errors. Specifically, it will enable the project team to focus on errors with the highest ranking, in order to put forward strategies to help prevent these types of mistakes from happening again.

The tables on the following pages contain a description of each observation, previously recorded as an error. Please state whether you agree or disagree that each observation was an error using definitions adapted from a previous study (Crowley 2006), by ticking the appropriate box. Then, rank the severity of each injectable drug preparation error in terms of its potential to cause clinical patient harm on a scale of zero to ten, by ticking the appropriate box. A score of zero indicates no harm at all, a score of between 1 and 3 indicates a low level of harm, a score between 4 and 6 indicates a moderate level of harm, a score between 7 and 9 indicates severe harm, and a score of 10 indicates a potential for patient death.
The questionnaire should take you less than two hours to complete. Once you have completed the questionnaire, please save the document and return the questionnaire to the researcher (aa687@bath.ac.uk) by email within two weeks. All data collected in this questionnaire will be will be analysed within the Department of Pharmacy and Pharmacology at the University of Bath. It will **treated confidentially and anonymised before publication**.

If you have any further queries, please contact:

Dr. Julie Letchford: J.A.Letchford@bath.ac.uk Tel 01225 386729
Dr. Matthew Jones: M.D.Jones@bath.ac.uk Tel 01225 383829
Mr. Abdulaziz Almatroudi (Researcher): aa687@bath.ac.uk Mobile [redacted]

Thank you for completing this questionnaire.

Ref: PL1	**Prescribed medicine:**	**Description of potential error:**
Using the following error definition, do you consider this observation to be an error?		☐ Yes ☐ No
Please click the level of potential clinical patient harm	**Level of potential clinical patient harm** No harm — Death ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10	

Appendix 3

CARDIFF AND VALE UNIVERSITY LOCAL HEALTH BOARD

HONORARY CONTRACT

Name:	**Abdulaziz Almatroudi**
Position:	**Postgraduate Student**
Dept/Directorate:	**Pharmacy Department,** **St Mary's Pharmaceutical Unit, Fieldway** **Directorate of Pharmacy and Medicines Management**
Date of Commencement:	**1st June 2014**
Date of expiry of Contract:	**1st August 2014**
Responsible to:	**Mr Paul Spark**

1. Standards of Conduct

You are required to ensure that your conduct and practice whilst at work are of the highest standard at all times, ensuring that any work you undertake is carried out in line with the agreed protocols, ensuring the integrity and confidentiality of patient, clinical and other records, and for reporting any events, incidents or misconduct through the appropriate systems, in line with UHB policy.

This includes complying with the appropriate code of conduct pertaining to your chosen profession.

Certain offences constitute unacceptable behaviour and must not be committed. You are required to observe the rules of behaviour that apply to all UHB staff, and any breach of these rules may lead to disciplinary action up to and including withdrawal of your honorary contract in accordance with section 2 below.

2. Discipline

All cases of alleged misconduct will be referred back to your **Employer / Academic Body** for the appropriate action. However, in cases of serious misconduct, the UHB reserves the right to suspend your placement pending the outcome of any investigation. Any student found guilty of a serious breach of conduct or rules will have their honorary contract withdrawn.

You should be aware of your **Employer / Academic Body's** policy for dealing with misconduct.

3. Confidentiality

At Cardiff and Vale University Local Health Board, we strive to provide the best quality care for patients and the highest standard of service to staff and managers. Respect for the confidential nature of personal information is fundamental to both these aims. Therefore, all information and matters of a confidential nature must not be divulged or passed on to an unauthorised person(s) or a third party under any circumstances, either during or after your placement with the UHB. Confidential information may therefore only be divulged in the proper course of your work undertaken during your placement or as required by law, by the UHB or both. Such matters will include without limitation:

- clinical and patient identifiable information, including all and any details relating to the treatment and care of patients;
- all and any personal information, including for example employees' confidential records;
- all and any business and commercial information, including for example, details of contract prices and terms.

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Hywel Dda
University Health Board

Ein cyf/Our ref:
Gofynnwch am/Please ask for: Ceri Williams, Workforce & ODManager
Rhif Ffôn /Telephone: 01267 227775
Ffacs/Facsimile: 01267 221978
E-bost/E-mail: Ceri.Williams10@wales.nhs.uk

Adnoddau Dynol
Ysbyty Glangwili, Heol Dolgwili, Caerfyrddin
Sir Gaerfyrddin, SA31 2AF
Rhif Ffôn: 01267 235151

Human Resources
Glangwili Hospital, Dolgwili Road,
Carmarthen, Carmarthenshire, SA31 2AF
Tel: 01267 235151

24 October 2014

[redacted]

Dear Mr Almatroudi

Re: Honorary Contract

Please find enclosed two copies of your Honorary Contract. I would be grateful if you could sign both copies returning one copy to The Human Resources Department, Glangwili General Hospital, Carmarthen, SA31 2AF and retain one copy for your own reference.

Yours sincerely

Avril Williams

pp **CERI WILLIAMS**
WORKFORCE MANAGER

Enc 2 copies of Honorary Contract

Hywel Dda Health Board

HONORARY CONTRACT

This statement sets out details of the main terms and conditions of your honorary contract with the Hywel Dda Health Board (herein referred to as the Health Board) in accordance with the requirement of the Employment Rights Act 1996.

NAME: [redacted]

ADDRE [redacted]

JOB TITLE: Observer @ Aseptic Services in Pharmacy

PLACE OF WORK: Pharmacy, West Wales General Hospital, Glangwili, Carmarthen, SA31 2AF

PERIOD OF HONORARY CONTRACT

10 November 2014 – 5 December 2014

HOURS OF DUTY:
Your recognised hours will be **08:45 – 11:45 am**

The Health Board reserves the right to alter working hours or working arrangements upon reasonable notice, following discussion, as the needs of the Health Board may dictate.

RESPONSIBLE TO: Andrew Daniel (Aseptic Services Manager)

ANNUAL LEAVE/PUBLIC HOLIDAYS
Leave from your honorary contract may be granted following approval by the person that you are responsible to or her deputy.

You will be entitled to take statutory holidays.

Appendix 4

Participant Information Leaflet.
Errors in the Preparation of Injectable Medicines in the Pharmacy Environment

You are being invited to take part in a research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read this information sheet. If there is anything that is not clear, if you would like more information or if you have any queries, please contact with the researcher. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this information sheet.

What is the purpose of the study?

Patient safety is paramount within healthcare as increasing numbers of patients are harmed by medical treatment. Injectable medicines have been identified as high risk of medication errors (NPSA, 2007). Between January 2005 and June 2006, the UK National Reporting and Learning System (NRLS) received 800 reports a month on medication safety incidents involving injectable medicines. These incidents accounted for 24% of all medication safety incidents (NPSA, 2007). Injectable medication errors accounted for 62% of incidents resulting in severe patient harm and death (NPSA, 2009). Consequently, the UK National Patient Safety Agency published Patient Safety Alert 20: Promoting the Safer Use of Injectable Medicines (NPSA, 2007).

Injectable medicines are unique in that they often require preparation in the clinical setting prior to administration to the patients. An analysis of 14,228 medication safety incident reports involving injectable medicines revealed that 10% of errors occurred during the preparation of injections (NPSA, 2007). The majority of UK research on preparation errors has evaluated both the preparation and administration of injectable medicines by nurses in the ward setting. However, very little is known about preparation errors in pharmacy aseptic production units. This study aims to gain an in-depth understanding of the process, incidence, types and causes of internal error and external error so that effective risk reduction strategies can be developed and implemented within pharmacy aseptic units to safeguard patient safety.

Why have I been chosen to participate?

Any member of pharmacy staff who is involved in the preparation of injectable medicines in the pharmacy environment is suitable for inclusion in the study. It is vital that injectable preparation errors are investigated to gain an in-depth understanding of their incidence. By sharing your experiences of preparation errors, an in-sight into the process of will be gained. This will enable the identification and implementation of strategies for minimising preparation errors.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw from the study at any time without giving a reason.
If you decide not to participate in the study, you are likely to be observed by the researcher present in the aseptic unit but your activities will not be documented. All activities witnessed by the researcher will be kept confidential.
Deciding not to take part or withdrawing from the study will not affect your employment in any way.

What would happen to me if I take part?

Over a period of four weeks, a researcher will be present in the aseptic unit observing the process of preparing injectable medicines. Any mistakes in the preparation of the injections that are observed by the researcher will be noted on an anonymous, standardised data collection form. This observation will enable the determination of the number and type of mistakes that happen during the preparation of injectable medicines in the pharmacy environment. The researcher is interested in mistakes occurring at worksheet preparation, label generation, assembly, and manufacture/preparation, packaging and final release. The researcher is only interested in internal errors i.e. mistakes that detected and reported during the preparation process, before the medication is released to the patient/ward.

If you are involved in a mistake during the preparation process, the researcher will invite you to take part in a short interview. The confidential interview will take approximately 15 to 20 minutes. The interview will take place at a time and location that is most convenient for you but as soon as possible after the mistake occurred. The purpose of the interview is to explore how the mistake occurred, what factors contributed to the mistake and what strategies could be implemented to prevent the mistake from happening again. With your permission, the researcher will audio-record the interview.

All data collected by the researcher, as part of the study is strictly confidential. Data from the interviews will be anonymised during data analysis. It will NOT be possible to link information used in the research report back to you.

What are the possible benefits of taking part?

This study will gain an in-depth understanding of the incidence, types and causes of mistakes occurring during the preparation of injectable medicines in the pharmacy environment. It allows pharmacy staff involved in the preparation of injectable medicines to share their experiences and suggestions for improvement. The findings will enable the development of strategies for minimising the risk of preparation errors, thereby improving patient safety.

The study findings will be useful for all UK hospitals but particularly for participating hospitals as these departments will receive feedback to allow them to act on issues identified.

What happens when the research study stops?

The pharmacy department is keen to learn of areas where practice in the preparation of injectable medicines can be improved and will welcome any comments or suggestions. These should be directed to the manager for technical services at your hospital pharmacy.

What if something goes wrong?

If taking part in this research harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you have a concern about any aspect of the study, the way you've been approached and treated during the course of this study, you should speak with the researcher who will do their best to answer any questions. If you remain unhappy and wish to complain formally, the normal National Health Service complaints procedures are available to you. Details can be obtained from the hospital.

Would my taking part in this study be kept confidential?

All information that is collected about you during the course of the research study is kept strictly confidential. The forms used by the researcher to record mistakes are anonymous. In addition, the interviews are confidential and the researcher will anonymise the data collected. All data collection forms will be stored securely at the University of Bath.

What would happen to the results of the research study?

Individuals will not be identified in any report or publication. The findings will be shared across hospital pharmacy departments to improve patient safety. It is hoped to publish and/or present at national level so all information gained is shared widely. If you would like a copy of any resultant publication, you will be sent one.

Who is organising the research?

The research is being organised by Dr Lynette James, Dr Julie letchford and Abdulaziz Almatroudi (University of Bath) the research team are providing their time and expertise free of charge.

Contacts for further information.

Should you have any further questions, or would like to enquire further please contact Abdulaziz Almatroudi or by either e-mail or phone number between 9am-5pm Monday to Friday.

Abdulaziz Almatroudi: aa687@bath.ac.uk; [redacted]

If you are happy to participate in this study, please complete the attached consent form and return them to the researcher based in your pharmacy department.

Thank you for reading this information sheet, which is yours to keep.

Appendix 5

Consent Form

Errors in the Preparation of Injectable Medicines in the Pharmacy Environment

Name of Researcher: Abdulaziz Almatroudi

You are provided with two copies of this consent form. Both forms should be returned to the researcher based in your pharmacy department. A copy signed by the researcher will be returned for you to keep. The second copy will be to Abdulaziz Almatroudi for secure storage.

Please initial box

1. **I have read and understand the information sheet (version1) for the Above study and have had the opportunity to ask questions.** ☐

2. **I understand that my participation is voluntary and that I am free to Withdraw at any time, without giving any reason, without my standing Or employment within the Trust or legal rights being affected.** ☐

3. **I agree that what I say during the interviews can be used, anonymously, In the presentation of the research.** ☐

4. **I agree to take part in the above study.** ☐

Please DO/DO NOT (delete as appropriate) send me a report on the results of this research project.

Address for those requesting a research report
……..

……

……

……

……. ……

Name of pharmacy staff **Signature**
Date

……. ……

Name of researcher **Signature**
Date

Appendix 6

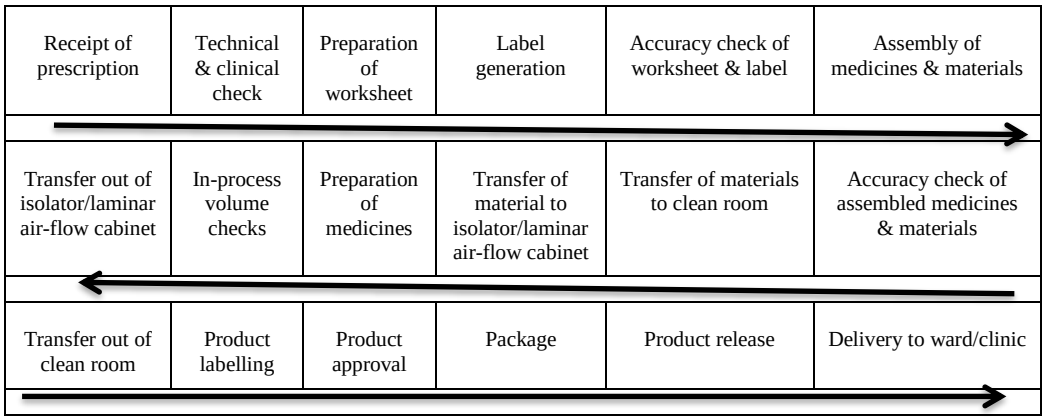


Figure: The process of preparing injectable medicines, from (James & Bateman, 2013)

Appendix 7

Transcribing Errors – RX to Worksheet					
Patient identifier		Staff identifier		No. Preparations completed	
Preparation type	❑ Parenteral nutrition	❑ Chemotherapy	❑ Other (please specify)		
Preparation phase		Preparation start time	……..hrs……..min	Preparation end time	……..hrs……..min
Observer name		Aseptic unit name/code			
Wrong patient name/identifier	❑(Please specify)		Wrong drug name	❑ (Please specify)	
Incorrect calculation of dose(s)	❑(Please specify)		Was this a:	❑ Rounding error	❑ Arithmetic error
Dose calculation method	Calculator	Pen/paper	In head only		
Wrong volume of diluent	❑(Please specify)		Inappropriate diluent	❑(Please specify)	
Incorrect batch number	❑(Please specify)		Error in logging information into batch record	❑(Please specify)	
Incorrect directions for administration	❑(Please specify)				

Labelling Errors					
Patient identifier		Staff identifier		No. Preparations completed	
Preparation type	Parenteral nutrition	Chemotherapy	Other (please specify)		
Preparation phase		Preparation start time	……..hrs……..min	Preparation end time	……..hrs……..min
Observer name		Aseptic unit name/code			
Wrong patient name/identifier	❑(Please specify)		Wrong drug	❑(Please specify)	
Incorrect strength of product	❑(Please specify)		Incorrect quantity of product specified	❑(Please specify)	
Wrong dosage information	❑(Please specify)		Missing dosage information	❑(Please specify)	
Wrong batch number	❑(Please specify)		Missing batch number	❑(Please specify)	
Incorrect directions for administration	❑(Please specify)		Wrong storage information	❑(Please specify)	
Wrong expiry date	❑(Please specify)		Missing expiry date	❑(Please specify)	
Missing necessary warnings/precautions	❑(Please specify)		Warnings/precautions not applicable	❑(Please specify)	

Setup Errors (1)					
Patient identifier		Staff identifier		No. Preparations completed	
Preparation type	Parenteral nutrition	Chemotherapy	Other (please specify)		
Preparation phase		Preparation start time	……hrs……min	Preparation end time	……hrs……min
Observer name		Aseptic unit name/code			
Wrong drug	❑(Please specify)		Wrong strength	❑(Please specify)	
Incorrect number of vials to make product	❑(Please specify)				
Wrong diluent	❑(Please specify)		Incorrect strength of diluent	❑(Please specify)	
Incorrect volume of diluent	❑(Please specify)				
Incorrect number of syringe(s) provided	❑(Please specify)		Incorrect volume of syringe(s) provided	❑(Please specify)	
Filters required but not provided	❑(Please specify)		Incorrect number of needles provided	❑(Please specify)	
Incorrect number of swabs provided	❑(Please specify)				

Setup Errors (2)					
Patient identifier		Staff identifier		No. Preparations completed	
Preparation type	Parenteral nutrition	Chemotherapy	Other (please specify)		
Preparation phase		Preparation start time	……hrs……min	Preparation end time	……hrs……min
Observer name		Aseptic unit name/code			
Is all equipment sprayed/wiped before entering clean room	❑ Yes	❑ No	If "No" please specify cases where spraying/wiping was omitted		
Are spraying/wiping activities adequate/sufficient	❑ Yes	❑ No	If "No" please specify how spraying/wiping was inadequate/ insufficient		
Do checks occur?	❑ Yes	❑ No	If "No" please specify omitted checks		
Are product checks adequate/appropriate?	❑ Yes	❑ No	If "No" please specify problem(s) with checks		
Wrong batch number	❑ Yes	❑ No	Missing batch number	❑ Yes	❑ No
Are drugs within expiry date range?	❑ Yes	❑ No	If "No" please specify discrepancy		
Are diluents within expiry date range	❑ Yes	❑ No	If "No" please specify discrepancy		
Signature omitted	❑ Yes	❑ No			

Errors in making the product					
Patient identifier		Staff identifier		No. Preparations completed	
Preparation type	Parenteral nutrition	Chemotherapy	Other (please specify)		
Preparation phase		Preparation start time	……..hrs…….. min	Preparation end time	……..hrs……..min
Observer name		Aseptic unit name/code			
Wrong drug	❑(Please specify)		Wrong drug strength	❑(Please specify)	
Wrong quantity of drug	❑(Please specify)		Wrong diluent	❑(Please specify)	
Wrong diluent concentration	❑(Please specify)		Wrong volume of diluent	❑(Please specify)	
Incorrect/Inappropriate method of preparation	❑(Please specify)		Is all equipment sprayed/wiped before entering hatch?	❑ Yes	❑ No
Were filters used as specified?	❑ Yes	❑ No	If "No" please specify problem with use of filters		
Were final volume checks conducted?	❑ Yes	❑ No	Were all tops of vials swabbed?	❑ Yes	❑ No
Were final volume checks appropriate?	❑ Yes	❑ No	If "No" please describe final volume checks and specify how they were inappropriate		
Were drug identity checks conducted	❑ Yes	❑ No	Signatures included for:	❑ Product maker	❑ Packager
Was label attached to final product?	❑ Yes	❑ No	If "Yes" was the label appropriately positioned	❑ Yes	❑ No
If product placed in two bags to protect from light, were labels attached to both bags?				❑ Yes	❑ No

Final checks						
	Patient identifier		Staff identifier		No. Preparations completed	
	Preparation type	Parenteral nutrition	Chemotherapy	Other (please specify)		
	Preparation phase		Preparation start time	……..hrs…….. min	Preparation end time	……..hrs ……..min
	Observer name		Aseptic unit name/code			
	Empty vials not counted/checked	❑ (Please specify)				
	Was final product visually inspected	❑ Yes	❑ No	If "Yes" was visual inspection adequate?	❑ Yes	❑ No
Did pharmacist check RX for:	Patient name/identifier	❑	Dosages	❑	Drug(s) used	❑
	Preparation method	❑	Diluent	❑	Diluent strength	❑
	Batch number	❑	Formulation	❑	Number of filters	❑
Did pharmacist check label for:	Patient name/identifier	❑	Dosages	❑	Drug(s) used	❑
	Preparation method	❑	Diluent	❑	Diluent strength	❑
	Batch number	❑	Formulation	❑	Number of filters	❑

Appendix 8

National Aseptic Error Reporting Scheme reporting categories

Licensed Status

A	Section 10, individual patient non-licensed unit
B	Section 10, batch non-licensed unit
C	Section 10, individual patient, licensed unit
D	Section 10, batch licensed unit
E	Licensed, individual patient
F	Licensed, batch

Product Category

1 A	Cytotoxic adult
2 B	Cytotoxic paediatric
3 C	Parenteral nutrition – adult
4 D	Parenteral nutrition – paediatric
5 E	Other IV additive
6 F	Other pre-filled syringes
7 G	Other
8	Not recorded

Error Type – Please include all errors

A	Incorrect transcription
B	Calculation error
C	Incorrect drug
D	Incorrect dose/strength
E	Incorrect diluent/Infusion fluid
F	Incorrect final volume
G	Labelling error
H	Incorrect expiry date
I	Incorrect container, eg infusor, bag
J	Other
K	Not recorded

Who Made/Detected Error

1 A	Pharmacist
2 B	Technician
3 C	ATO
4 D	Student Technician
5 E	Pre Reg
6 F	Nurse
7 G	Doctor
8 H	Patient
9 I	Other
10 J	Not recorded

When was Error Detected

1 A	First check in assembly area
2 B	Operator check in preparation area
3 C	During labelling
4 D	Final check prior to release
5 E	At release stage
6 F	In clinical area prior to administration
7 G	In clinical area during or after administration
8 H	Other
9	Not recorded

Who Made the Error

As in "Who Detected Error" above. More than one person may be involved since one person may have compounded the error or missed a check.

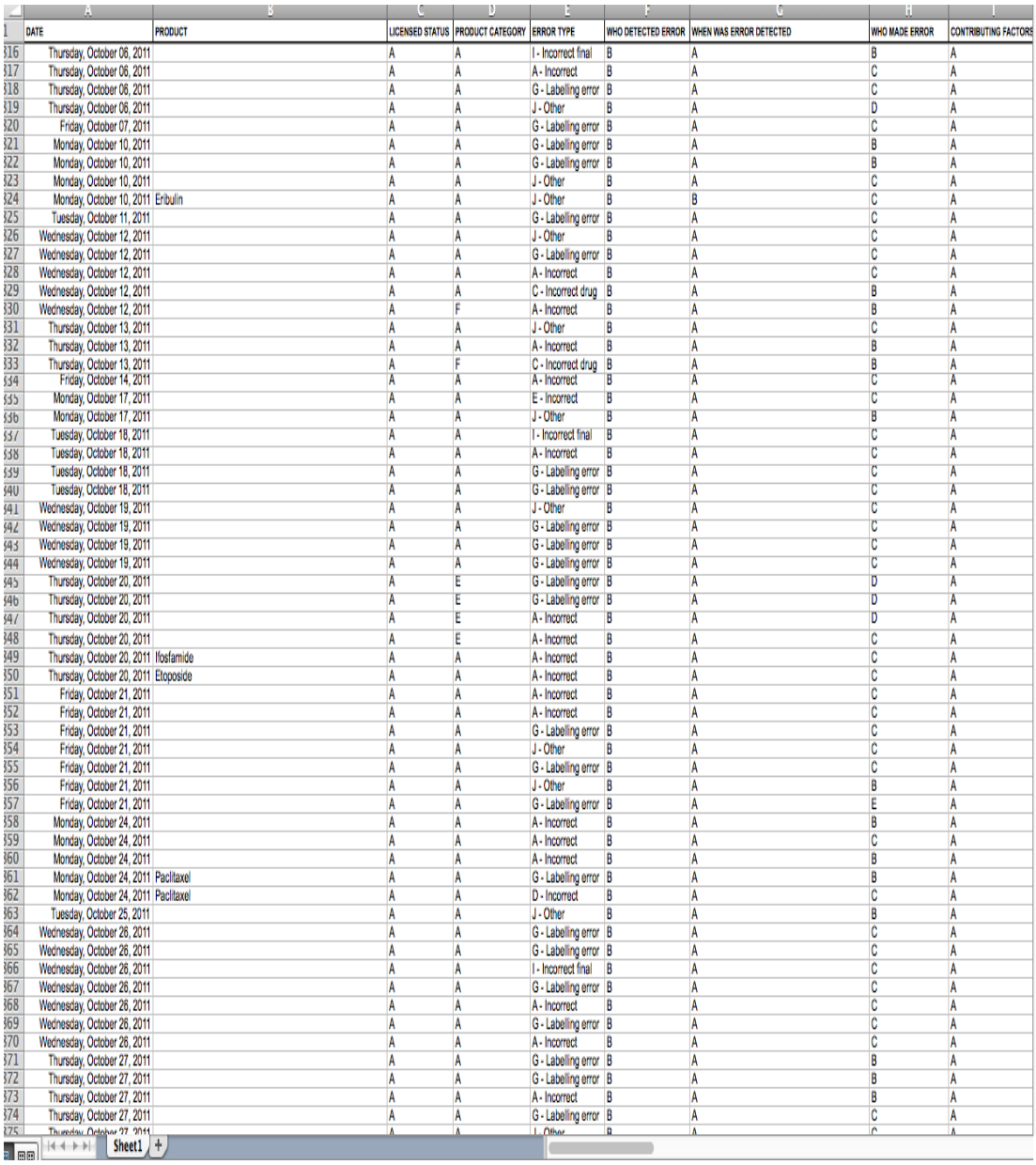
Contributory Factors

There may be more than one

A	Staff error
B	Inadequate training
C	Facility/equipment error
D	Poor quality of starting materials used
E	Inadequate computer system
F	Process design
G	Poor storage/distribution
H	Staffing level below establishment
I	1A
J	Poor segregation
K	Distraction/interruptions
L	Other
M	Not recorded

Potential Outcome

Letter Code	Meaning	Number Code
A	Catastrophic	1
B	Major	2
C	Moderate	3
D	Minor	4
E	None	5
Not recorded, N		6



	A	B	C	D	E	F	G	H	I
1	DATE	PRODUCT	LICENSED STATUS	PRODUCT CATEGORY	ERROR TYPE	WHO DETECTED ERROR	WHEN WAS ERROR DETECTED	WHO MADE ERROR	CONTRIBUTING FACTORS
316	Thursday, October 06, 2011		A	A	I - Incorrect final	B	A	B	A
317	Thursday, October 06, 2011		A	A	A - Incorrect	B	A	C	A
318	Thursday, October 06, 2011		A	A	G - Labelling error	B	A	C	A
319	Thursday, October 06, 2011		A	A	J - Other	B	A	D	A
320	Friday, October 07, 2011		A	A	G - Labelling error	B	A	C	A
321	Monday, October 10, 2011		A	A	G - Labelling error	B	A	B	A
322	Monday, October 10, 2011		A	A	G - Labelling error	B	A	B	A
323	Monday, October 10, 2011		A	A	J - Other	B	A	C	A
324	Monday, October 10, 2011	Eribulin	A	A	J - Other	B	B	C	A
325	Tuesday, October 11, 2011		A	A	G - Labelling error	B	A	C	A
326	Wednesday, October 12, 2011		A	A	J - Other	B	A	C	A
327	Wednesday, October 12, 2011		A	A	G - Labelling error	B	A	C	A
328	Wednesday, October 12, 2011		A	A	A - Incorrect	B	A	C	A
329	Wednesday, October 12, 2011		A	A	C - Incorrect drug	B	A	B	A
330	Wednesday, October 12, 2011		A	F	A - Incorrect	B	A	B	A
331	Thursday, October 13, 2011		A	A	J - Other	B	A	C	A
332	Thursday, October 13, 2011		A	A	A - Incorrect	B	A	B	A
333	Thursday, October 13, 2011		A	F	C - Incorrect drug	B	A	B	A
334	Friday, October 14, 2011		A	A	A - Incorrect	B	A	C	A
335	Monday, October 17, 2011		A	A	E - Incorrect	B	A	C	A
336	Monday, October 17, 2011		A	A	J - Other	B	A	B	A
337	Tuesday, October 18, 2011		A	A	I - Incorrect final	B	A	C	A
338	Tuesday, October 18, 2011		A	A	A - Incorrect	B	A	C	A
339	Tuesday, October 18, 2011		A	A	G - Labelling error	B	A	C	A
340	Tuesday, October 18, 2011		A	A	G - Labelling error	B	A	C	A
341	Wednesday, October 19, 2011		A	A	J - Other	B	A	C	A
342	Wednesday, October 19, 2011		A	A	G - Labelling error	B	A	C	A
343	Wednesday, October 19, 2011		A	A	G - Labelling error	B	A	C	A
344	Wednesday, October 19, 2011		A	A	G - Labelling error	B	A	C	A
345	Thursday, October 20, 2011		A	E	G - Labelling error	B	A	D	A
346	Thursday, October 20, 2011		A	E	G - Labelling error	B	A	D	A
347	Thursday, October 20, 2011		A	E	A - Incorrect	B	A	D	A
348	Thursday, October 20, 2011		A	E	A - Incorrect	B	A	C	A
349	Thursday, October 20, 2011	Ifosfamide	A	A	A - Incorrect	B	A	C	A
350	Thursday, October 20, 2011	Etoposide	A	A	A - Incorrect	B	A	C	A
351	Friday, October 21, 2011		A	A	A - Incorrect	B	A	C	A
352	Friday, October 21, 2011		A	A	A - Incorrect	B	A	C	A
353	Friday, October 21, 2011		A	A	G - Labelling error	B	A	C	A
354	Friday, October 21, 2011		A	A	J - Other	B	A	C	A
355	Friday, October 21, 2011		A	A	G - Labelling error	B	A	C	A
356	Friday, October 21, 2011		A	A	J - Other	B	A	B	A
357	Friday, October 21, 2011		A	A	G - Labelling error	B	A	E	A
358	Monday, October 24, 2011		A	A	A - Incorrect	B	A	B	A
359	Monday, October 24, 2011		A	A	A - Incorrect	B	A	C	A
360	Monday, October 24, 2011		A	A	A - Incorrect	B	A	B	A
361	Monday, October 24, 2011	Paclitaxel	A	A	G - Labelling error	B	A	B	A
362	Monday, October 24, 2011	Paclitaxel	A	A	D - Incorrect	B	A	C	A
363	Tuesday, October 25, 2011		A	A	J - Other	B	A	B	A
364	Wednesday, October 26, 2011		A	A	G - Labelling error	B	A	C	A
365	Wednesday, October 26, 2011		A	A	G - Labelling error	B	A	C	A
366	Wednesday, October 26, 2011		A	A	I - Incorrect final	B	A	C	A
367	Wednesday, October 26, 2011		A	A	G - Labelling error	B	A	C	A
368	Wednesday, October 26, 2011		A	A	A - Incorrect	B	A	C	A
369	Wednesday, October 26, 2011		A	A	G - Labelling error	B	A	C	A
370	Wednesday, October 26, 2011		A	A	A - Incorrect	B	A	C	A
371	Thursday, October 27, 2011		A	A	G - Labelling error	B	A	B	A
372	Thursday, October 27, 2011		A	A	G - Labelling error	B	A	B	A
373	Thursday, October 27, 2011		A	A	A - Incorrect	B	A	B	A
374	Thursday, October 27, 2011		A	A	G - Labelling error	B	A	C	A
375	Thursday, October 27, 2011		A	A	J - Other	B	A	C	A

Sheet1

Appendix 9

Interview

Introduction

The purpose of this interview is to find out what happened in relation to the error(s) observed. This study has been conducted within a range of Aseptic processing units throughout the UK and is one of the first UK empirical studies to actively investigate errors that occur during real working within this complex domain. All responses you provide in this interview will be completely confidential. You will never be identified within this study or the subsequent analyses and reports by your actual name, only by your participant number. Correspondences between participant names and numbers will never be disclosed to anyone beyond the research team the duration of the study or at any time after it has been completed. Furthermore, while we would like to find out about the error in as much detail as possible, please be assured that we are not interested in assigning any blame to yourself or anyone else the errors observed or in penalising you in any way for what has transpired. Furthermore, the findings of this interview will have absolutely no implications in terms of your career here at [Aseptics unit]. It is important for any research into such an important area as Aseptic processing that answers given are truthful and accurate as only by truly establishing context in this way is it possible for lessons to be learned and research within this important area to proceed/develop in a meaningful and constructive way.

The main purposes of this interview are:

1. To find out about a little bit more about the error(s) observed.

2. To determine the context in which it/they occurred.

3. To understand the potential causes of the error as you see them.

Establishing the chronology of the error

As part of the [procedure] we noticed that you [error]. The correct/appropriate course of action when [doing x] is……Therefore, in [doing x this constituted an error]
Do you agree with this assessment?

Have you encountered this error or similar types of error in the past either perpetrated by yourself or other staff?

Please describe the events leading up to this error. You were... (describe what they were doing a stage or two before the error took place).

Please try to recall your thoughts and feelings at this point. Please feel free to include any information you feel relevant (e.g. stresses you might have been feeling, worries you might have been having, how routine the process was, level of workload you experienced).

Now please go on to describe your frame of mind and any thoughts, feelings or impressions you had when the error occurred.

Were you distracted at the time the error occurred?
Were you aware at any time that your mind had wandered from the task at hand?

If the answer is yes, discuss this further. Determine whether they often get distracted in performing their role and the extent to which this may impact upon their job. However, explain to them that distraction is normal particularly when carrying out routine or sometimes mundane tasks.

Based on your thoughts/feelings at the time and on the various aspects of your job, please imagine a scale ranging on a scale of 1 to 5 ranging from 1 (not at all likely) to 5 (very likely). How likely do you feel that this error might have occurred?

Did you notice or realise that an error had occurred at this time?

Do you feel that you may have made such an error in the past or would you say based on your experience that this is the first time you have made this particular error?

Using the scale outlined previously, how likely do you think it is that you will make this particular error at this stage in the preparation process in the future?

There will then be a further discussion about the particular error observed. Given the range of potential errors, it is difficult here to suggest precise questions for the particular error observed, it will depend on the circumstances of the error and the idiosyncrasies of that particular error type. The error will be discussed in an informal manner according to the precise error observed.This will be very dependent upon the situation but it will then be important to determine the type of error. If the error occurred due to a deviation from normal clinical practice from rules and regulations of the particular aseptic unit then it would constitute a violation. It is important to establish whether it was a violation or a slip/lapse or a mistake.

Responsibility for the error

We are now going to try to assess the extent of responsibility for the observed error. Although they are often only observed at the front-end of working by personnel such as yourself, research from many domains shows us that full responsibility for error rarely lays completely with a single person. Errors are complex events and an error may reflect problems or instability within the entire system that your [Aseptic unit] comprises. For example, the error may be related to:

• Individual level factors (e.g. High workload, timing, fatigue, stress, lapses in memory/attention).

.Team level factors eg.inter/intrateam coordination, communication, roles/responsibilitis.

• Organisational level factors (e.g. Training, organisational climate/culture).

Individual level questions

1. Do you feel you had sufficient knowledge/experience to deal with the tasks you were assigned?

2. Did you feel tired, hungry or unwell around the time that the error occurred?
3. Do you feel appreciated in your work environment and do you have high morale/self-esteem in relation to the job you are doing?

4. Do you feel that the expectations of the work you do are realistic in the preparation phase in which the error occurred?

Team level questions

1. Do you feel that you are able to communicate effectively with all members of your team.

2. Do you ever encounter language/cultural problems between yourself and other team members. Do you feel that such problems may have been salient in committing the error that was observed?

3. Do you feel that you can ask for help or advice from members of your team and that help/advice is readily available. To what extent could extra help/advice have been useful around the time of the error?

4. Do you feel that your opinions and competence are accepted by other people within your team?

5. How tight is the coordination between yourself and other members of your team in completing tasks set for you?

6. Do you feel that all member of your team have clearly defined roles? Do you understand your role and the roles of others and how you fit in with the rest of the team?

Organisational level questions

1. Do you feel that you have received adequate training for what you are required to do in this job?

2. To what extent do you feel that the error that was observed could be attributed to a lack of or insufficient/inadequate training?

3. Can you suggest how the training regime might be altered to reduce the frequency with which this type of error occurs?

4.Do you feel that the rules, regulations and procedures within your unit made any contribution to the error observed?

5. Can you suggest potential changes to the rules, regulations and procedures within your unit that might make this particular error occur less frequently?

Finally before closing this interview, we would like you to tell us about any ways not previously mentioned that you feel this particular error or similar types of error might be prevented in the future.

Closing the interview

Thank you for taking part in this interview. The information you have provided us with will be extremely valuable in both our own analyses and in ensuring the potential for error is further eliminated in the future within your own working environment and within other similar working environments throughout the country. would also like to take this final opportunity to remind you that your responses in this interview were completely confidential. While they may be drawn upon in our analyses and report you will never be identified by name, only by your participant number. Furthermore, your responses will have no impact upon your career here at (aseptic unit) either now or in the future. If you have any questions about the entire study please feel free to ask me now and i will try our best to answer them for you. Once again thank you very much for your participation.

……End of interview……..

Appendix 10

OBSERVATION SCHEDULE FOR INVESTIGATING ERRORS IN PREPARING INJECTABLE MEDICINES IN HOSPITAL CLINICAL AREAS

BATH

Date:	Time:	Department/ Ward name: Reference Number:

Was a clear, uncluttered, and cleaned surface and adequate space created for preparation?	☐ Y ☐ N	
Was hand hygiene acceptable according to the National Patient Safety Agency standard operating procedure?	☐ Y ☐ N	(If 'N,' what is missed) ☐ Hands cleaned properly with alcohol / soap /hands visibly solid ☐ Gloves and apron worn before preparation
Did the nurse wear jewellery during preparation?	☐ Y ☐ N	(If 'Y', then identify)
Were all materials and equipment assembled in a sterile field during preparation?	☐ Y ☐ N	(If 'N', then identify)
Were medicines stored as recommended before preparation?	☐ Y ☐ N	(If 'N', then identify)
Were all medicines, materials, and equipment sealed/ unopened?	☐ Y ☐ N	(If 'N', then identify)
Was all equipment and materials sprayed or wiped with alcohol before preparation?	☐ Y ☐ N	(If 'N', then identify)

Observation of Injectable Medicine Preparation

Final Product name		Formulation (Starting material)*	☐ Powder ☐ Solution ☐ Suspension	Start & Finish	___hrs___min ___hrs___min

What was the method(s) for the preparation of the final product?	**(Tick one or all that apply)** ☐Withdrawing solution from an ampoule (glass or plastic) into a syringe ☐Withdrawing a solution or suspension from a vial into a syringe ☐Reconstituting powder in a vial and drawing the resulting solution or suspension into a syringe ☐Adding a medicine to an infusion ☐Diluting a medicine in a syringe for use in a pump or syringe-driver ☐Reconstituting powder or solution in a vial using a reconstitution device for administration by infusion ☐Adding a drug to a bag with integral reconstitution device ☐Adding a drug to a bag using a vial with integrated transfer device

Correct starting material name?	☐ Y ☐ N (If 'N', then identify)	Correct dose?	☐ Y ☐ N	Correct route of administration?	☐ Y ☐ N
Correct expiry date For starting material?	☐ Y ☐ N	Correct expiry date for diluent?	☐ Y ☐ N	Correct expiry date for final product?	☐ Y ☐ N

Correct strength of Starting material used?	☐ Y ☐ N (If 'N', then identify)	Correct formulation of starting material selected?	☐ Y (If 'N', then identify) ☐ N
Correct calculation in preparation process?	☐ Y ☐ N (If 'N,' then tick all that apply) ☐ Dose (strength) of the final product ☐ Volume of the final product	Correct volume of starting material used?	(If 'N', then identify) ☐ Y ☐ N
Correct diluent used?	☐ Y ☐ N	Correct strength of diluent used?	☐ Y (If 'N', then identify) ☐ N
Correct volume of diluent used?	☐ Y (If 'N', then identify) ☐ N	Correct method of preparation?	☐ Y (If 'N', then identify) ☐ N
Correct formulation?	☐ Y (If 'N', then identify) ☐ N		

Method(s) of the preparation used

Was the solution withdrawn from an ampoule (e.g., plastic or glass) into a syringe using the correct technique as defined by NPSA?	☐ Y (If 'N', then identify) ☐ N ☐ Method not used	Was the suspension or solution withdrawn from a vial into a syringe using the correct technique as defined by NPSA?	☐ Y (If 'N', then identify) ☐ N ☐ Method not used
Was the powder reconstituted in a vial and the resulting suspension or solution withdrawn into a syringe using the correct technique as defined by NPSA?	(If 'N', then identify) ☐ Y ☐ N ☐ Method not used	Was medicine added to an infusion bag using the correct technique as defined by NPSA?	(If 'N', then identify) ☐ Y ☐ N ☐ Method not used
Was the medicine diluted in a syringe for use in a pump or syringe driver using the correct technique as defined by NPSA?	(If 'N', then identify) ☐ Y ☐ N ☐ Method not used		

*Starting material: medicine prescribed

Were indicated were filters used as recommended by NPSA?	☐ Y (If 'N', then identify) ☐ N ☐ N/A	Was there no contact of critical points (e.g., needle or syringe hub) "ANTT"[1]?	(If 'N', then identify) ☐ Y ☐ N
Was the total final volume of the product correct?	(If 'N', then identify) ☐ Y ☐ N	Was the final product acceptable? (No particulates, precipitation, or bubbles)	(If 'N', then identify) ☐ Y ☐ N
Did the nurse preparing the injection sign the drug chart?	☐ Y ☐ N	Did the nurse performing 2nd nurse to sign the drug chart?	

Did the nurse check label the final product?

(If "Y" Tick all that apply)

☐ Patient name
☐ Name of the product
☐ Dose prescribed
☐ Route of administration prescribed
☐ Expiry date of final product
☐ Strength of the final product
☐ Necessary warnings/precautions
☐ Amount of final product
☐Name of the nurse preparing the product

Did the nurse check the final product? (Self check)	☐ Y ☐ N	Did the nurse check the label? (Self check)	☐ Y ☐ N ☐ Don't know
Did 2nd nurse check the final product? (2nd check)	☐ Y ☐ N	Did 2nd nurse check the label? (2nd check)	☐ Y ☐ N ☐ Don't know

Did the nurse labell the injection and infusion containers before administer?	(If 'N', then identify) ☐ Y ☐ N ☐ Not required

Did the nurse(s) double-check (2nd check) the label for: (2nd check)

(Tick all that apply)

☐ Correct patient
☐ Correct product
☐ No particulates, precipitation, or bubbles
☐ Correct strength of the final product
☐ Correct diluent used
☐ Correct dose prescribed
☐ Correct route of administration prescribed
☐ Necessary warnings/precautions
☐ Correct amount of final product
☐ Signature of the nurse who prepared the product
☐ No label to check

Was the final product placed in a sterile field before being given to the patient?	☐ Y (If 'N', then identify) ☐ N

Summary of Observation

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[1] Aseptic non-touch technique. According to the National Patient Safety Agency (2007), a *non-touch procedure* means to 'Avoid touching areas where bacterial contamination may be introduced (e.g., syringe tips, needles, vial tops). Never put down a syringe attached to an unsheathed needle'.

Appendix 11

Date:	Time:	Department/ Ward name:
Observer name:		Nurse identity:

Was a clear, uncluttered, and cleaned surface and adequate space created for preparation?	☐ Y ☐ N	(If 'N,' then identify)
Was hand hygiene acceptable according to the National Patient Safety Agency standard operating procedure?	☐ Y ☐ N	(If 'Y,' then tick all that apply) ☐ Hands cleaned properly with alcohol ☐ Gloves and apron worn before preparation ☐ Other
Was there access to hand-washing facilities for medicine preparation yet not next to sinks?	☐ Y ☐ N	
Did the nurse wear jewellery during preparation?	☐ Y ☐ N	(If 'Y', then identify)
Were all materials and equipment placed on a plastic tray during preparation?	☐ Y ☐ N	(If 'N', then identify)
Were medicines stored as recommended before preparation?	☐ Y ☐ N	(If 'N', then identify)
Were all medicines, materials, and equipment sealed?	☐ Y ☐ N	(If 'N', then identify)
Was all equipment and materials sprayed or wiped with alcohol before preparation?	☐ Y ☐ N	(If 'N', then identify)

Observation of Injectable Medicine Preparation

Medicine name		Dosage form	☐ Powder ☐ Solution ☐ Suspension	Start and Finish	__hrs__min __hrs__min
Dose and route of administration	Incorrect medicine name? ☐ Y ☐ N (If 'Y', then identify)			Incorrect expiry date?	☐ Y ☐ N
Unauthorised medicine?	(If 'Y', then identify) ☐ Y ☐ N	Incorrect medicine selected?		(If 'Y', then identify) ☐ Y ☐ N	
Incorrect medicine strength selected?	☐ Y (If 'Y', then identify) ☐ N	Incorrect route of administration?		(If 'Y', then identify) ☐ Y ☐ N	
Incorrect calculation of doses?	☐ Y (If 'Y', then identify) ☐ N	Incorrect diluent name?		☐ Y ☐ N Incorrect diluent selected?	☐ Y ☐ N
Incorrect strength of diluent selected	☐ Y (If 'Y', then identify) ☐ N	Incorrect volume of diluent selected?		☐ Y (If 'Y', then identify) ☐ N	
Was the solution properly withdrawn from an ampoule (e.g., glass or plastic) into a syringe?	☐ Y (If 'N', then identify) ☐ N	Was the solution or suspension properly withdrawn from a vial into a syringe?		☐ Y (If 'N', then identify) ☐ N	
Was the reconstituting powder properly placed into a vial for drawing the resulting solution or suspension?	☐ Y (If 'N', then identify) ☐ N	Was medicine properly added to an infusion bag?		(If 'N', then identify) ☐ Y ☐ N	
Was the medicine properly diluted in a syringe for use in a pump or syringe driver?	☐ Y (If 'N', then identify) ☐ N	Was the reconstituting powder or solution properly put in a vial with a reconstitution device for administration to the patient by infusion?		☐ Y (If 'N', then identify) ☐ N	
Was the medicine properly added to a bag with an integral reconstitution device?	☐ Y (If 'N', then identify) ☐ N	Did medicine adding to a bag using a vial with integrated transfer device properly?		☐ Y (If 'N', then identify) ☐ N	
Did the nurse use ready-to-administer bags?	☐ Y ☐ N	Were filters used as recommended?		☐ Y (If 'N', then identify) ☐ N	
Was there any contact of critical points (e.g., needle or syringe hub)?	(If 'Y', then identify) ☐ Y ☐ N	Was the total final volume of the product correct?		(If 'N', then identify) ☐ Y ☐ N	

Was the medicine formulation correct?	☐ Y ☐ N	Was the medicine formulation omitted?	☐ Y ☐ N
Was the final product acceptable?	(If 'N', then identify) ☐ Y ☐ N	Were essential cautions and warnings omitted?	(If 'Y', then identify) ☐ Y ☐ N
Did the nurse implement a non-touch procedure (ANTT)[1]?	(If 'N', then identify) ☐ Y ☐ N	Was the signature of the nurse who prepared the medicine missing?	☐ Y ☐ N
Were there distractions or interruptions during preparation?	☐ Y ☐ N	(If 'Y', then tick all that apply) ☐ Phone calls ☐ Changes to other procedures ☐ Noise ☐ Other	
Was the cleaning technique acceptable (ANTT)?	☐ Y (If 'N', then identify) ☐ N	Was the final product placed in a plastic tray before being given to the patient?	☐ Y (If 'N', then identify) ☐ N
Was final product checked?	☐ Y ☐ N	If 'Y', then was the check adequate?	☐ Y ☐ N
Did the nurse double-check the final product before labelling injection and infusion containers?	☐ Y ☐ N (If 'Y', then tick all that apply) ☐ Correct patient ☐ Correct medicine ☐ Correct dosage ☐ Correct diluent ☐ Aseptic ampoule access (ANTT) ☐ Aseptic diluent access (ANTT) ☐ No particulates, precipitation, or bubbles ☐ Aseptic catheter hub access (ANTT) ☐ Infusion pump settings ☐ Infusion rate (no pump) ☐ Signature of physician and pharmacist ☐ Signature of the nurse who prepared the medicine		
Did the nurse labelling the injection and infusion containers before administer?	(If 'N', then identify) ☐ Y ☐ N	Were all prepared infusions and injections labelled with an appropriately sized label?	☐ Y ☐ N

Summary of Observation	Errors Occurred
.....	☐ Y ☐ N
.....	**If 'Y', then specify type of error:**
.....	☐ Incorrect medicine
.....	☐ Unauthorised medicine
.....	☐ Incorrect expiry date
.....	☐ Incorrect diluent
.....	☐ Incorrect diluent strength
.....	☐ Incorrect dosage
.....	☐ Incorrect route
.....	☐ Incorrect formulation
.....	☐ Incorrect aseptic methods of preparation
.....	☐ Incorrect labelling
.....	☐ Other

[1]Aseptic non-touch technique. According to the National Patient Safety Agency (2007), a *non-touch procedure* means to 'Avoid touching areas where bacterial contamination may be introduced (e.g., syringe tips, needles, vial tops). Never put down a syringe attached to an unsheathed needle'.

Appendix 12

CAR PARKING QUERIES
ruh-tr.carparking@nhs.net
ACCESS CONTROL
ruh-tr.AccessControl@nhs.net
for access to Pharm

Royal United Hospitals Bath NHS
NHS Foundation Trust

Human Resources
Royal United Hospital
Combe Park
Bath
BA1 3NG

Tel: 01225 825937

alixramelli@nhs.net
www.ruh.nhs.uk

19th September 2016

[redacted]

Dear Abdulaziz,

Re: Honorary Contract with the Royal United Hospital

I have pleasure in confirming your attachment to the Pharmacy department within the Women and Children's division at the Royal United Hospital Bath NHS Trust, working under the supervision of Dr Regina Brophy.

The duration of the contract is three months, from Monday 19th September 2016 to Friday 16th December 2016.

As you will be aware, this honorary appointment attracts no remuneration, including expenses (unless otherwise agreed by your supervisor).

In the undertaking of this attachment you need to abide by the Trust's 'Guidelines and Expectations for Honorary Contract holders and those undertaking Observer attachments'.

The notice period required by either yourself or the Trust to terminate this attachment will in normal circumstances be one week.

Will you please confirm your acceptance of this honorary attachment on the terms and conditions stated by signing the enclosed duplicate of this letter and return it to me within HR as promptly as you able.

Should you have any queries or concerns regarding the nature of your attachment, please do not hesitate to contact me or any other member of the Human Resources department.

Yours sincerely

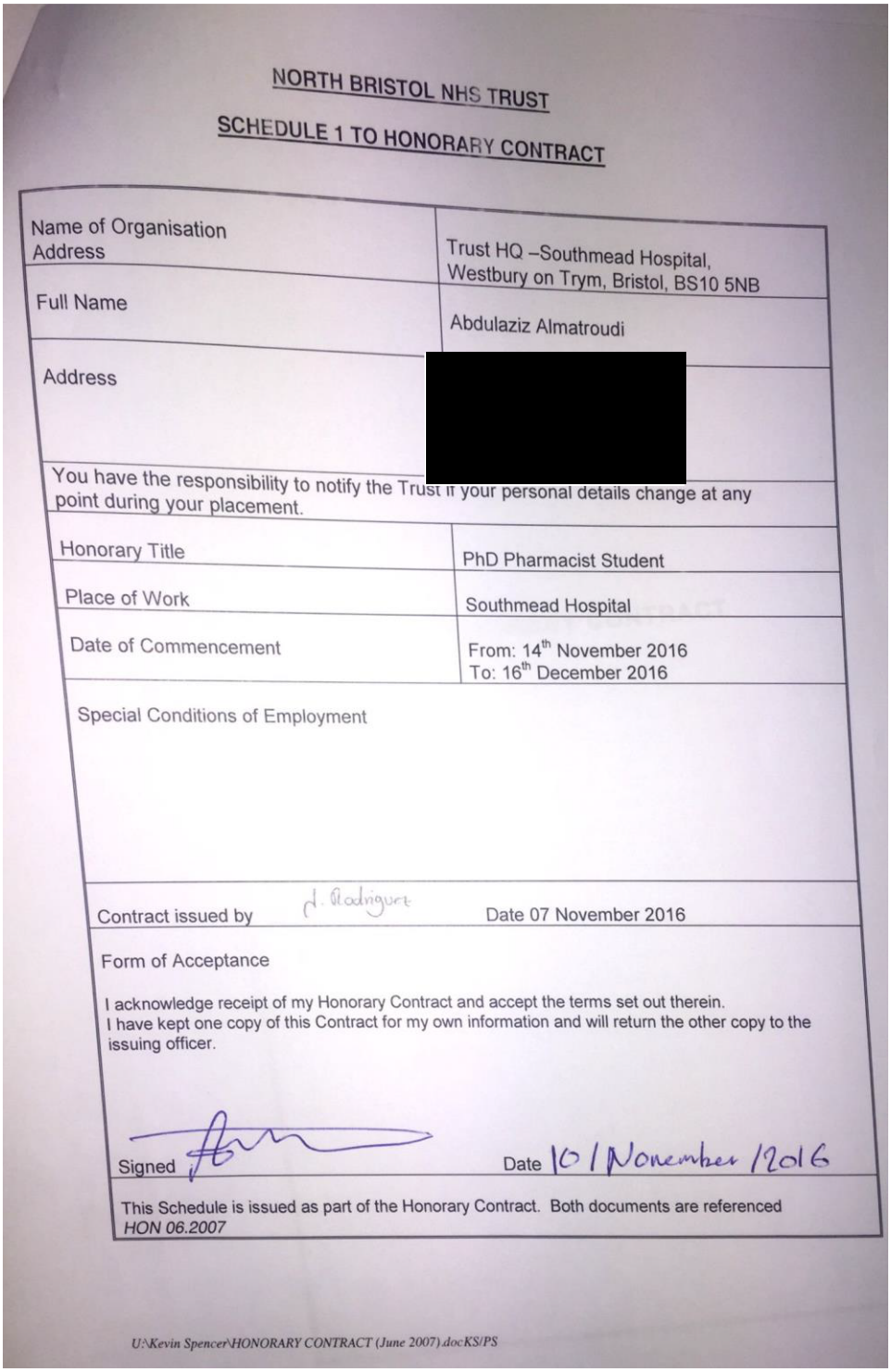
Alix Ramelli
Recruitment Officer

Enc: Guidelines and Expectations for Honorary Contract holders and those undertaking Observer Attachments

I accept the above appointment on the terms stated:

Signed: Date: 19/9/16

Chairman, Brian Stables
Chief Executive, James Scott



NORTH BRISTOL NHS TRUST

SCHEDULE 1 TO HONORARY CONTRACT

Name of Organisation Address	Trust HQ –Southmead Hospital, Westbury on Trym, Bristol, BS10 5NB
Full Name	Abdulaziz Almatroudi
Address	[redacted]
You have the responsibility to notify the Trust if your personal details change at any point during your placement.	
Honorary Title	PhD Pharmacist Student
Place of Work	Southmead Hospital
Date of Commencement	From: 14th November 2016 To: 16th December 2016
Special Conditions of Employment	
Contract issued by [illegible]	Date 07 November 2016

Form of Acceptance

I acknowledge receipt of my Honorary Contract and accept the terms set out therein.
I have kept one copy of this Contract for my own information and will return the other copy to the issuing officer.

Signed [signature] Date 10 / November / 2016

This Schedule is issued as part of the Honorary Contract. Both documents are referenced *HON 06.2007*

U:\Kevin Spencer\HONORARY CONTRACT (June 2007).docKS/PS

Appendix 13

1. Background

A medication error is any preventable event in the prescription, preparation, or administration of a therapeutic product while in the control of the healthcare professional (HCP) that can harm the patient (European Medicines Agency, 2015). Cousins and colleagues have reported that the cost of medication incidents in the United Kingdom alone was nearly £985 million in 2008 and more than £2 billion in 2012 (Cousins et al., 2012). Among those medication incidents, medications posing the greatest risk are those administered by injection. According to the National Patient Safety Agency (NPSA), *injectable drugs* are 'Medicines intended for administration by bolus injection, perfusion or infusion by any of the following routes: intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intradermal, intraventricular, epidural, intravascular, intravitreal, intrapleural and intraocular' (NPSA, 2007, p. 9). These medicines pose great risk due to the immediate onset of their systemic effects, the difficulty of reversing pharmacological effects after their administration, and the low therapeutic index of many of them (MEDMARX Database 2002–2006, 2008). As such, injectable drugs need to be prepared and administered carefully, and patients receiving them should be monitored closely.

In 2006, the UK National Reporting and Learning System (NRLS) received 9,000 reports of medication safety incidents related to injectable drugs. That year, injectable drugs accounted for 53% of patient mortality or harm due to medication (NPSA, 2006). In response, the following year the UK NPSA published 'Patient Safety Alert 20: Promoting the Safer Use of Injectable Medicines' (NPSA, 2007).

In that context, an injectable preparation error is defined as *'the preparation of an injectable medication that deviates from the prescription, manufacturer's guidelines, nationally or locally agreed-upon policy, procedure, or guidance, or generic standards for clean or aseptic preparation'* (Crowley, 2006, p. 136). As Figure 1 illustrates, a previous study counted 526,376 medication incident reports in the National Health Service (NHS) in England and Wales from 2005 to 2010, 17% of which resulted from preparation errors (Cousins et al., 2012).

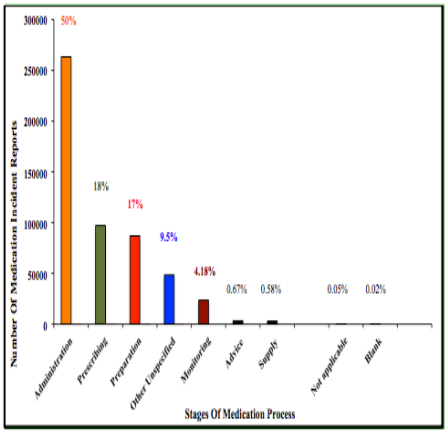


Figure 1: Medication incidents and the respective stages of the medication process in England and Wales, 1 January 2005–31 December 2010 (adapted from Cousins et al., 2012)

In UK and European hospitals, many injectable medicines are prepared in clinical areas by nurses into a form ready to give to patients (EMA, 2013). In the United Kingdom, Breckenridge (1979) reported the outcomes of an analysis of injectable preparations and recommended that injectable drugs need to be prepared under the supervision of a specialised pharmacist in an adequate workplace (i.e., aseptic environment) (Breckenridge, 1979). In pharmacies, the preparation of injectable medicines is performed in a well-established environment—for example, an aseptic preparation room. However, environment and work process controls in clinical areas are less stringent in the environment of the hospital ward, and as a result, medication errors are more frequent (Beaney and Goode, 2003; Crowley, 2006; Beaney, 2010). Nevertheless, the majority of injectable medications are prepared in the ward environment, whereas items such as cytotoxic chemotherapy, total parenteral nutrition and products not used immediately prepared in pharmacy aseptic units. To reduce the risk of ward-based injectable medication preparation, standards and competency-based training are often used (NMC, 2008).

Most UK and European research on preparation errors has used observation to investigate both the preparation and administration of injectable medicines by nurses in clinical settings (Wirtz et al., 2003; Taxis and Barber, 2003; Cousins et al., 2005; Crowley, 2006). Though researchers have generally identified rates of preparation errors ranging from 7% to 53%, little is known about the steps that nursing staff take when preparing injectable medicines in real-life situations, what problems they meet, and how they solve these problems (RCN, 2003; Taxis and Barber, 2003; ICN, 2012). Elucidating those issues is thus the next step in developing practical solutions to safeguard patients.

In 2003, using disguised and direct observation, Wirtz and colleagues investigated intravenous medication errors in the United Kingdom and Germany, to not only describe differences in practice between UK and German hospitals, but also to analyse the occurrence of various error types within those settings. Ultimately, they found a high rate of intravenous preparation errors that could harm patients. Specifically, to reduce the risk of intravenous preparation errors and make injectable drugs safer for patients, the authors proposed implementing a few practical changes, including useful medication-error classification schemes, error severity schemes, and descriptions of error types. Though they moreover list the types of drug most commonly associated with each different error type, two weaknesses of their study are its limited focus on one type of ward (i.e., surgical wards) and its failure to investigate causes of errors.

That same year, Taxis and Barber (2003a, 2003b) conducted two studies to examine errors in the preparation and administration of intravenous medications. In one study, they investigated the incidence of errors in the preparation and administration of intravenous drugs on two wards in a German non-university hospital (Taxis and Barber, 2003a), and in the other, they investigated the causes of errors in the drugs' preparation and administration (Taxis and Barber, 2003b). Unlike other researchers, Taxis and Barber (2003b) evaluated errors according to Reason's (2000) classification system—that is, in terms of slips, lapses, mistakes, violations, and active or latent failures. They furthermore used an ethnographic approach, which entailed observation by a subject expert and follow-up with face-to-face, semistructured interviews with staff involved in errors, in order to explore the causes of the errors according to human error theory.

Ultimately, Taxis and Barber (2003b) found that the causes of the errors included the lack of knowledge about the preparation and administration procedure, the complex design of technology, the lack of communication between nurses, and the inadequate use of technology. They moreover identified that intravenous drug errors were caused not only by the direct action of the nurse preparing the medicine, but also by a range of organisational and managerial influences, including those of training, the cultural context, the choice of product, and the design of technology. In

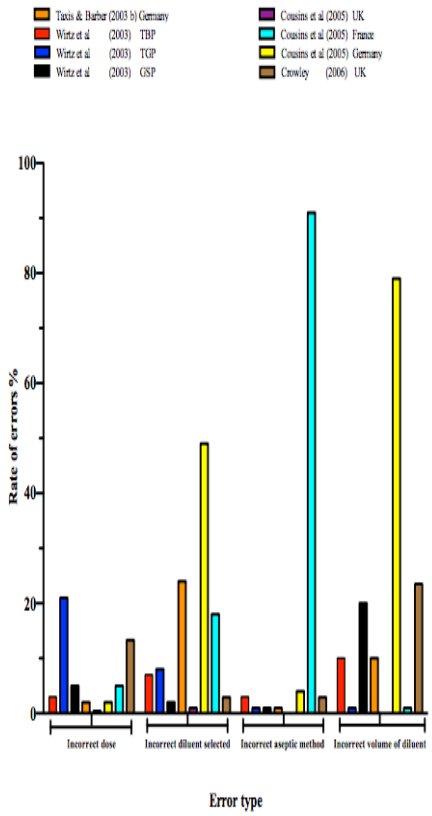
response, Taxis and Barber (2003b) suggested that intravenous drug errors can be reduced by involving clinical pharmacists in clinical areas, removing nurses from the task of preparing injectable drugs, restricting the supply and stock of key reagents in clinical areas, and implementing the central preparation of injectable medications. Among their study's limitations, though interviews with staff were part of the method, they were not discussed in detail, and the research focused on administration errors more than on preparation errors (Taxis and Barber, 2003a, 2003b).

In 2005, Cousins and colleagues also conducted an observational study on intravenous drug preparation and administration in hospital wards in United Kingdom, France, and Germany, where they focused on the preparation of intravenous medicines by nurses in clinical areas. They observed several violations in aseptic techniques and, in response, presented the UK aseptic clean-room scenario, with stringent associated training, as a model for eliminating aseptic errors. Yet, the study was limited by its use of different observers in different countries, focus on process errors, and failure to connect observed process errors to possible clinical consequences.

The following year, Crowley (2006) observed errors in the preparation of intravenous medications in clinical areas in a UK hospital. In addition to errors stated, the author documented two particular practical deficits: the use of syringes with inappropriate productions and the withdrawal from glass ampoules using syringes without needles. Crowley (2006) noted that although no staff member began drug preparation with soiled hands, there was inconsistency in handwashing, use of an alcoholic gel, and the wearing of gloves. Among its limitations, this study focused solely on the preparation of intravenous medicine, ignoring other routes of injectable administration. Another limitation was that interviews were conducted with nurses in general, which sharply decreases the robustness of its outcomes.

More recently, Dehmel and colleagues (2011) compared the drug concentrations of infusion solutions prepared in a central pharmacy to preparations made manually by nurses in a clinical area. Though the authors detected more errors in medications prepared in clinical areas, a significant error rate also emerged among medications prepared in the pharmacy. The chief weakness of the study is that the authors, in using a quantitative method only, could not determine the causes of errors.

The most common types of injectable preparation errors in hospital clinical areas reported in UK and European studies appear in Figure 2. Table 1 summarises previous studies of the types, incidences, causes, and common factors contributing to injectable medications errors in hospital clinical areas.



Notes:
TBP: Traditional British ward pharmacy service.
TGP: Traditional German ward pharmacy service.
GSP: German satellite pharmacy service.

Figure 2: Most common types of injectable preparation errors in the hospital clinical areas

Table 1: A summary of the research, investigating the types, incidences of injectable preparation errors, and methods used in hospital clinical areas. All error rates were defined as the sum of all recorded preparation/administration errors divided by the sum of the prepared/administered drug dose observed except where indicated (■) in table 1.

Study	Location	Duration	Method	Overall preparation and administration error rate	Preparation Internal Errors Rate	Authors recommendation
Wirtz et al. (2003)	UK and Germany	6 consecutive days in each ward May–June 2000	**Design** Disguised, direct observation of three ways of handling injectable medications *TBP, TGP, and GSP **Participants** Nurses and junior doctors **Sample** Three large teaching hospitals	Not stated	22%	Lack of guidelines or policies on aseptic techniques
Taxis and Barber (2003b)■	Germany	6–7 consecutive days, including weekends, in two wards, in March 2000	**Design** Ethnographic-disguised observation and follow-up, unstructured interviews, with errors evaluated within Reason's (2000) human error framework **Participants** Nurses **Sample** Two hospitals	49% of doses had errors Both preparation and administration errors had 57.9 errors per 100 doses	7%	Lack of training Lack of knowledge Inadequate verbal communication with colleagues
Cousins et al. (2005)	UK, Germany, and France	UK data collection took 5–6 weeks German data collection took 6 weeks French data collection took 3 months	**Design** Direct observation **Participants** Nurses **Sample** Six hospitals	824 doses were prepared and 798 doses administered. The product was either not labelled or incorrectly labelled in 43%, 99%, and 20% of doses administered in the UK, German, and French hospitals, respectively.	Not stated	Insufficient training for task High workload
Crowley (2006)	UK	Data were collected in April–May 2005	**Design** Direct observation **Participants** Nurses **Sample** One hospital	Not stated	27/68 (39.7%)	Lack of guidance on preparation Incorrect or incomplete knowledge or experience
Dehmel et al. (2011)	Germany	Study conducted in January–March 2008	**Design** Objective analysis of solutions **Participants** Intensive care unit nurses **Sample** One hospital	Not stated	Drug concentration deviates by: >=5% - 53/100 preparations (53%) (Clinical area) >10% - 22/100 preparations (22%) (Pharmacy)	Distraction / Interruption Complexity

* Traditional British ward pharmacy service (TBP), the German method involving large stocks of commonly prescribed medicines on wards (TGP), Or another German method where a satellite pharmacy service is used (GSP).

■ Taxis & Barber (2003b) defined error rate by two ways as: the sum of all recorded preparation/administration errors divided by: 1. The sum of the prepared/administered drug doses observed. 2. The sum of the prepared/administered process stage observed.

In summary, the literature review has shown that the most commonly reported errors regarding injectable preparation were incorrect dose, incorrect diluent, incorrect aseptic method, and incorrect diluent volume (Figure 2). In other studies, factors contributing to ward preparation errors included lack of detailed guidelines or policies on aseptic techniques, lack of training or insufficient training for task, lack of knowledge, poor labelling, complexity, distractions, and interruptions. In response, Taxis and Barber (2003b) have suggested that careful drug chart reading could reduce incorrect dose and diluent errors in hospital clinical areas, as well as that good training and national standardised guidelines might reduce the risk of injectable preparation errors in those same areas.

Other studies performed outside Europe (Abbasinazari et al., 2012; Shamsuddin and Shafie, 2012 Nguyen et al., 2013; Vaismoradi et al., 2013) on errors that arise during the preparation or administration of injectable medicines in hospital clinical areas have posited that training nurses effectively can reduce the risk of such errors. To that end, training programmes should provide nurses with a greater ability to understand and calculate injectable medications, while education programmes for nurses should address aspects of injectable medications and related safety issues. In these training programmes, sharing the experiences of experts (e.g., pharmacists) with preparing injectable medicines would be useful to minimising issues related to preparing injectable medicines. For purpose of the present review, however, only studies based in Europe will be considered in detail.

Though a variety of definitions have been used to describe injectable preparation errors, as summarised in Table 2, the one used for this protocol is adapted from Crowley (2006). The advantages of adopting a consistent definition include allowing the comparison of injectable drugs' preparation errors. By using Crowley's study in particular, the protocol can take advantage of that study's links with Patient Safety Alert 20 (Crowley, 2006).

Table 2. A summary of definitions of injectable drug preparation error

Study	Definition
Wirtz et al. (2003), p. 105 UK	'Any deviation in preparation of an IV dose from the original prescription, or any act in the preparation that deviates from the manufacturer's instructions or the hospital's drug policy'
Wirtz et al. (2003), p. 106 Germany	'The German hospitals researched had no medicine policy, so the leaflets produced by the manufacturer (Fachinformation), which were mainly designed for health care professionals, were used as the definition of correct practice. Errors identified by nurses and patients and corrected before administration were not recorded as errors'.
Taxis and Barber (2003), p. 816 Germany	'A deviation in preparation of a drug from a doctor's prescription, the hospital's IV policy, or the manufacturer's instructions'
Cousins et al. (2005), p. 191 UK	'A deviation in the preparation of a medicine from a doctor's prescription, hospital intravenous procedures, or the manufacturer's instructions'
Crowley (2006), p. 138 UK	'The preparation of an injectable medication that deviates from the prescription; manufacturer's guidelines; nationally or locally agreed-upon policy, procedure, or guidance; or generic standards for clean or aseptic preparation'
Dehmel et al. (2011), p. 1312 Germany	'Drug concentration deviates from intended concentration'

The focus of this project is to investigate the rates and types of internal errors during the preparation of injectable drugs in clinical settings. Internal errors—that is, near misses—are defined as errors discovered during the work process before the product's delivery to the patient.

1.1 Summary of justifications for the project

The preparation of injectable medicines is a complex, high-risk procedure, and very little is known about preparation errors, especially in hospital clinical areas. There is thus a need for prospective investigations that can expand current understandings of factors influencing injectable drug preparation in clinical areas and how incidents threatening patient safety arise. Only with the discussion of those factors can applicable solutions be developed to improve patient safety. In response, this project, in meeting the requirements of Patient Safety Alert 20, will investigate the preparation of injectable medicines (NPSA, 2007). An observational study will be conducted in different wards involving follow-up questionnaires and interviews with hospital staff who make errors. By providing an in-depth understanding of causes of injectable preparation errors, it will ultimately raise staff awareness and promote patient safety.

Most studies summarised in the literature review reported an error rate as the sum of all recorded preparation or administration errors, divided by the sum of the prepared or administered drug doses observed. The authors of those studies evaluated both the preparation and administration errors of intravenous drugs in specific wards (e.g., intensive care units and surgical wards) and reported a wide range (i.e., 7–53%) of error rates during preparation, though such could have partly resulted from different study durations. Another explanation for the wide range in reported percentages may be the use of different definitions of what constitutes an error. In terms of limitations, most of the studies did not extensively explore the causes of errors and lacked comprehensive descriptions of error characteristics. In response, the proposed study seeks to partly resolve the above issues, for the following reasons:

I. Using the proposed method can improve the detection of the incidence of internal errors during injectable drug preparation in hospital clinical areas. Many previous studies have focused on injectable preparation and administration errors. For example, Crowley (2006) specifically examined injectable preparation errors, yet did not solely interview nurses involved in errors. By contrast, the proposed observational study and follow-up interviews or questionnaires will be conducted with staff who committed errors, which should provide an in-depth understanding of the underlying causes of injectable preparation errors and, more importantly, raise staff awareness and promote patient safety.

II. The analysis in the proposed investigation will be more robust and link better with Human Error Theory than former work. Previous studies addressing injectable medicine preparation errors have focused on quantifying the problem (Wirtz et al., 2003; Taxis and Barber; 2003; Cousins et al., 2005; Crowley, 2006; Dehmel et al., 2011). Yet, to effectively reduce injectable drug preparation errors, a rich understanding of how and why errors occur is required (Leape, 1994). To that end, the NPSA adopted a systems approach to safety, in which applying a human error or human factors approach to understand and analyse incidence is appropriate (NPSA, 2003). In this context, human factors have been defined as *'an applied science of system design that evaluate human strength and compensates for human limitation'* (Schneider, 2002, p. 1156).

The analysis will not only address active failures that lead to injectable medicine preparation errors, but also further explore the local task, team-based factors, individual factors, working environment, and organisational factors present when the error occurred and that might have contributed to errors being made.

2. Aims and objectives

This study aims to gain an in-depth understanding of the incidence, types, and causes of internal injectable preparation errors so that effective risk reduction strategies can be developed to safeguard patient safety. The objectives are as follows:

I. Determine the incidence of injectable medicine preparation errors in hospital clinical areas;
II. Identify the types of injectable medicine preparation errors in hospital clinical areas;
III. Determine the drugs involved in injectable medicine preparation errors in hospital clinical areas;
IV. Establish the causes of injectable medicine preparation errors in hospital clinical areas;
V. Identify strategies for reducing the risk of injectable medicine preparation errors in hospital clinical areas.

2.1 Theoretical framework

Reason's accident causation model based on human error theory will be used as the theoretical framework (Reason, 2000) to provide a psychological understanding of the causes of internal errors in injectable medicines prepared in hospital clinical areas. By identifying the causes, strategies for minimising the risks of injectable preparation can be identified. Human errors occur for two reasons: individual factors and systemic factors. On the one hand, individual factor errors result from inattention and forgetfulness (Reason, 2000) and are deeply integrated within healthcare; on the other, systemic factor errors relate to the environment in which the work is performed. Reason hypothesises that human error results from one or more levels of failure (Reason, 1990; Ritchie & Spencer, 2002). In that sense, using Reason's accident causation model as one of the most commonly used frameworks in previous healthcare studies will help to:

1. Guide data collection and analysis;
2. Detect accident causation at different levels of the organisation; and
3. Avoid ascribing blame to individuals (Dekker, 2003).

Vincent et al. (1998) applied Reason's model to healthcare, as shown in Figure 3.

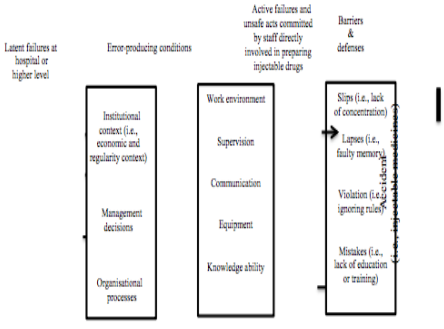


Figure 3: Organisational accident model based on work (i.e., error-producing condition) by Reason (adapted from Vincent et al., 1998, p. 1152).

3. Study design and strategic methods

This evaluation will use a case study design, defined as *'an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident'* (Yin, 2009, p. 18). In practice, a case study design allows an observational study to be performed in the environment in which errors occur. A case study design was chosen for the proposed project because it is a flexible, useful approach for identifying the types, incidents, and causes of errors in preparing injectable medicines (Creswell, 2009). A case study can moreover provide in-depth insight into the causes of errors and produce unexpected findings (Hodkinson & Hodkinson, 2001). The project will employ a mixed-methods approach combining qualitative and quantitative methods. Whereas a quantitative method is useful for identifying the types and incidents of errors made during the preparation of injectable medicines (Flynn et al., 1997; Wirtz et al., 2003; Parshuram et al., 2008), qualitative methods allows for an exploration of the causes of errors (Flynn et al., 1997; Wirtz et al., 2003; Parshuram et al., 2008; Neergaard et al., 2009).

3.1 Study setting

It is anticipated that this study will be conducted in a range of clinical areas, both in a large teaching hospital with 1,500 beds and a medium-size district general hospital with 650 beds. The sample will include both surgical and general medicine wards.

3.1.2 Recruitment of participants

Prior to data collection, the investigator will request permission to observe and interview nursing staff, at which time a suitable schedule for observations will be agreed. A week prior to observations, the investigator will distribute an information leaflet (Appendix 1) to all nursing staff likely to be preparing injectable medicines during the study period. Before each nurse's first observation, he or she will be invited to participate and provide their written consent (Appendix 2). Nurses who do not provide their consent will not be observed.

3.2 Quantitative method (observational data)

3.2.1 Determining incidences and types of errors in preparing injectable medicines in hospital clinical areas

An investigator will be present in up to four wards (two in each hospital) for ten days each in order to observe the process of preparing injectable medicines. Preliminary observations have shown that it is reasonable to observe 15 preparations during an 8-hour shift. Since studies (Wirtz et al. 2003; Taxis & Barber, 2003; Crowley, 2006; Dehmel et al. 2011) have reported an internal error rate of 7–53%, the investigator expects to observe 5–30 errors over the course of 5 days in a single ward, which will provide sufficient data to assess the causes of errors.

Direct observation, the so-called 'the gold standard method' (Allan & Barker, 1990), will be used to determine the incidence and types of errors in the preparation of injectable medicines, and data will be collected using a standard structured observation schedule (Appendix 3). Direct observation is a valuable tool that enables investigators to record actual events instead of trusting reports that might not accurately represent what happened (Allen & Barker, 1990; Dean & Barber, 2001; Bowling, 2002; Smith, 2002; Carthey, 2003; Bryman, 2004) and that has been used previously (Hoppe-Tichy et al., 2002; Crowley, 2006).

Throughout data collection and with participants' consent, the investigator will watch, but not interrupt, nursing staff as they prepare injectable drugs. The investigator will record all injectable medicines prepared on the piloted observation schedule, as well as any errors, which might include the stage of preparation, the location of the error, and a description of the type of error. Any mistakes observed by the investigator will be kept confidential and identified using a reference number, and no personal information will be collected on the observation schedule.

Observations will commence when the equipment is collected until the drug is ready for administration—on a normal day (Monday to Friday), from 9 am to 5:30 pm—as recommended by a previous study (Crowley, 2006). During that time, the investigator will be available to watch all drugs prepared; however, the investigator will not observe the evening drug round, which is thus a limitation of this observational study. Another major limitation of the observational method is the observer effect, or Hawthorne effect, defined as *'the presence of the researcher, and the knowledge that the study is taking place, may influence the behaviours of the individuals being observed'* (Smith, 2002; p. 168). This effect may influence the validity of the evaluation, though according to Bowling (2002) and Smith (2002), several strategies can be used to reduce the effect. For one, the observer should communicate with staff in the area of study before data collection and, to control behavioural changes, collect as much data as possible (Bowling, 2002; Smith, 2002).

3.2.2 Data analysis

A coding framework will be developed for the observation schedule, and coded data will be entered into the Statistical Package for the Social Sciences for analysis. The overall rate of errors in the preparation of injectable medicines will be calculated as defined by Allan and Barker (1990), as follows.

Rate of internal errors during the preparation of the injectable drug (%)

The equation for this rate is: Number of actual errors (incorrect in one or more ways) × 100 / Number of observations

Rates of types of internal errors (%)

The equation for this rate is: Number of types of internal errors (incorrect in at least one way) × 100 / Number of observations

Frequency tables will be created for types of errors and their stages of occurrence in the preparation process, and a chi-square test will be used to measure the difference between wards. Any result in which $p \leq .05$ will be considered statistically significant.

In a subsequent phase of the project, any observed errors will be retrospectively graded for severity by a panel consisting of experienced healthcare professionals (two doctors, two pharmacists and a nurse) using a method validated by Dean and Barber (1999).

3.3 Qualitative method

3.3.1 Investigation of causes of injectable medicine preparation errors in hospital clinical areas

All nurses involved in an error will be invited to complete a questionnaire and to be interviewed. Nurses who do not wish to be interviewed will still be invited to complete the questionnaire; those who complete a questionnaire and agree to be interviewed will discuss their questionnaire responses during the interview.

The questionnaire has been designed to include a mixture of close- and open-ended questions and has been piloted among nursing staff (Appendix 4). A questionnaire will be given to the relevant nurse after each observed error and take less than 10 minutes to complete. The questions aim to explore the nurse's views and opinions on the causes of the error, as well as to inform strategies for preventing or minimising such mistakes from recurring. Respondents will be asked to return their completed questionnaires to the investigator or to an agreed location in their clinical area either within 48 hours or before their interview. All data collected from the questionnaire will be anonymised before data analysis to prevent the disclosure of information in any report that could be linked to individual participants or organisations.

A semi-structured, face-to-face interview model will be adopted using a topic guide (Appendix 5). Nursing staff involved in an error while being observed will be invited to an interview within 48 hours. The interview will implement the systems approach to establish the cause of error and aim to identify what the nurse thought caused the error and why established barriers and defences failed to prevent the error. In this type of interview, it is important to listen to participants' views of what is significant, though the aim is to collect rich data about a certain topic (Bryman, 2012). Among the advantages of this type of interview are its open-endedness and focus on a specific situation or action, not simply the opinion of the interviewee (King, 2004). Participants will be asked how the error occurred, what factors contributed to its occurrence, and what strategies could have prevented the error. Due to the qualitative nature of the study, no formal sample size calculation is necessary to determine the number of interviews to be conducted.

Each interview will take approximately 10 to 15 minutes. With the consent of participants, interviews will be audio-recorded and transcribed verbatim. All data collected during interviews will be anonymised before data analysis. Participants will have the opportunity to view the transcripts of their interviews and may withdraw their data from the study at any point.

Observations, questionnaire responses, and interview data will be linked via reference numbers. Once data collection is complete, it will become impossible to link an individual reference to a particular staff member.

3.3.2 Questionnaire and interview data analysis

Audio recordings of interviews will be transcribed verbatim and anonymised. The transcripts and free-text answers to questionnaires will therefore be entered into NVivo software for thematic data analysis. Data will be analysed according to the principles of framework analysis using Reason's accident causation model as the theoretical framework (Reason, 1990; Ritchie & Spencer, 2002).

4. Ethical approval

This project has been approved via the University of Bath's ethics procedures. The study will be conducted as a service evaluation at each participating NHS organisation in England, with the approval of the relevant medicines governance committees. The investigator will hold an honorary contract and have the same duties of care and responsibilities as any other member of staff employed by the NHS organisation. All activities, discussions, and details of personnel and patients witnessed by the investigator will be kept strictly confidential.

During observation, the observer will observe only the process of preparing an injectable medicine and not interfere with that process unless an error is observed. If the investigator observes an error, then he will inform the relevant staff member, who will then follow the normal procedure to correct the error. If having carried out observations and interviews, the investigator has reason to doubt the fitness to practice of a member of staff, he will discuss this with the supervisorial team (which includes two registered pharmacists with NHS experience). If the supervisorial team agree that there

are grounds to be concerned about fitness to practice, they will disclose this to the relevant ward manager.

Data collection of internal errors will be confidential and errors identified only by reference number linked to the data. During the study, a temporary list of staff names with reference numbers will be compiled to facilitate the operation of the study; this list will be stored securely and confidentially and destroyed once data collection is complete and interviews have been transcribed. Demographic data will be stored confidentially and reported only in aggregate form. Electronic files will be stored exclusively in the University of Bath's secure data management facility. All hard copies (e.g., written consent forms) will be stored in a filing cabinet at the University of Bath.

The results of the project may be published, but participating organisations and individuals will not be identifiable.

4.1 Data storage

Raw data will be securely retained for five years before secure destruction. Coded data may be retained indefinitely. All data apart from consent forms will be identifiable by reference number only. Audio recordings will be destroyed once they have been transcribed.

5. Benefits of the study

This project can allow problems with injectable preparation to be identified and quantified, as well as highlight areas of good practice. Accordingly, the findings can enable the development of strategies for reducing the risk of preparation errors and thereby improving patient safety. They will be particularly helpful for participating hospitals, whose clinical areas observed will receive specific feedback to guide them in resolving issues identified.

6. Study funding

The author received an award from the government of Saudi Arabia to fund his doctoral study.

Contacts for further information

If you have any questions or concerns about the study, then please contact:

Dr. Julie Letchford	J.A.Letchford@bath.ac.uk	(012) 2538 6729
Dr. Lynette James	Lynette.James@wales.nhs.uk	(029) 2074 4351
Dr. Matthew Jones	M.D.Jones@bath.ac.uk	(012) 2538 3829
Abdulaziz Almatroudi	aa687@bath.ac.uk	[redacted]

Appendix 14

APPENDIX 1

PARTICIPANT INFORMATION LEAFLET

INVESTIGATING ERRORS IN PREPARING INJECTABLE MEDICINES IN HOSPITAL CLINICAL AREAS

I am a student of the University of Bath University undertaking a project for a patient safety doctorate and would like to ask you to take part in a study. You need to understand why the project is being done and what it would involve for you, before you decide whether to take part. All information gathered in this study will be treated in confidence. Please take time to read the following information carefully. Talk to your colleagues about the study if you wish. The leaflet tells you the purpose of the study and what will happen if you take part. Please take time to decide if you wish to take part.

What is the purpose of the study?

Patient safety is an important issue in health care today due to the large amount of unintentional harm resulting from medical treatment. Medicine is responsible for 10-20% of these injuries and, since almost all hospital patients receive medication, tackling medication errors is a high priority. The project is a study to explore, discuss and explain how the incidence of injectable preparation errors can be reduced and prevented in hospital clinical areas. The investigator will observe nurses preparing injectable drugs in clinical areas. The overall objective is to assess reliability of preparation and find out where errors might occur for the purposes of optimising patient safety.

Why have I been chosen to participate?

In order to investigate the incidence of errors in the preparation of injectable medicines in the hospital clinical areas, I need to observe people preparing injectable drugs. Your clinical area has been chosen because it has a high use of drugs prepared on the ward. You have been invited to be observed, as you are one of the staff qualified to prepare drugs for injectable administration. It is essential to obtain an in-depth understanding of injectable preparation errors and by observing preparation errors, an insight into the process of will be gained. This in turn will enable the identification and implementation of strategies for reducing injectable preparation errors in the hospital clinical areas.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. If you decide not to participate in the study, you may be observed by the investigator present in the clinical area but your activities will not be documented. All activities witnessed by the investigator will be kept confidential. This study will not affect your employment in any way.

What would happen to me if I take part?

Over a period of up to two weeks, an investigator will be present in your clinical area to observe the process of preparing injectable medicines. You will be asked to allow a trained observer to watch you prepare injectable medicines. This will involve watching what you do, from the time you start preparing medication until you are ready to administer it to the patient, and recording information on a data collection sheet. Administration to the patient will not be observed. Any mistakes in the preparation of the injections that are observed by the investigator will be noted on an **anonymous**, standardised data collection form. This observation will enable the determination of the number and type of mistakes that happen during the preparation of injectable medicines in the clinical area. The investigator is interested in errors relating to the prescription (medicine chart), the injectable drug guide, the actual preparation and the final check. The investigator is only interested in internal errors i.e. mistakes that are detected during the preparation process, before the medication is given to the patient. If you are involved in a mistake during the preparation process, the investigator will invite you to complete a short questionnaire and take part in a short interview. The **confidential** interview will take approximately 10 to 15 minutes. The interview will take place at a time and location that is most convenient for you but within 48 hour of the error being made. The purpose of the interview or self-completion questionnaire is to explore how the error occurred, what factors contributed to the error and what strategies could be implemented to prevent the error from happening again. With your permission, the investigator will audio-record the interview.

All data collected by the investigator, as part of the study is strictly **confidential.** Data from the interviews or self-completion questionnaire will be **anonymised** during data analysis. It will **NOT** be possible to link information used in the report back to you.

What are the possible disadvantages and risks of taking part?

Normally there will be no disadvantages and risks except the inconvenience of being watched. If taking part in this project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you have a concern about any aspect of the study, the way you've been approached and treated during the course of this study, you should speak with the investigator who will do their best to answer any questions. If you remain unhappy and wish to complain formally, the normal National Health Service complaints procedure is available to you. Details can be obtained from your hospital.

What are the possible benefits of taking part?

This project will allow any problems with injectable preparation to be identified and quantified. It will also highlight areas of good practice, which will be shared. The findings will enable the development of strategies for reducing the risk of preparation errors, so improving patient safety. The study findings will be useful for participating hospitals as these clinical areas will receive feedback to allow them to act on issues identified.

Will my taking part in this study be kept confidential?

Absolutely, all information that is collected about you during the course of the audit study would be kept strictly confidential. Personal details are not being collected. The forms used by the investigator to record mistakes are **anonymous.**

What would happen to the results of the project?

The study will be described in full as part of a PhD thesis. Individuals and organisations will not be identified in any report or publication. It is hoped to publish and/or present at national level so all the information gained is shared widely. Your clinical area will be sent a copy of any resultant publication; if you would like a personal copy you will also be sent one. In addition, the interviews or self-completion questionnaire are confidential and the investigator will anonymise the data collected. All data collection forms will be stored securely at the University of Bath.

Who is organising the project?

The project is being organised by Abdulaziz Almatroudi (PhD candidate, Department of Pharmacy and Pharmacology, University of Bath), Dr Lynette James (Cardiff and Vale University Health Board Pharmacy Department), Dr Julie Letchford

(Senior Teaching Fellow, Department of Pharmacy and Pharmacology, University of Bath) and Dr Matthew Jones (Lecturer, Department of Pharmacy and Pharmacology, University of Bath). The project team are providing their time and expertise free of charge.

What if bad practice is observed?

The study is not designed to catch anyone out but to identify risks associated with the injectable preparation process. There is, a duty on all healthcare professionals to do all they can to prevent patient harm. If bad practice is observed then there is a duty of care to report this. This is no different to the duty of care placed on all nurses through the Nursing and Midwifery Council. Therefore, if having carried out observations and interviews, the investigator has reason to doubt the fitness to practice of a member of staff, he will discuss this with his supervisors. If they agree that there are grounds to be concerned about fitness to practice, they will disclose this to the relevant ward manager.

What happens afterwards?

I would be happy to come back to the ward when the project is complete to explain any findings.

Contacts for further information.

Should you have any further questions, or would like to enquire further please contact a member of the projecy teamr by either e-mail or phone (9am-5pm Monday to Friday).

Dr Julie Letchford: J.A.Letchford@bath.ac.uk Tel (01225 386729).

Dr Lynette James: Lynette.James@wales.nhs.uk Tel (02920 744351).

Dr Matthew Jones: M.D.Jones@bath.ac.uk Tel (01225 383829).

Abdulaziz Almatroudi: aa687@bath.ac.uk Mobile [redacted]

If you are happy to participate in this study, please complete the attached consent form and return them to the investigator based in your hospital clinical areas.

Thank you for reading this information sheet, which is yours to keep.

Appendix 15

CONSENT FORM

INVESTIGATING ERRORS IN PREPARING INJECTABLE MEDICINES IN HOSPITAL CLINICAL AREAS

Name of Investigator: Abdulaziz Almatroudi

You are provided with two copies of this consent form. Both forms must be returned to the investigator based in your hospital clinical area. The first copy signed by the investigator will be returned for you to keep. The second copy will be stored securely by Abdulaziz Almatroudi.

Please initial box

I. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

II. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my standing or employment within the Trust or legal rights being affected. ☐

III. I agree that what I write on questionnaire or say during the interviews can be used, **anonymously**, in the presentation of the project. ☐

IV. I understand that if the investigator has reason to doubt my fitness to practice, he will be obliged to discuss this with his supervisors, who may disclose these concerns to my ward manager. ☐

V. I agree to take part in the above study. ☐

Please **DO/DO NOT** (delete as appropriate) sends me a report on the results of this project.

Address for those requesting a report:

Name of nurse	**Signature**	**Date:**
Name of investigator Abdulaziz Almatroud	**Signature**	**Date:**

Appendix 16

1: Description of all errors that occurred on the surgical ward (S).

Prescribed medicine	Description of potential error	Type of error
Adrenaline I.V. infusion 1mg in 100ml 0.9% NaCl	**1.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (leakage of drug solution onto sink/floor and continued preparation without any corrective action). **2.** A plastic apron was not worn during preparation.	**1.** Wrong preparation technique. Ward (S) 2016, p24 **2.** Wrong preparation technique. (RCN, p22)
Phytomenadione I.V. infusion 10 mg in 50ml 0.9% NaCl	**1.** Disregard for clean, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (leakage of drug solution onto sink/floor and continued preparation without any corrective action). **2.** A plastic apron was not worn during preparation.	**1.** Wrong preparation technique. Ward (S) 2016, p24 **2.** Wrong preparation technique. (RCN, p22)
Phytomenadione I.V. infusion 10 mg in 50ml 0.9% NaCl	**1.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (leakage of drug solution onto sink/floor and continued preparation without any corrective action). **2.** A plastic apron was not worn during preparation.	**1.** Wrong preparation technique. Ward (S) 2016, p24 **2.** Wrong preparation technique. (RCN, p22)
Furosemide I.V. infusion 40 mg in 50ml 0.9% NaCl	**1.** A plastic apron was not worn during preparation. **2.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (syringes; plastic bottles and gauze on sink/floor).	**1**. Wrong preparation technique. (RCN, p22) **2.** Wrong preparation technique. Ward (S) 2016, p24
Furosemide I.V. infusion 40 mg in 50ml 0.9% NaCl	**1.** A plastic apron was not worn during preparation. **2.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (syringes; plastic bottles and gauze on sink/floor).	**1**. Wrong preparation technique. (RCN, p22) **2.** Wrong preparation technique. Ward (S) 2016, p24

Prescribed medicine	**Description of potential error**	**Type of error**
Tazocin I.V. infusion 4.5 g in 100ml 0.9% NaCl	**1**. Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume	**1.** Wrong addition/mixing. (IV Policy,2016, p39)
	2. Signature of member of staff who prepared product missing from drug chart.	**2**. Wrong preparation technique. Ward (S) 2016, p18
	3. Failure to swab septum of vial with alcohol wipe.	**3.** Wrong preparation technique. Ward (S) 2016, p25
	4. Signature of member of staff who prepared product missing from the label.	**4.** Wrong preparation technique. Ward (S) 2016, p15
Tazocin I.V. infusion 4.5 g in 100ml 0.9% NaCl	**1**. Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume.	**1.** Wrong addition/mixing. (IV Policy,2016, p39)
	2. Drug not fully dissolved in diluent (e.g. final product not clear "cloudiness").	**2.** Wrong addition/mixing. Ward (S) 2016, p27
Tazocin I.V. infusion 4.5 g in 100ml 0.9% NaCl	Violation of "aseptic non touch technique" (ANTT) where the maker touches areas that may cause contamination (needle hub and syringe).	Wrong preparation technique. (ANTT, p7)
Amoxicillin I.V. infusion 1 g in 100ml 0.9% NaCl	**1.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (dropping uncapped syringe and needle in sink and continuing preparation without any corrective action).	**1.** Wrong preparation technique. Ward (S) 2016, p24
	2. Failure to double-check the final product by another nurse.	**2.** Wrong preparation technique. Ward (S) 2016, p4
	3. Signature of 2nd checker who checked product missing from the label.	**3**. Wrong preparation technique. Ward (S) 2016, p15
Amoxicillin I.V. infusion 1 g in 100ml 0.9% NaCl	Leakage from vial resulted in dose being too low.	Wrong dose. Ward (S) 2016, p29

Prescribed medicine	Description of potential error	Type of error
Amoxicillin I.V. infusion 1 g in 100ml 0.9% NaCl	**1.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (dropping uncapped syringe and needle in sink and continuing preparation without any corrective action).	**1.** Wrong preparation technique. Ward (S) 2016, p24
	2. Failure to double-check the final product by another nurse.	**2.** Wrong preparation technique. Ward (S) 2016, p4
	3. Signature of 2nd checker who checked product missing from the label.	**3**. Wrong preparation technique. Ward (S) 2016, p15
Amoxicillin I.V. infusion 1 g in 100ml 0.9% NaCl	A dose of medicine not prepared by the time of the next scheduled dose.	Omitted medicine. (NPSA, 2007;p13)
Amoxicillin I.V. infusion 1 g in 100ml 0.9% NaCl	**1**. Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume.	**1.** Wrong addition/mixing. (IV Policy,2016, p39)
	2. Drug not fully dissolved in diluent (Final product not "cloudiness" clear).	**2.** Wrong addition/mixing. Ward (S) 2016, p27
Amoxicillin I.V. infusion 1 g in 100ml 0.9% NaCl	**1**. Strongly shaking a drug that foams/bubbles – risk of air embolism or incorrect volume of treatment.	**1.** Wrong addition/mixing. (IV Policy,2016, p39)
	2. Violation of "aseptic non touch technique" (ANTT) where the maker touches areas that may cause contamination (needle hub).	**2.** Wrong preparation technique. (ANTT, p7)
	3. Not wearing protective clothing (gloves and apron).	**3.** Wrong preparation technique. (RCN, p11; IV Policy, p19)
Amoxicillin I.V. infusion 1 g in 100ml 0.9% NaCl	Wrong medicine selected: co-amoxiclav 1.2g /100ml instead of amoxicillin 1g/100ml.	Wrong medicine (NPSA, 2007;p14)
Co-amoxiclav I.V. infusion 1.2 g in 100ml 0.9% NaCl	**1.** Signature of member of staff who prepared product missing from the label.	**1.** Wrong preparation technique. RUH, Bath 2016, p18
	2. Failure to double-check the final product by another nurse.	**2.** Wrong preparation technique. Ward (S) 2016, p4
	3. Signature of 2nd checker who checked product missing from the label.	**3**. Wrong preparation technique. Ward (S) 2016, p15

Continue Table: 5.10

Prescribed medicine	**Description of potential error**	**Type of error**
Co-amoxiclav I.V. infusion 1.2 g in 100ml 0.9% NaCl	Leakage from vial resulted in dose being too low.	Wrong dose. Ward (S) 2016, p29
Paracetamol I.V. infusion 1g/100ml	Wrong medicine selected: metronidazole 500mg/100ml instead of paracetamol 1g/100ml.	Wrong medicine (NPSA, 2007; p14).
Ondansetron I.V. infusion 2mg in 50ml 0.9% NaCl	**1.** Failure to double-check the final product by another nurse. **2.** Signature of 2nd checker who checked product missing from the label.	**1.** Wrong preparation technique. Ward (S) 2016, p4 **2**. Wrong preparation technique. Ward (S) 2016, p15
Actrapid 50 units in 50mL of 0.9% NaCl Infusion pump	**1.** Wrong strength of diluent picked to prepare final product: 0.45% NaCl instead of 0.9% NaCl. **2.** Wrong volume of diluent: Picked 100ml 0.9%Nacl instead of 50 ml 0.9% NaCl.	**1.** Wrong diluent. (NPSA, 2007; p3). **2.** Wrong volume of diluent used. (NPSA, 2007; p3).
Metronidazole I.V. infusion 500mg/100ml	**1.** Violation of "aseptic non touch technique" (ANTT) where the maker touches areas that may cause contamination (needle hub). **2.** Deficient to performing a proper infection control after break on 'ANTT' (continuing preparation without changing the needle or swabbing it with alcohol after a needle touched by the maker.	**1.** Wrong preparation technique. (ANTT, p7) **2.** Wrong preparation technique. (ANTT, p7)
Meropenem I.V. infusion 1 g in 50ml 0.9% NaCl	Preparing product outside treatment room in unsuitable location such as nurse reception.	Wrong preparation technique. Ward (S) 2016, p24
Teicoplanin I.V. infusion 600mg/ml	Physician changed dose after being made up. Additional 200mg added to infusion but label not changed.	Wrong labelling. (IV Policy, p7)
Morphine Sulphate I.V. infusion 10mg/5ml in 10ml water injection	Filter needle not used during making product.	Wrong preparation technique. (RCN, 2010;P20)

2: Description of all errors that occurred at the medical ward (C).

Prescribed medicine	Description of potential error	Type of error
Tazocin I.V infusion 4.5 g in 100ml 0.9%NaCl	**1.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (syringes; needle; plastic bottles and gauze on bench; sink/floor and continuing preparation without any corrective action).	**1.** Wrong preparation technique. Ward (C) 2016, p24
	2. Strongly shaking a drug that foams/bubbles – risk of air embolism or incorrect volume of treatment.	**2.** Wrong addition/mixing. (IV Policy,2016, p39)
	3. Open window in the area where the injectable dose is prepared (Bees and spiders inside treatment room).	**3.**Wrong preparation technique Ward (C) 2016, p24
Tazocin I.V. infusion 4.5 g in 100ml 0.9%NaCl	**1.** Failure to double-check the final product by another nurse.	**1.** Wrong preparation technique. Ward (C) 2016, p4
	2. Signature of 2nd checker missing from the label.	**2**. Wrong preparation technique. Ward (C) 2016, p15
Tazocin I.V. infusion 4.5 g in 100ml 0.9% NaCl	**1.** Failure to double-check the final product by another nurse.	**1.** Wrong preparation technique. Ward (C) 2016, p4
	2. Signature of 2nd checker missing from the label.	**2**. Wrong preparation technique. Ward (C) 2016, p15
	3. Open window in the area where the injectable dose is prepared (insects inside treatment room).	**3.** Wrong preparation technique. Ward (C) 2016, p24
Tazocin I.V. infusion 4.5 g in 100ml 0.9% NaCl	**1.** Failure to double-check the final product by another nurse.	**1.** Wrong preparation technique. Ward (C) 2016, p4
	2. Drug not fully dissolved in diluent (final product not "cloudiness" clear).	**2.** Wrong addition/mixing. Ward (C) 2016, p27
Tazocin I.V. infusion 4.5 g in 100ml 0.9% NaCl	Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume of.	Wrong addition/mixing. (IV Policy,2016, p39)

Prescribed medicine	Description of potential error	Type of error
Tazocin I.V. infusion 4.5 g in 100ml 0.9% NaCl	**1.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (insects inside treatment room).	1. Wrong preparation technique. Ward (C) 2016, p24
	2. Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume.	**2.** Wrong addition/mixing. (IV Policy,2016, p39)
Tazocin I.V. infusion 4.5 g in 100ml 0.9% NaCl	**1.** Failure to double-check the final product by another nurse.	**1.** Wrong preparation technique. Ward (C) 2016, p4
	2. Signature of 2nd checker missing from the label.	**2.** Wrong preparation technique. Ward (C) 2016, p15
	3. Drug not fully dissolved in diluent (final product not "cloudiness" clear).	**3.** Wrong addition/mixing. Ward (C) 2016, p27
Amoxicillin I.V. infusion 1 g in 100ml 0.9% NaCl	**1**. Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume.	**1.** Wrong addition/mixing. (IV Policy,2016, p39)
	2. Drug not fully dissolved in diluent (final product not "cloudiness" clear).	**2.** Wrong addition/mixing. Ward (C) 2016, p27
Amoxicillin I.V. infusion 1 g in 100ml 0.9% NaCl	A 1.2g dose of the antibiotic co-amoxiclav was prepared an I.V. bolus injection instead of 1g of amoxicillin.	Wrong medicine (NPSA, 2007; p14).
Wilate F.VIII I.V. infusion 2000U	Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume.	Wrong addition/mixing. (IV Policy,2016, p39)
Wilate F.VIII I.V. infusion 2000U	Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume.	Wrong addition/mixing. (IV Policy,2016, p39)

Prescribed medicine	Description of potential error	Type of error
Wilate F.VIII I.V. infusion 2000U	Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume.	Wrong addition/mixing. (IV Policy,2016, p39)
Cyclizine I.V. infusion 50mg/ml in 10ml 0.9% NaCl	**1.** Failure to double-check the final product by another nurse. **2.** Signature of 2nd checker missing from the label. **3.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (syringes; needle; plastic bottles and gauze on bench; sink/floor and continuing preparation without any corrective action).	Wrong preparation technique. Ward (C) 2016, p4 **2**. Wrong preparation technique. Ward (C) 2016, p15 **3.** Wrong preparation technique. Ward (C) 2016, p24
Cyclizine I.V. infusion 50mg/ml in 10ml 0.9% NaCl	Filter needle not used during making product (packaged ampoule).	Wrong preparation technique. (RCN, 2010;P20)
Melphalan I.V. infusion 220mg in 176ml 0.9% NaCl	**1.** When a melphalan infusion (prepared in pharmacy) was about to be administered but it was noticed by the observer that it had expired two hours ago. **2.** Open window in the area where the injectable dose is prepared (resulting in insects inside treatment room).	**1.** Wrong expiry date. (IV Policy, p17-18) **2.** Wrong preparation technique. Ward (C) 2016, p24
Melphalan I.V. infusion 220mg in 250ml 0.9% NaCl	**1.** When a melphalan infusion (prepared in pharmacy) was about to be administered but it was noticed by the observer that it had expired two hours ago. **2.** Open window in the area where the injectable dose is prepared (resulting in insects inside treatment room).	**1.** Wrong expiry date. (IV Policy, p17-18) **2.** Wrong preparation technique. Ward (C) 2016, p24
Paracetamol I.V. infusion 1g/100ml	**1.** Failure to double-check the final product by another nurse. **2.** Signature of 2nd checker missing from the label.	Wrong preparation technique. Ward (C) 2016, p4 **2**. Wrong preparation technique. Ward (C) 2016, p15

Prescribed medicine	Description of potential error	Type of error
Furosemide I.V. infusion 40 mg in 50ml 0.9% NaCl	**1.** Failure to double-check the final product by another nurse. **2.** Signature of 2nd checker missing from the label.	Wrong preparation technique. Ward (C) 2016, p4 **2**. Wrong preparation technique. Ward (C) 2016, p15
Teicoplanin I.V. infusion 600mg in 100ml 0.9% NaCl	**1.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (syringes; needle; plastic bottles and gauze on bench; sink/floor and continuing preparation without any corrective action). **2**. Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume. **3.** Drug not fully dissolved in diluent (final product not "cloudiness" clear).	**1.** Wrong preparation technique. Ward (C) 2016, p24 **2.** Wrong addition/mixing. (IV Policy,2016, p39) **3.** Wrong addition/mixing. Ward (C) 2016, p27
Digoxin I.V. infusion 500mcg in 100ml 5% glucose	**1.** Disregard for cleanliness, uncluttered and free from interruption and distraction as possible before/during I.V. drug preparation (syringes; needle; plastic bottles and gauze on bench; sink/floor and continuing preparation without any corrective action). **2.** Failure to double-check the final product by another nurse. **3.** Signature of 2nd checker missing from the label. **4.** Filter needle not used during making product (packaged ampoule).	**1.** Wrong preparation technique. Ward (C) 2016, p24 2. Wrong preparation technique. Ward (C) 2016, p4 **3.** Wrong preparation technique. Ward (C) 2016, p15 **4.** Wrong preparation technique. (RCN, 2010;P20)
Co-amoxiclav I.V. infusion 1.2 g in 100ml 0.9% NaCl	Strongly shaking a drug that foams/bubbles – risk of air embolism or measurement of incorrect volume.	Wrong addition/mixing. (IV Policy,2016, p39)
0.9% NaCl 20ml I.V. infusion	Violation of "aseptic non touch technique" (ANTT) where the maker touches areas that may cause contamination (needle hub).	Wrong preparation technique. (ANTT, p7)
Morphine Sulphate I.V. infusion 10mg/5ml in 10ml water injection	Signature of member of staff who prepared product missing from the label.	Wrong preparation technique. Ward (C) 2016, p15

3: Description of all errors that occurred on the medical ward (B).

Description of error **Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action** **Policy violated: Ward (B), 2015, p3.** **The above error was observed with all the following medicines.**	
Prescribed medicine	
1. Furosemide I.V infusion 80 mg in 100 ml 0.9% sodium chloride.	**2. Meropenem I.V injection 500 mg in 10 ml water for injections (x 2) [1].**
3. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride.	**4. Meropenem I.V injection 1 g in 20 ml water for injections.**
5. Digoxin I.V infusion 250 micrograms in 100 ml 5% glucose.	**6. Ceftazidime I.Vinfusion 2 g in 100 ml 0.9% sodium chloride.**
7. Paracetamol I.V infusion 1g/100 ml.	**8. Heparin sodium 600 units / 6 ml.**
9. Levomepromazine hydrochloride S.C injection 5mg.	**10 0.9% sodium chloride 10 ml I.V injection.**
11. Levofloxacin I.V infusion 500 mg in 100 ml 0.9% sodium chloride (x 2) [1].	**12. Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride (x 2) [1].**
13. Pabrinex I.V infusion (4 pairs) in 100 ml 0.9% sodium chloride	**14. Aciclovir I.V infusion 500 mg in 100 ml 0.9% sodium chloride.**

Description of potential errors **A plastic apron was not worn during preparation.** **Policy violated: RCN, 2010, p22.** **The above error was observed with all the following medicines.**	
Prescribed medicine	
1. Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	**2. Meropenem I.V injection 1 g in 20 ml water for injections**
3. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride (x 2) [1].	**4. Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride (x 2) [1].**
5. Metronidazole I.V infusion 500 mg in 100 ml	**6. Actrapid 50 units in 50 mL 0.9% sodium chloride**
7. Clarithromycin I.V infusion 500 mg in 250 ml 0.9% sodium chloride	**8. Heparin sodium 600 units / 6 ml**
9. Methylprednisolone I.V infusion 750 mg in 100 ml 0.9% sodium chloride	**10. 0.9% sodium chloride 10ml I.V injection**
11. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 2) [1].	**12. Ondansetron I.V injection 4 mg in 20 ml 0.9% sodium chloride**
13. Pabrinex (3 pairs) I.V infusion in 100 ml 0.9% sodium chloride.	

Description of potential errors Gloves were not worn during preparation. Policy violated: NBT, 2015, p14. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	**2. Actrapid 50 units in 50 mL 0.9% sodium chloride**
3. Ondansetron I.V injection 4 mg in 20 ml 0.9% sodium chloride	**4. Heparin sodium 600 units / 6 ml**
5. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride (x 2) [1].	**6. 0.9% sodium chloride 10ml I.V injection**
7. Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride (x 2) [1].	

[1] Two medicines prepared.

Description of potential errors Piercing the rubber septum of a vial without wiping with an alcohol wipe. Policy violated: Ward (B), 2015, p4. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 2) [1].	**2. Teicoplanin I.V infusion 400 mg in 100 ml 0.9% sodium chloride.**
3. Meropenem I.V injection 1g in 20 ml water for injections.	**4.Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride**
5. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride (x 3) [2].	

[1] Two medicines prepared.
[2] Three medicines prepared.

Description of potential errors Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker. Policy violated: NBT, 2015, p14; RCN, 2010, p5. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 3) [2].	2. 0.9% sodium chloride 10 ml I.V injection (x 7) [3].
3. Pabrinex (4 pairs) I.V infusion in 100 ml 0.9% sodium chloride	4. Heparin sodium 600 units / 6 ml (X 2) [1].
5. Hydrocortisone I.V infusion 100 mg in 4 ml water for injections (x 2) [1].	6. Furosemide I.V infusion 80 mg in 100ml 0.9% sodium chloride
7. Ondansetron I.V injection 4 mg in 20 ml 0.9% sodium chloride	8. Aciclovir I.V infusion 500 mg in 100 ml 0.9% sodium chloride

Description of potential errors Drug was strongly shaken, causing foam/bubbles. Policy violated: Ward (B), 2015, p5. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 4) [4].	2. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride.

Description of potential errors Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”). Policy violated: Ward (B) 2015, p5; p6; p15. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 3) [2].	2. Meropenem I.V injection 500 mg in 10 ml water for injections
3. Meropenem I.V injection 1 g in 20 ml water for injections	

Description of potential errors

Filter needle not used whilst making product packaged in a glass ampoule.

Policy violated: Ward (B), 2015, p4.

The above error was observed with all the following medicines.

Prescribed medicine	
1. Furosemide I.V infusion 80 mg in 100 ml 0.9% sodium chloride (x 5) [5].	**2. Furosemide I.Vinjection 40 mg in 10 ml 0.9% sodium chloride.**
3. Pabrinex (3 pairs) I.V infusion in 100 ml 0.9% sodium chloride (x 2) [1].	**4. Phytomenadione I.V infusion 10 mg in 50 ml 0.9% sodium chloride (x 3) [2].**
5. Heparin sodium 600 units / 6 ml (x 7) [3].	**6. Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride (x 2) [1].**

Description of potential errors

Preparing product outside treatment room in unsuitable location, such as ward reception desk

Policy violated: **Ward (B), 2015, p3.**

The above error was observed with all the following medicines.

Prescribed medicine	
1. Meropenem I.V injection 1 g. in 20 ml water for injections (x 3) [2].	**2. Co-trimoxazole I.V infusion 960 mg in 250 ml 0.9% sodium chloride**
3. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 4) [4].	**4. Levofloxacin I.V infusion 500 mg in 100 ml 0.9% sodium chloride**
5. Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride.	**6. Heparin sodium 600 units / 6 ml (x 3) [2].**
7. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	**8. 0.9% sodium chloride 10 ml I.V injection**
9. Furosemide I.V injection 40 mg in 10 ml 0.9% sodium chloride	**10. Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride (x 2) [1].**
11. Aciclovir I.V infusion 500 mg in 100 ml 0.9% sodium chloride	**12. Digoxin I.V infusion 250 micrograms in 100 ml 5% glucose**

[1] Two medicines prepared.
[2] Three medicines prepared.
[3] Seven medicines prepared.
[4] Four medicines prepared.
[5] Five medicines prepared.

Description of potential errors **Wrong spelling of drug name on label.** Policy violated: **Ward (B), 2015, p6.** **The above error was observed with the following medicine.**
Prescribed medicine
1. Methylprednisolone I.V infusion 1 g in 100 ml 0.9% sodium chloride.

[1] Two medicines prepared.

Description of potential errors **Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose was prepared on plastic tray).** **Policy violated: Ward (B), 2015, p6.** **The above error was observed with all the following medicines.**	
Prescribed medicine	
1. Meropenem I.V injection 1 g in 20 ml water for injections (x 3) [2].	**2. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride (x 3) [2].**
3. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 6) [6].	**4. Levofloxacin I.V infusion 500 mg in 100 ml 0.9% sodium chloride.**
5. 0.9% sodium chloride 10 ml I.V injection.	**6. Heparin sodium 600 units / 6 ml (x 2) [1].**
7. Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride (x 2) [1].	

Description of potential errors **Signature of nurse who checked product missing from drug chart.** **Policy violated: Ward (B), 2015, p4; p7; p14.** **The above error was observed with the following medicine.**
Prescribed medicine
1. Pabrinex I.V infusion (4 pairs) in 100 ml 0.9% sodium chloride

Description of potential errors **A second nurse did not check the dose prepared by the first nurse.** **Policy violated: Ward (B), 2015, p8-p10.** **The above error was observed with the following medicine.**
Prescribed medicine
1. Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride.

[2] Three medicines prepared.
[6] Six medicines prepared.

Description of potential errors **Leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10%.** **Policy violated: Ward (B), 2015, p5; p6.** **The above error was observed with all the following medicines.**
Prescribed medicine
1. Pabrinex I.V infusion (4 pairs) in 100 ml 0.9% sodium chloride **2. Enoxaparin sodium S.C 110 mg / 0.74 ml (x 2) [1].**
3. Ondansetron i.v injection 2 mg in 10 ml 0.9% sodium chloride.
Description of potential errors **Dose not prepared, omission not documented.** **Policy violated: Ward (B), 2015, p32.** **The above error was observed with all the following medicines.**
Prescribed medicine
1. 0.9% sodium chloride 10 ml I.V injection. **2. Hydrocortisone I.V infusion 100 mg in 4 ml water for injections**
3. Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride
Description of potential errors **Wrong medicine selected: co-amoxiclav 1.2 g in 100 ml instead of amoxicillin 1 g in 100 ml.** **Policy violated: Ward (b), 2015, p3.** **The above error was observed with all the following medicines.**
Prescribed medicine
1. Amoxicillin I.V infusion 1 g in 100ml 0.9% sodium chloride.
Description of potential errors **Wrong medicine selected: metronidazole 500mg in 100 ml instead of paracetamol 1 g in 100 ml.** **Policy violated: Ward (B), 2015, p3.** **The above error was observed with the following medicine.**
Prescribed medicine
1. Paracetamol I.V infusion 1g in 100ml

[1] Two medicines prepared.

Description of potential errors **Wrong volume of diluent picked to prepare final product: 100 ml 0.9% sodium chloride instead of 50ml or 30ml 0.9% to prepare final product.** **Policy violated: Ward (B), 2015, p3.** **The above error was observed with all the following medicines.**	
Prescribed medicine	
Sodium ferric gluconate (unlicensed) medicine, Germany) I.V infusion 30ml	Magnesium sulfate 50% I.V infusion 20 mmol in 50ml 0.9% sodium chloride

4: Description of all errors that occurred at the surgical ward (H).

Description of potential errors **Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.** **Policy violated: Ward (H), 2015, p3.** **The above error was observed with all the following medicines.**	
Prescribed medicine	
1. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 6) [6].	**2. Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride**
3. 0.9% sodium chloride 10 ml I.V injection (x 2) [1].	**4. Flucloxacillin I.V injection 1 g in 20 ml water for injections (x 4) [4].**
5. Flucloxacillin I.V infusion 2 g in 100 ml 0.9% sodium chloride	**6. Co-trimoxazole I.V infusion 960 mg in 250 ml 0.9% sodium chloride (x 2) [1].**
7. Morphine sulphate I.V injection 10 mg in 10ml water for injections.	

1

Two medicines prepared.
[4] Four medicines prepared.
[6] Six medicines prepared.

Description of potential errors A plastic apron was not worn during preparation. Policy violated: RCN, 2010, p22. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Amoxicillin I.V. infusion 1 g in 100 ml 0.9% sodium chloride.	**2. Tramadol I.V. infusion 100 mg in 100 ml 0.9% sodium chloride**
3. Piperacillin and tazobactam I.V infusion 4.5g in 100 ml 0.9% sodium chloride	**4. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 4) [4]**
5. **0.9% sodium chloride 10 ml i.v. injection (x 6)[6]**	**6. Morphine sulphate I.V injection 10 mg in 10 ml water for injections**
7. Flucloxacillin I.V injection 1 g in 20 ml water for injections.	**8. Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride**

Description of potential errors Gloves were not worn during preparation. Policy violated: Ward (H), 2015, p14. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride.	**2. Tramadol I.V infusion 100 mg in 100 ml 0.9% sodium chloride.**
3. Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride.	**4. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 4) [4].**
5. 0.9% sodium chloride 10 ml I.V injection (x6) [6]	**6. Morphine sulphate I.V injection 10 mg in 10 ml water for injections.**
7. Flucloxacillin I.V injection 1 g in 20 ml water for injections.	**8. Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride.**

[4] Four medicines prepared.
[6] Six medicines prepared

Description of potential errors Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker. Policy violated: Ward (H), 2015, p14; RCN, 2010, p5. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride.	**2. Flucloxacillin I.V infusion 2 g in 100 ml 0.9% sodium chloride**
3. Meropenem I.V injection 1 g in 20 ml water for injections	**4. Vancomycin I.V infusion 500 mg in 100 ml 0.9 % sodium chloride**
5. 0.9% sodium chloride 10 ml I.V injection (x 8)[7]	**6. Morphine sulphate I.V injection 10 mg in 10 ml water for injections**
7. Flucloxacillin I.V injection 1 g in 20 ml water for injections (x 2) [1]	**8. Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride**

Description of potential errors Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”). Policy violated: Ward (H), 2015, p5; p6; p15. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride (x2)[1]	**2. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 7) [3].**

[1] Two medicines prepared.
[3] Seven medicines prepared.
[7]Eight medicines prepared

Description of potential errors Filter needle not used whilst making product packaged in a glass ampoule. Policy violated: Ward (H), 2015, p4. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Pabrinex I.V infusion (4 pairs) in 100 ml 0.9% sodium chloride	**2. Ondansetron I.V infusion 4 mg in 50 ml 0.9% sodium chloride (x 2) [1].**
3. Gentamicin I.V infusion 300 mg in 250 ml 0.9% sodium chloride (x 3) [2].	**4. Ranitidine I.V infusion 50 mg in 50 ml 0.9% sodium chloride**
5. Oxycodone hydrochloride 20 mg and midazolam 50 mg in 17 ml 0.9% sodium chloride for 24-hour subcutaneous infusion.	**6. Morphine sulphate I.V injection 10 mg in 10 ml water for injections (x 4) [4]**
7. Amiodarone I.V infusion 200 mg in 250 ml 5% glucose	**8. Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride (x 7) [3].**
9. Calcium gluconate I.V infusion 950 mg in 100 ml 0.9% sodium chloride	
Description of potential errors Preparing product outside treatment room in unsuitable location such as ward reception desk. Type of error Wrong preparation technique: Ward (H), 2015, p3. The above error was observed with all the following medicines.	
Prescribed medicine	
1. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 2) [1]	**2. 0.9% sodium chloride 10 ml I.V injection (x 2) [1].**
3. Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	**4. Morphine sulphate I.V injection 10 mg in 10 ml water for injections**

[1] Two medicines prepared.
[2] Three medicines prepared.
[3] Seven medicines prepared.
[4] Four medicines prepared

Description of potential errors **Wrong spelling of drug name on label.** **Policy violated: Ward (H), 2015, p6.** **The above error was observed with all the following medicines.**
Prescribed medicine
1. Flucloxacillin I.V injection 1 g in 20 ml water for injections
Description of potential errors **Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).** **Policy violated: Ward (H), 2015, p6.** **The above error was observed with all the following medicines.**
Prescribed medicine
1. Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride (x 2) [1] **2. Meropenem I.V injection 1 g in 20 ml water for injections**
3. Amoxicillin I.V injection 1 g in 20 ml water for injections **4. Ceftazidime I.V injection 2 g in 10 ml water for injections**
5. Piperacillin and tazobactam I.V injection 4.5 g in 20 ml water for injections (x 16) [8] **6. Flucloxacillin I.V injection 1 g in 20 ml water for injections (x 4)** [4]
Description of potential errors **A second nurse did not check the dose prepared by the first nurse.** **Policy violated: Ward (H), 2015, p8-p10.** **The above error was observed with the following medicine.**
Prescribed medicine
1. Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride

[1] Two medicines prepared.
[4] Four medicines prepared.
[8] Sixteen medicines prepared

Description of potential errors **Leakage from syringe resulted in the dose being reduced by more than 10%.** **Policy violated: Ward (H), 2015, p5; p6.** **The above error was observed with the following medicine.**
Prescribed medicine
1. Enoxaparin Sodium S.C 110 mg / 0.74 ml (x 2) [1].
Description of potential errors **Wrong volume of diluent picked to prepare final product: 100 ml 0.9% sodium chloride instead of 250ml/500ml 0.9% to prepare final product.** **Policy violated: Ward (H), 2015, p3.** **The above error was observed with all of the following medicines.**
Prescribed medicine
1. Co-trimoxazole I.V infusion 960 mg in 250 ml 0.9% sodium chloride **2. Aminophylline I.V infusion 290 mg in 500 ml 0.9 % sodium chloride**
Description of potential errors **Incorrect dose of drug due to wrong calculation of volume needed: prepared 8.6 ml instead of 11.6 ml dose needed.** **Policy violated: Ward (H), 2015, p14.** **The above error was observed with the following medicine.**
Prescribed medicine
1. Aminophylline I.V infusion 290 mg in 500 ml 0.9 % sodium chloride

[1] Two medicines prepared.

5: Mean Severity Score assigned by panel for each individual error observed on the four wards (n = 372).

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors n = 372
Surgical (S)	S1•	Adrenaline I.V infusion 1 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.2
	S1	Adrenaline I.V infusion 1 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	S2	Phytomenadione I.V infusion 10 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	S3	Phytomenadione I.V infusion 10 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	S4	Phytomenadione I.V infusion 10 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	S5	Phytomenadione I.V infusion 10 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	S6	Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	S7	Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	S8	Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8

•More than one error in one product

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (S)	S9	Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	S10	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	S11	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	S12	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	5.4
	S13	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	Rubber septum not wiped	Piercing the rubber septum of a vial without wiping with an alcohol wipe.	4.8
	S14	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	----------	Signature of nurse who prepared product missing from drug chart.	4.6
	S15	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Faulty labelling	----------	Signature of member of staff who prepared product missing from the label	3
	S16	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (S)	S17	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned, e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	S18	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned, e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	S19	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	No double-check	A second nurse did not check the dose prepared by the first nurse.	5.4
	S20	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	No double-check	A second nurse did not check the dose prepared by the first nurse.	5.4
	S21	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■
	S22	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■
	S23	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong dose	----------	Leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10%	5
	S24	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Omitted medicine	----------	Dose not prepared, omission not documented	6.4
	S25	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	S26	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	S27	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	5

■Lowest severity score

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (S)	S28	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6
	S29•	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	S29	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	S30	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong medicine	----------	Wrong medicine selected: co-amoxiclav 1.2 g in100 ml instead of amoxicillin 1 g in 100 ml.	6
	S31	Co-amoxiclav I.V infusion 1.2 g in 100 ml 0.9% sodium chloride	Faulty labelling	----------	Signature of member of staff who prepared product missing from the label	3
	S32	Co-amoxiclav I.V infusion 1.2 g in 100 ml 0.9% sodium chloride	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.4
	S33	Co-amoxiclav I.V infusion 1.2 g in 100 ml 0.9% sodium chloride	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■
	S34	Co-amoxiclav I.V infusion 1.2 g in 100 ml 0.9% sodium chloride	Wrong dose	----------	Leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10%	5
	S35	Paracetamol I.V infusion 1g in 100ml	Wrong medicine	----------	Wrong medicine selected: Co-amoxiclave 1.2g instead of amoxicillin 1 g.	6.6
	S36	Ondansetron I.V infusion 4 mg in 50 ml 0.9% sodium chloride Patient: adult / TB	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.4
	S37	Ondansetron I.V infusion 4 mg in 50 ml 0.9% sodium chloride Patient: adult / TB	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■

•More than one error in one product
■Lowest severity score

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (S)	S38•	Actrapid 50 units in 50 mL of 0.9% sodium chloride infusion pump	Wrong diluent	Wrong strength of diluent	Wrong strength of diluent picked to prepare final product: 0.45% sodium chloride instead of 0.9% sodium chloride.	6.6
	S38	Actrapid 50 units in 50 mL of 0.9% sodium chloride infusion pump	Wrong diluent	Wrong volume of diluent	Wrong volume of diluent picked to prepare final product: 100 ml 0.9% sodium chloride instead of 50ml 0.9% to prepare final product.	8.6★
	S39	Metronidazole I.V infusion 500mg/100ml	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6
	S40	Meropenem I.V infusion 1 g in 50 ml 0.9% sodium chloride Patient: adult/ skin infections	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	S42	Morphine sulphate I.V injection 10 mg in 10 ml water for injections	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	S43	Teicoplanin I.V infusion 600 mg in 100 ml 0.9% sodium chloride	Faulty labelling	----------	Physician changed dose after being made up. Additional 200 mg added to infusion but label not changed.	5.4
Medical (C)	C22	Melphalan I.V infusion 220mg in 176ml 0.9% sodium chloride Patient: adult on chemo	Wrong expiry date	----------	The final product expired: out of date drug delivered to ward due to error in logging expiry date in fridge record.	6.4
	C30	Melphalan I.V infusion 265mg in 220ml 0.9% sodium chloride Patient: adult on chemo	Wrong expiry date	----------	The final product expired: out of date drug delivered to ward due to error in logging expiry date in fridge record.	6.4
	C43	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned, e.g. Open window in the area where the injectable dose is prepared, resulting in insects inside treatment room.	6.2

•More than one error in one product

★Highest severity score.

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (C)	C44	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.2
	C45	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	C46	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	C47	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	C48	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.2
	C49	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.2
	C50	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.4
	C51	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.4

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (C)	C52	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.4
	C53	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.4
	C54	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■
	C55	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■
	C56	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■
	C57	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	5.4
	C58	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	5.4
	C59	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong medicine	----------	A 1.2g dose of the antibiotic co-amoxiclav was prepared as an I.V. bolus injection instead of 1 g of amoxicillin.	6.2

■Lowest severity score

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (C)	C60	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	C61	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	5
	C62	Wilate factor VIII I.V infusion 2000 units Patient: adult / haemophilia A	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	7.2
	C63	Wilate factor VIII I.V infusion 2000 units Patient: adult / haemophilia A	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	7.2
	C64	Wilate factor VIII i.v infusion 2000 units Patient: adult / haemophilia A	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	7.2
	C65•	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned, e.g. Open window in the area where the injectable dose is prepared, resulting in insects inside treatment room.	6
	C65	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.4
	C66•	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	C66•	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	C66	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■

•More than one error in one product
■Lowest severity score

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (C)	C67	Paracetamol I.V infusion 1 g / 100 ml	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■
	C68	Melphalan I.V infusion 220 mg in 176 ml 0.9% sodium chloride Patient: adult on chemo	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned, e.g. Open window in the area where the injectable dose is prepared, resulting in insects inside treatment room**.**	7.2
	C70	MelphalanI.V infusion 220 mg in 176 ml 0.9% sodium chloride Patient: adult on chemo	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned, e.g. Open window in the area where the injectable dose is prepared, resulting in insects inside treatment room**.**	7.2
	C71	Paracetamol I.V infusion 1 g / 100 ml	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.8
	C72•	Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.4■
	C72	Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	6
	C73•	Teicoplanin I.V infusion 600 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned, e.g. Open window in the area where the injectable dose is prepared, resulting in insects inside treatment room**.**	6.2
	C73	Teicoplanin I.V infusion 600 mg in 100 ml 0.9% sodium chloride	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	C73	Teicoplanin I.V infusion 600 mg in 100 ml 0.9% sodium chloride	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	5.6

•More than one error in one product. ■Lowest severity score

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (C)	C74•	Digoxin I.V infusion 500 micrograms in 100 ml 5% glucose	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. Open window in the area where the injectable dose is prepared, resulting in insects inside treatment room**.**	6
	C74	Digoxin I.V infusion 500 micrograms in 100 ml 5% glucose	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	C74	Digoxin I.V infusion 500 micrograms in 100 ml 5% glucose	Faulty labelling	----------	Signature of nurse who checked product missing from label.	2.6
	C74	Digoxin I.V infusion 500 micrograms in 100 ml 5% glucose	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	6.2
	C75	Co-amoxiclav I.V infusion 1.2 g in 100 ml 0.9% sodium chloride	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6
	C76	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.7
	C77	Morphine sulphate I.V injection 10 mg in 10 ml water for injections	Faulty labelling	----------	Signature of member of staff who prepared product missing from the label	7.2
Surgical (H)	H91	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.2
	H181	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	5.4

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H182	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	5.4
	H183•	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	H183	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H183	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: Staff nurse not using a plastic tray to prepare IV medications.	6
	H184•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	6
	H184	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H185	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H186•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	6
	H186	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H187•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	6
	H187	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H188	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H189	Piperacillin and tazobactam I.V infusion 4.5 g in 100 ml 0.9% sodium chloride Patient: adult/bacterial infection	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H190	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H191	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H192•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.4
	H192	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H193•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.4
	H193	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H194•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.4
	H194	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H195•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	H195	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.8
	H195	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H196	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.4

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H197•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	H197	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.8
	H197	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	6
	H197	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H198•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	5.2
	H198	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.4
	H198	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	6
	H198	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H199•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	H199	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.8
	H199	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	6
	H199	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H200•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	5.2
	H200	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H201•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	H201	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.8
	H201	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H202	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/ lung abscess	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	H203	Flucloxacillin I,V injection 1 g / 20 ml water for injections Patient: adult/ lung abscess	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	H204	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/ lung abscess	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	H205	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/bacterial infection	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.8
	H206	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/bacterial infection	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.8
	H207	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/bacterial infection	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.8

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H208•	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/ lung abscess	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	H208	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/ lung abscess	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	H208	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/ lung abscess	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H208	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/ lung abscess	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6
	H209•	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/ lung abscess	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6
	H209	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/bacterial infection	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.8
	H210•	Flucloxacillin I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/ pneumonia	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	H210	Flucloxacillin I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/ pneumonia	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H211	Flucloxacillin I.V injection 1 g / 20 ml water for injections Patient: adult/bacterial infection	Faulty labelling	----------	Wrong spelling of drug name on label.	5.2
	H212	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H213	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H214	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H215	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H216	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H217•	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	H217	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H218•	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	H218	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H219•	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	H219	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H220•	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	H220	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H220	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H221•	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	H221	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	H221	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H221	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H222•	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	H222	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	H222	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H222	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H222	0.9% sodium chloride 10 ml I.V injection	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	H224•	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	H224	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	H224	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H224	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H224	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H224	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H225	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H226	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H227	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H228	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H229	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H230	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H231	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H232	Cyclizine I.V injection 50 mg in 10 ml 0.9% sodium chloride	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	H233	Co-trimoxazole I.V infusion 960 mg in 250 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.4
	H234	Co-trimoxazole I.V infusion 960 mg in 250 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6.4
	H235	Co-trimoxazole I.V infusion 960 mg in 250 ml 0.9% sodium chloride	Wrong diluent	Wrong volume of diluent	Wrong volume of diluent picked to prepare final product: 100 ml 0.9% sodium chloride instead of 250ml 0.9% to prepare final product.	6.2

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H236•	Morphine sulphate I.V injection 10 mg in 10ml water for injections	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	H236	Morphine sulphate I.V injection 10 mg in 10ml water for injections	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	H236	Morphine sulphate I.V injection 10 mg in 10ml water for injections	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.8
	H236	Morphine sulphate I.V injection 10 mg in 10ml water for injections	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H236	Morphine sulphate I.V injection 10 mg in 10ml water for injections	Wrong preparation technique	Not used a filter needle	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H236	Morphine sulphate I.V injection 10 mg in 10ml water for injections	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	H237	Morphine sulphate I.V injection 10 mg in 10ml water for injections	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H238	Morphine sulphate I.V injection 10 mg in 10ml water for injections	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H239	Morphine sulphate I.V injection 10 mg in 10ml water for injections	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H240	Gentamicin I.V infusion 300 mg in 250 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.6
	H241	Gentamicin I.V infusion 300 mg in 250 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H242	Gentamicin I.V infusion 300 mg in 250 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.6
	H243	Ondansetron I.V infusion 4 mg in 50 ml 0.9% sodium chloride Patient: adult / TB	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H244	Ondansetron I.V infusion 4 mg in 50 ml 0.9% sodium chloride Patient: adult / TB	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H245	Enoxaparin sodium S.C 110 mg / 0.74 ml	Wrong dose	----------	Leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10%	5.8
	H246	Enoxaparin sodium S.C 110 mg / 0.74 ml	Wrong dose	----------	Leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10%	5.8
	H247	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ skin infections	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.4
	H248	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ skin infections	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H249•	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	H249	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	H249	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.4
	H250•	Amoxicillin I.V injection 1 g / 20 ml water for injections	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	5.2
	H250	Amoxicillin I.V injection 1 g / 20 ml water for injections	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.4

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Surgical (H)	H251•	Tramadol I.V infusion 100 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	H251	Tramadol I.V infusion 100 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.8
	H252	Ranitidine I.V infusion 50 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H253	Oxycodone hydrochloride 20 mg and midazolam 50 mg in 17 ml 0.9% sodium chloride for 24 hour S.C infusion	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4
	H255	Amiodarone I.V infusion 200 mg in 250 ml 5% glucose Patient: adult / HIV	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H256	Ceftazidime I.V injection 2 g / 10 ml water for injections Patient: adult HIV/respiratory infection	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.4
	H257	Calcium gluconate I.V infusion 950 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	H258	Vancomycin I.V infusion 500 mg in 100 ml 0.9 % sodium chloride Patient: adult/ bacterial infection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	H259•	Aminophylline I.V infusion 290 mg in 500 ml 0.9 % sodium chloride Patient: adult / severe acute asthma	Wrong diluent	Wrong volume of diluent	Wrong volume of diluent picked to prepare final product: 100 ml 0.9% sodium chloride instead of 500 ml 0.9% to prepare final product.	8
	H259	Aminophylline I.V infusion 290 mg in 500 ml 0.9 % sodium chloride Patient: adult / severe acute asthma	Calculation error	----------	Incorrect dose of drug due to wrong calculation of volume needed: prepared 8.6 ml instead of 11.6 ml dose needed.	7.6
	H260	Pabrinex I.V infusion (4 pairs) in 100 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B78	Furosemide I.V infusion 80 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B79	Furosemide I.V infusion 80 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B80	Furosemide I.V infusion 80 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B81	Furosemide I.V injection 40 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B82	Paracetamol I.V infusion 1g in 100ml	Wrong medicine	----------	Wrong medicine selected: metronidazole 500 mg in 100 ml instead of paracetamol 1 g in100 ml.	6.6
	B83	Methylprednisolone I.V infusion 1 g in 100 ml 0.9% sodium chloride	Faulty labelling	----------	Wrong spelling of drug name on label.	5
	B84	Sodium ferric gluconate (unlicensed medicine, Germany) I.V infusion 30ml in 100ml of 0.9% sodium chloride	Wrong diluent	Wrong volume of diluent	Wrong volume of diluent picked 250 ml 0.9% sodium chloride instead of 100 ml 0.9% to prepare final product.	6
	B85	Paracetamol I.V. infusion 1 g / 100 ml	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B86	Co-trimoxazole I.V infusion 960 mg in 250 ml 0.9% sodium chloride	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.8
	B87	Metronidazole I.V infusion 500 mg / 100 ml	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B88	Magnesium sulfate 50% I.V infusion 20 mmol in 50 ml of 0.9% sodium chloride	Wrong diluent	Wrong volume of diluent	Wrong volume of diluent picked 100 ml 0.9% sodium chloride instead of 50 ml 0.9% to prepare final product.	6.2
	B89	Clarithromycin I.V infusion 500 mg in 250 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B90	Methylprednisolone I.V infusion 750 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3.6

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B92	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6.6
	B93	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	6
	B94	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	6
	B95	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, "cloudiness").	6
	B96•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Rubber septum not wiped	Piercing the rubber septum of a vial without wiping with an alcohol wipe.	5.6
	B96	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	5.2
	B96	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B97•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Rubber septum not wiped	Piercing the rubber septum of a vial without wiping with an alcohol wipe.	5.6
	B97	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	5.2
	B97	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	B98•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.6
	B98	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	B99•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.6
	B99	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B100•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B100	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.6
	B101•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B101	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.6
	B102•	Piperacillin and tazobactamI I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	5.2
	B102	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	B103•	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	5.2
	B103	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6
	B104	Levomepromazine hydrochloride S.C injection 5mg Patient: adult/respiratory infection	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B105	Levofloxacin I.V infusion 500 mg in 100 ml 0.9% sodium chloride Patient: adult/ pneumonia	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B106•	Levofloxacin I.V infusion 500 mg in 100 ml 0.9% sodium chloride Patient: adult/ management of pneumonia	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	B106	Levofloxacin I.V infusion 500 mg in 100 ml 0.9% sodium chloride Patient: adult/ pneumonia	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.4
	B107	Levofloxacin I.V infusion 500 mg in 100 ml 0.9% sodium chloride Patient: adult/ pneumonia	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B108	Pabrinex (3 pairs) I.V infusion in 100 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.6
	B109	Pabrinex (3 pairs) I.V infusion in 100 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.6
	B110	Pabrinex (3 pairs) I.V infusion in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	B111•	Pabrinex I.V infusion (4 pairs) in 100 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B111	Pabrinex I.V infusion (4 pairs) in 100 ml 0.9% sodium chloride	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B111	Pabrinex I.V infusion (4 pairs) in 100 ml 0.9% sodium chloride	Wrong dose	----------	Leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10%	5.4

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B111	Pabrinex I.V infusion (4 pairs) in 100 ml 0.9% sodium chloride	Wrong preparation technique	----------	Signature of nurse who prepared product missing from drug chart.	4
	B112	Teicoplanin I.V infusion 400 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Rubber septum not wiped	Piercing the rubber septum of a vial without wiping with an alcohol wipe.	4.8
	B114•	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ intra-abdominal infections	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.8
	B114	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ intra-abdominal infections	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.4
	B115•	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ intra-abdominal infections	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.8
	B115	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ intra-abdominal infections	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.4
	B116•	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ skin infections	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B116	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ skin infections	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.4
	B117•	Meropenem I.V injection 500 mg / 10 ml water for injections Patient: adult/ skin infections	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B117	Meropenem I.V injection 500 mg / 10 ml water for injections Patient: adult/ skin infections	Wrong preparation technique	Rubber septum not wiped	Piercing the rubber septum of a vial without wiping with an alcohol wipe.	5

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B118	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ intra-abdominal infections	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.8
	B119	Meropenem I.V injection 500 mg / 10 ml water for injections Patient: adult/ skin infections	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B120	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ skin infections	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B121	Meropenem I.V injection 500 mg / 10 ml water for injections Patient: adult/ skin infections	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	5.6
	B122	Meropenem I.V injection 1 g / 20 ml water for injections Patient: adult/ skin infections	Wrong addition/mixing	Undissolved powder left in vial	Drug not fully dissolved in diluent (e.g. final product not clear, “cloudiness”).	5.6
	B123•	Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/respiratory infection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B123	Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/respiratory infection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	B123	Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/respiratory infection	Wrong preparation technique	Rubber septum not wiped	Piercing the rubber septum of a vial without wiping with an alcohol wipe.	4.8
	B123	Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/respiratory infection	No double-check	----------	A second nurse did not check the dose prepared by the first nurse.	5.4

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B124•	Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/respiratory infection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B124	Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/respiratory infection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	B124	Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/respiratory infection	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	B125	Ceftazidime I.V infusion 2 g in 100 ml 0.9% sodium chloride Patient: adult/respiratory infection	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B126•	Actrapid 50 units in 50 mL of 0.9% sodium chloride Infusion pump	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3.6
	B126	Actrapid 50 units in 50 mL of 0.9% sodium chloride Infusion pump	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	6
	B128	Phytomenadione I.V infusion 10 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B129	Phytomenadione I.V infusion 10 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B130	Phytomenadione I.V infusion 10 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B131	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B132	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B133	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B136	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B137•	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	B137	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	B138•	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	B138	Heparin sodium 600 units / 6 ml	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.8
	B139•	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	B139	Heparin sodium 600 units / 6 ml	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.8
	B140•	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B140	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B140	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	B141	Heparin sodium 600 units / 6 ml	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B142•	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B142	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B143•	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	B143	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Rubber septum not wiped	Piercing the rubber septum of a vial without wiping with an alcohol wipe.	4.8
	B144•	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B144	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	B144	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	B145•	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Rubber septum not wiped	Piercing the rubber septum of a vial without wiping with an alcohol wipe.	4.8
	B145	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong addition/mixing	Air bubbles not expelled before volume checked	Drug was strongly shaken, causing foam/bubbles.	6.2
	B145	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.8
	B146•	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Rubber septum not wiped	Piercing the rubber septum of a vial without wiping with an alcohol wipe.	4.8
	B146	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.4

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B147	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B148	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Wrong medicine	----------	Wrong medicine selected: co-amoxiclav 1.2 g in100 ml instead of amoxicillin 1 g in 100 ml.	6
	B149	Enoxaparin sodium S.C 110 mg / 0.74 ml	Wrong dose	----------	Leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10%	5.8
	B150	Enoxaparin sodium S.C 110 mg / 0.74 ml	Wrong dose	----------	Leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10%	5.8
	B151•	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	B151	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	B152	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B153	0.9% sodium chloride 10ml I.V injection	Omitted medicine	----------	Dose not prepared, omission not documented	3.4
	B154•	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	B154	0.9% sodium chloride 10ml I.V injection	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	5.2
	B155	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B156	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B157	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B158	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B159	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B160	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B161	0.9% sodium chloride 10ml I.V injection	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B162	Hydrocortisone I.V infusion 100 mg in 4 ml water for injections Patient: adult/acute asthma	Omitted medicine	----------	Dose not prepared, omission not documented	7.4

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B163	Hydrocortisone I.V infusion 100 mg in 4 ml water for injections Patient: adult/acute asthma	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B164	Hydrocortisone I.V infusion 100 mg in 4 ml water for injections Patient: adult/acute asthma	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B165•	Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	2.8
	B165	Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.4
	B165	Furosemide I.V infusion 40 mg in 50 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B166	Furosemide I.V infusion 80 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B167	Furosemide I.V infusion 80 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B168	Furosemide I.V injection 40 mg in 10 ml 0.9% sodium chloride	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6
	B169	Furosemide I.V infusion 80 mg in 100 ml 0.9% sodium chloride	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	5.8
	B170	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / HIV	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B171•	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / HIV	Wrong preparation technique	Filter needle not used	Filter needle not used whilst making product packaged in a glass ampoule.	4.4
	B171	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / HIV	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.8
	B171	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / HIV	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.2
	B172•	Ondansetron I.V injection 4 mg in 20 ml 0.9% sodium chloride Patient: adult with hepatitis C	Wrong preparation technique	Unused apron	A plastic apron was not worn during preparation	3
	B172	Ondansetron I.V injection 4 mg in 20 ml 0.9% sodium chloride Patient: adult with hepatitis C	Wrong preparation technique	Unused gloves	Gloves were not worn during preparation.	5.6
	B173•	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / HIV	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.8
	B173	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / HIV	Omitted medicine	----------	Dose not prepared, omission not documented	4.2
	B173	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / HIV	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.2
	B174	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / TB	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	5.6

•More than one error in one

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B175•	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / TB	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	5.6
	B175	Ondansetron I.V injection 2 mg in 10 ml 0.9% sodium chloride Patient: adult / TB	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6
	B176	Aciclovir I.V infusion 500 mg in 100 ml 0.9% sodium chloride Patient: adult / immunocompromised	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	5.6
	B177	Aciclovir I.V infusion 500 mg in 100 ml 0.9% sodium chloride Patient: adult / immunocompromised	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	5.6
	B178	Aciclovir I.V infusion 500 mg in 100 ml 0.9% sodium chloride Patient: adult / immunocompromised	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6.6
	B179	Digoxin I.V infusion 250 micrograms in 100 ml 5% glucose	Wrong preparation technique	Gross disregard for clean/ uncluttered treatment room	Treatment room was cluttered. Inadequate space created for preparation and surface was not cleaned e.g. leakage of drug solution onto sink/floor and continued preparation without any corrective action.	6
	B180	Digoxin I.V infusion 250 micrograms in 100 ml 5% glucose	Wrong preparation technique	Inappropriate location of medicine preparation	Preparing product outside treatment room in unsuitable location such as nurse reception	4.6

Ward	Ref	Prescribed medicine	Type of error	Subtype of error	Description of error	Mean severity score for all errors *n* = 372
Medical (B)	B181	Enoxaparin sodium S.C 110 mg / 0.74 ml	Wrong dose	----------	Leakage from ampoule/vial/syringe resulted in the dose being reduced by more than 10%	5.8
	B184	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6.6
	B199	Piperacillin and tazobactam I.V injection 4.5 g / 20 ml water for injections Patient: adult/management of sepsis	Wrong preparation technique	Breach of ANTT	Deficient in performing infection control after break in ANTT: continuing preparation without changing the needle or swabbing with alcohol after a needle touched by maker.	6.6
	B249	Amoxicillin I.V infusion 1 g in 100 ml 0.9% sodium chloride	Faulty labelling	----------	Nurse prepared a dose, placed it on a plastic tray and administered it to the patient without labelling it (more than one dose is prepared on plastic tray).	6.4

•More than one error in one

Appendix 17

Date:
Time:
Reference Number:

QUESTIONNAIRE FOR INVESTIGATING ERRORS IN PREPARING INJECTABLE MEDICINES IN HOSPITAL CLINICAL AREAS

This study conducted in collaboration between the Department of Pharmacy and Pharmacology at the University of Bath and (…….) hospital. It aims to investigate the causes of injectable preparation errors in order to identify strategies to prevent similar mistakes happened in the future.

All data collected by this questionnaire will be identified only by a reference number and will be stored securely and confidentially at University of Bath.

Please complete this questionnaire to help us with our project. You should answer all the questions within 48 hour of the mistake occurring by either ticking appropriate boxes or completing the open text box as requested, which should take around 10 minutes to complete. When you have completed the questionnaire, could you please return it to the investigator or place it in the tray at (……..……).

If you have any further queries, please contact

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Abdulaziz Almatroudi: aa687@bath.ac.uk Mobile [redacted]

Thank you for answering this questionnaire.

Q1 a. Describe the mistake?

Please write your answer in the box below.

b. Describe the circumstances that lead to the mistake? (e.g. what was going on around you when the mistake happened)

Please write your answer in the box below.

Q2 a. What of the following contributed to the mistake occurring? **Tick all that apply.**

Management decision	**Knowledge issues**
Protocol design Pressure to do job No opportunity for training at induction No opportunity for training updates	Incorrect/incomplete knowledge or experience Unfamiliar with policies or protocols Unfamiliar with equipment/medicine Unfamiliar with environment
Equipment/materials	**Rule issues**
Inappropriate equipment (e.g. syringe/needle) Lack of equipment (e.g. syringe/needle) Failure of equipment Unavailability of drug/diluent Poor labelling	Failure to use aseptic non touch technique Failure to check equipment/ material Failure to follow policy/ protocol /procedure Use of wrong policy or protocol Misunderstanding policy/protocol/procedure
Staff issues	**Personal issues**
Insufficient staff for task Insufficient training for task Inexperience	Distraction/interruption Inattention or absent mindedness Unwell Hungry Haste Fatigue Stress
Task and environment work issues	**Protocols/policies issues**
Inadequate lighting Inadequate space Noisy work environment The room was to hot) Insufficient rest breaks High workload Low workload Poor layout of work environment Complexity Preparing multiple injections at the same time	Non-existent protocol/policy Failure to enforce policy/protocol Difficult to use policy/protocol Out of date protocol Unavailable policy
	Team issues
	Inadequate verbal communication with colleagues Inappropriate behaviour of other team member Poor teamwork Insufficient support from colleagues Lack of supervision from senior staff Unclear written communication (e.g. ambiguous handwriting)
☐ Other (please specify)	

Q2 b. Explain how the contributory factors identified in question **(2a)** led to the occurrence of the mistake?

Please write your answer in the box below.

Q3. How do you think the mistake could be prevented from recurring?

Please write your answer in the box below.

Q4. Demographics: **(Please tick box or specify your answer in the box provided)**

a. Gender

☐ Female

☐ Male

b. Do you work at this hospital?

☐ Full time

☐ Part time

c. Do you usually work in the ward where the mistake occurred?

☐ Yes

☐ No

d. What type of contract you have?

☐ Permanent

☐ Fixed term

☐ Bank staff

☐ Agency staff

☐ Other (please specify)

e. Agenda for change band

f. How many years of post registration experience do you have?

g. How many years experience at this hospital do you have?

h. Usually how many injectable medicines you prepare per day?

i. What ward do you work in?

Q5. Do you have any other comments?

Please write your answer in the box below.

Thank you very much for taking time to complete this questionnaire.

Appendix 18

Date:
Time:
Reference Number:

INTERVIEW SCHEDULE FOR INVESTIGATING ERRORS IN PREPARING INJECTABLE MEDICINES IN HOSPITAL CLINICAL AREAS

Hello, my name is Abdulaziz Almatroudi. This project is part of my PhD which is an investigation injectable preparation mistakes. As part of study you agreed to be observed preparing injectable medicine. During observation I noticed that
you (……).

The **Purpose** of this interview to explore how the mistake occurred, what factors contributed to the mistake occurring and how the mistake could be avoided in the future. I am interested in your thoughts and opinions on these issues and would like to spend up to 10 - 15 minutes to discussing them. All responses you provide in this interview will be **completely confidential**.

Can I confirm you have read the participant information leaflet and signed the consent form?

I intend to record the interview and I will delete the recording after I have transcribed it. Could confirm you are happy for me to record the interview?

Main questions

1. **Can you describe the circumstances that lead to the mistake?**
    a. In a stepwise manner describe how you prepared the product.
    b. What was going on around you when the mistake occurred?
    c. Explain how you think the mistake occurred.

2. **What factors do you feel contributed to the mistake occurring?**
    a. What was the work environment like at the time the mistake occurred (e.g. lighting, temperature, layout, interruptions/distractions)?
    b. Were you preparing multiple injections at the same time?
    c. What was the workload like at the time the mistake occurred?
    d. What was the staffing level like at the time the mistake occurred? In your opinion, was the number of staff sufficient?
    e. At what point in your shift did the mistake occur? Do you feel that this contributed to the mistake?
    f. Did you have access to guidance or procedures related to the preparation of this injectable medicine? Do you feel this guidance is sufficient to accurately and safely prepare the injection?
    g. Were there any issues with the equipment used to prepare the injection, which may have contributed to the mistake occurring? Was the equipment / materials easy to use? Were you familiar with how to use the equipment / materials?
    h. Did any communication issues contribute to this mistake? Did you have sufficient support from your team or colleagues when you are prepared this injectable medicine?
    i. Do you feel as if you had all the necessary knowledge and skills to prepare the injectable medicine? Please explain your answer.
    j. Do you feel that there were personal factors (e.g. tired/hungry/unwell) that contributed to this mistake?
    k. Did any patient issues contribute to this mistake?

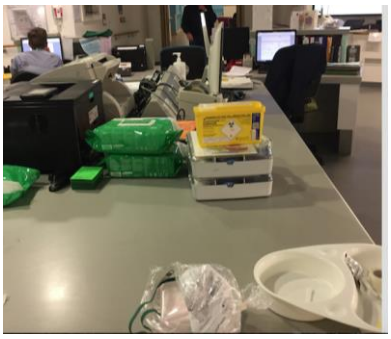
3. **How do you think the mistake could be prevented from occurring again?**

(Consider the following if not mentioned during discussion: colour coding, separating drugs on shelves, packaging, quiet room, use ready to administer products, minimising number of staff in room).

We are coming to the end of this interview. Is there any information you want to share, that has not previously been mentioned, about how the mistake occurred or could be prevented in future?

Thank you for taking part in this interview. The information obtained will be valuable for this project.

Preparing product outside treatment room in unsuitable location such as nurse reception.



Gross disregard for clean/ uncluttered treatment room

No 2nd checker