INVESTIGATING INTRAVENOUS MEDICATION PREPARATION ERRORS IN HOSPITAL CLINICAL AREAS

A thesis submitted in accordance with the conditions governing candidates for the degree of

DOCTOR OF PHILOSOPHY

in the

UNIVERSITY OF WALES

Presented by

Clare Crowley

Department of Clinical Pharmacy
Welsh School of Pharmacy
Cardiff University

July 2006

ProQuest LLC
789 East Eisenhower Parkway
P.O. Box 1346
Ann Arbor, MI 48106-1346

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Abstract

Medication is a leading cause of iatrogenic injury throughout the world and this has spawned a rapidly growing body of patient safety research. Lack of standardisation of terminology and research methods, and international variations in healthcare delivery pose problems when interpreting study findings. Within the UK, intravenous medicines prepared in hospital clinical areas have been identified as an area requiring further investigation.

A Delphi consensus technique was used to agree a practical error definition for intravenous medicines assembly and preparation in hospital clinical areas, suitable for multiprofessional and international use. This included a framework of inclusion and exclusion criteria which, if adopted for future research, would reduce variability and allow comparison of results. The definition and framework was translated into an observational data collection tool and validated for observational audit in adult and paediatric ward areas.

In depth interviews were used to elucidate nurses' views and opinions regarding problems they experienced with intravenous medicines assembly and preparation and how they resolved them. They suggested that priority should be given to minimising interruptions, to the design and provision of a dedicated workspace, and to use of needle-free devices. Appropriate information on intravenous preparation needed to be readily accessible within clinical areas.

Standardisation of the taxonomy, standards applied, and competency required for intravenous medicines preparation is needed. Pharmaceutical manufacturers should improve product design to minimise the number and complexity of manipulations required in the workplace. A human factors approach should be used to analyse and plan medicines safety solutions.

Acknowledgements

Special thanks Dr Whittlesea and Dr Scott for their unwavering support, guidance and encouragement throughout this thesis.

I would like to thank: Professor Luscombe for giving the opportunity to pursue a part-time external thesis, Charles Tugwell for his enthusiasm and computer expertise, and Dr Duggan for her advice.

Thanks are extended to staff and colleagues that gave me the inspiration for and participated in this study.

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List of abbreviations

ADE	adverse drug event
ADR	adverse drug reaction
CIVAS	central intravenous additive service
CNST	Clinical Negligence Scheme for Trusts
HBN	Health Building Note
HMPS	Harvard Medical Practice Study
ISMP	Institute for Safe Medication Practices
IV	intravenous
IVMPE	intravenous medicine/medication preparation error
MHRA	Medicines and Healthcare products Regulatory Agency
MUP	medicines-use process
NAO	National Audit Office
NCC MERP	National Co-ordinating Council for Medication Error Reporting and Prevention
NHS	National Health Service
NHSE	National Health Service Executive
NICE	National Institute for Healthcare and Clinical Excellence
NMC	Nursing and Midwifery Council
NPSA	National Patient Safety Agency
NOC	Nuffield Orthopaedic Centre
NRLS	National Reporting and Learning System
NSF	National Service Framework
ORH	Oxford Radcliffe Hospitals
PGD	Patient Group Direction
PSI	Patient Safety Incident
PSO	Patient Safety Observatory
QAHCS	Quality in Australian Health Care study
RCN	Royal College of Nursing
SOP	standard operating procedure
TDM	total design method
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

"A man should never be ashamed to own he has been in the wrong, which is but saying, in other words, that he is wiser today than he was yesterday."

Alexander Pope: 'Miscellanies' (1727)

Chapter 1
Introduction

1.0 General introduction

The founding principles of medical ethics include *non-maleficence*, the avoidance of evil or harm, sometimes expressed as '*primum non-nocere*', above all, do no harm. These phrases can be traced back to ancient historical records, such as the Oath of the Hindu Physician, c.1500 BC [Kanoti, 1986; p.3]. *"First, do no harm,"*
and Hippocrates [c.460-377 BC]

"As to diseases make a habit of two things – to help or at least to do no harm."

This principle is applied to clinical trials as the Helsinki Declaration [World Medical Association, 2004].

Each time any treatment is planned for a patient, the healthcare professional must consider this principle and only proceed if, on balance, the potential for patient benefit outweighs harm. On each and every occasion a medication is ordered and administered there is the possibility that it may produce undesirable as well as desirable effects [Anon., 1998; van den Bemt *et al.*, 2000]. This bears special relevance as medicines are the most common healthcare intervention [Classen & Metzer, 2003] and the leading cause of iatrogenic injury [Morimoto *et al.*, 2004].

1.1 Risks in healthcare

Risk is inherent as part of everyday life, and healthcare delivery is no exception [Wilson, 2004]. Risk has been defined as

"The probability or likelihood that harm may occur, coupled with the consequences of that harm" [Burrows, 2004;p.10].

Harm interferes with the organisation's goal, which for the National Health Service (NHS) is to deliver healthcare. This can be manifest in numerous ways, e.g. physical or emotional injury, litigation, or loss of reputation.

The concept of risk management was introduced into the NHS in the 1990s, as a comprehensive process to identify, assess and control risk; it has been described simply as 'good management practice' [Burrows, 2004]. Risk management encompasses all types of risk, and those related to patient care are clinical risks.

A landmark government report [Department of Health, 2000a] revealed that the NHS made unacceptable mistakes and failed to learn from mistakes and prevent future errors. It revealed that one out of every ten hospital admissions suffered due to errors or negligent care, half of which were avoidable. The NHS was mandated to review its approach and learn from failures; patient safety emerged as a high profile issue. This coincided with a series of well publicised incidents that focused public attention on NHS deficiencies, such as the enquiry into paediatric cardiac surgery at The Bristol Royal Infirmary, the Ritchie inquiry of gynaecologist Rodney Leward, the murders by the general practitioner Harold Shipman, the retention of organs at The Royal Liverpool Children's Hospital and the intrathecal administration of vincristine at Queen's Medical Centre [Ashraf 2000; Department of Health, 2000b, 2001a; Kennedy, 2001; Redfern, 2001; Toft, 2001, Woods, 2001]. The provision of safe healthcare became a national priority. In tandem, patient safety was recognised internationally as a major risk to world health [World Health Organisation, 2002]. It has been proposed that for most countries, the key issue in healthcare quality and risk management is patient safety [National Audit Office, 2005].

1.1.1 Healthcare reforms in England

The key focus of the late 1980s and early 1990s healthcare reforms were financial savings, maximising throughput, and achieving value for money, which led to the establishment of an internal market [Department of Health, 1998; Smith, 1998]. This detracted from issues such as care and quality [Scally and Donaldson, 1998]. Headline news of unsatisfactory or negligent care, combined with concerns about waiting times and wide regional variations had undermined public confidence in the NHS [Department of Health, 1997, 1998; Scally & Donaldson, 1998; King's Fund, 1999]. The Government attempted to readdress this imbalance, using quality as the key driving force behind modernisation of the NHS, so that quality and efficiency were essential partners [Department of Health, 1997, 1998]. Their aim was to provide consistent and equitable health care based solely on an individual's need [Department of Health, 1997]. Quality was made a personal and collective responsibility of everyone in an NHS organisation, with the Chief Executive taking statutory responsibility for quality [Department of Health, 1998; Kings Fund, 1999]. This was taken a step further with the publication of '*Standards for Better Health in England*', in which quality and safety are priorities. Ten core standards are described which organisations should achieve and the public can expect; with safety pivotal as the first of seven domains [Department of Health, 2004].

1.1.2 Clinical governance

The concept of clinical governance was introduced as the means to achieve, monitor and maintain quality in healthcare [NHS Executive, 1999a]. Its generally accepted definition is

> *"A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."* [NHS Executive, 1999a;p.6].

This has been rephrased succinctly as *"corporate responsibility for clinical quality"*, in reality ensuring that all healthcare professionals provide patient care that is satisfactory, consistent and responsive [Anon., 1999;p.288; Wilson, 2004].

It is proposed that clinical governance is composed of the following key features [Anon., 1999]:

a. Defining standards.
b. Ensuring the capability and resources are available to deliver those standards.
c. Measuring that the standards were achieved.

The final goal is to implement and manage any change required to ensure the standards are consistently met, and preferably exceeded [Gilmore, 2000].

Wilson [2004] has defined the component processes that make up clinical governance as:

- Clinical audit.
- Evidence-based practice.
- Promoting clinical effectiveness.
- Detecting and investigating adverse healthcare events.
- Analysing the root causes of adverse events.
- Improving practice using data leaned from claims, complaints, adverse event investigations, monitoring standards and out comes of care.

Clinical Governance is not a new concept; it incorporates under an umbrella term many quality issues that have been around for decades, and raises the quality profile whilst attaching to it a patient centred emphasis [Dean, 2000].

It was thought unrealistic to expect the quality framework to be implemented overnight; it was envisaged it would take ten years to achieve [Department of Health, 1997] but this deadline is rapidly approaching. Many of the suggested tools for achieving clinical governance are well established including clinical audit, critical incident reporting,

guidelines, care pathways, individual appraisal and evidence based medicine. It has been suggested that pharmacy could play an invaluable role in this process, both within the profession itself and also on a larger scale by applying its skills at the medicines usage level [Smith, 1998]. Medicines management performance indicators that could be employed include adverse drug reaction reporting, medication error rates, competency assessment and pharmacist intervention recording [Anon., 1999].

1.1.2.1 External clinical governance monitoring

Comprehensive national standards for priority health areas are being developed by the National Institute for Healthcare and Clinical Excellence (NICE) and through National Service Frameworks (NSF) [Anon., 1999; Kings Fund, 1999]. NICE is responsible for providing national guidance on health promotion, preventing 'ill health'; new and existing medicines, treatments and interventional procedures within the NHS from both clinical and cost effectiveness standpoints [National Prescribing Centre, 2006]. NSFs will lay down what care a patient with a particular condition should expect from the NHS. It will map out a 'blueprint' of how services for care areas should be offered, with scheduled performance targets against which progress will be judged. They were designed to abolish regional variations in patient care [Anon., 1999]. The prime role of these national standards was to provide guidance on global clinical effectiveness; the responsibility for translating this into the most appropriate action for an individual patient remains with their doctor. Cost should not feature within the guidance, indeed decisions on the availability of resources for funding their recommendation lies with the Secretary of State [Anon., 1999]. Accountability for monitoring standards, such as these, has been delegated to an independent body, the Healthcare Commission. Its core role is to assess the provision, quality, economy and efficiency of healthcare. Its other responsibilities include an annual performance review of each NHS Trust in England, as well as investigating and remedying service failures and unresolved complaints [Commission for Healthcare Audit and Inspection, 2005]. Other agencies also perform assessments and inspections of healthcare; these include the Health and Safety Executive, National Audit Office (NAO) and Clinical Negligence Scheme for Trusts (CNST).

1.1.2.2 Internal clinical governance processes

The Government envisages professional self-regulation, regulated in turn by the Health Professions Council, and life long learning through continual professional development, as

the means to ensure that staff delivering care are competent, suitably trained, keeping abreast of developments and conforming to their own profession's standards, so ensuring healthcare staff are equipped to deliver quality patient care. [Department of Health, 1998; Wilson, 2004].

1.1.2.3 Corporate governance

This ensures that organisations have robust internal control systems for identifying risks that could affect their aims and objectives, for evaluating the type and extent of these risks, and then for effectively, efficiently and economically managing them [Wilson, 2004]. In addition, between 1999 and 2004 Controls Assurance Standards existed, where organisation undertook self-assessments against predefined criteria which were subsequently signed off by the Trust Board. This included standards on the risk management system and the safe and secure handling of medicines, within medicines management. From August 2004 this was superseded by assessment against *'Standards for Better Health'* [NAO, 2005]. In addition a new standard in 'safe medicines practice' was introduced into the CNST risk management standards with compliance required by 2005. This was developed in conjunction with the NHS Litigation Authority and the National Patient Safety Agency (NPSA) [Devaney *et al.*, 2003].

1.2 The patient safety agenda in England

Concern about the quality of healthcare provision in the United Sates of America (USA) fuelled global interest [Kohn *et al.*, 2000] and prompted a comprehensive review of the NHS which culminated in the publication of the Chief Medical Officer's report *'An Organisation with a Memory'* [Department of Health, 2000a]. The findings revealed that errors in healthcare killed more people than motor vehicle accidents or breast cancer. The report identified the nature and scale of unintentional injury, and that little reporting, learning and sharing had arisen from incidents; patients were suffering unnecessary harm. It highlighted the need for cultural change with preventative measures to be implemented following learning from adverse events and near misses. As a result of repeated serious errors, four key targets were set. The two medicines-related targets were:

- To reduce to zero the number of patients dying or being paralysed by maladministered spinal injections by 2001.
- To reduce by 40% the number of serious errors in the use of prescribed drugs by 2005.

The follow-on response report '*Building a Safer NHS for Patients*' detailed how the Government planned to address patient safety [Department of Health, 2001b].

Pivotal to achieving this NHS learning was the establishment in 2001 of a national coordinating body, the NPSA, a special health authority to spearhead patient safety efforts. Its goal was to improve the quality and safety of patient care through the reporting, analysing and learning from adverse events and near misses [Department of Health, 2001b]. Central to the NPSA was the establishment of a national system for collating reports of patient safety incidents, using a standard terminology and format, enabling analysis and identification of priority areas for action. This has been called the National Reporting and Learning System (NRLS). Other important achievements required were a change in culture, sharing learning from other government bodies and enquiries and the embedding of root cause analysis expertise in NHS organisations.

The NPSA document '*Seven Steps to Patient Safety*' described what NHS organisations should do to improve patient safety [NPSA, 2003a], the component steps being:

1. Building a safety culture.
2. Leading and supporting your staff.
3. Integrating risk management activity.
4. Promoting reporting.
5. Involving and communicating with patients and the public.
6. Learning and sharing safety lessons.
7. Implementing solutions to prevent harm.

This good practice guide allowed Trusts to benchmark how their organisation was performing and to create action plans to improve patient safety.

In 2005, the NAO examined whether the targets of improving the safety culture and reporting of, and learning from, incidents had been achieved by a survey of 265 acute hospitals, ambulance and mental health trusts [NAO, 2005]. At local level they found improvements in incident reporting, establishing a safety culture and less under-reporting. However, there remained areas where the blame culture prevailed and there was under-reporting of certain incidents, mainly medication-related and those producing serious harm. Further work was advocated to address these failings; increase reporting, improve

communication, ensure learning was disseminated widely and that organisations developed from being predominately reactive to proactive.

The report highlighted delays with national initiatives that had prevented compliance with the Government's previously established timescales [Department of Health, 2001b]. The core objectives of establishing common patient safety taxonomy and implementing the NRLS had been achieved [NAO, 2005].

1.3 Medicines safety

Medicines are important within healthcare as they are received by virtually all inpatients, with a typical hospital administering 7,000 individual doses per day. Hospitals were spending £1.5 billion/year on medicines, but these were not always optimally used, with errors occurring too often [Audit Commission, 2001]. Medication errors were an early priority for the NPSA [Smith, 2004]. They accounted for 10-20% of adverse events and were one of the main culprits for iatrogenic injury. Iatrogenic mortality and morbidity were important for hospitals as they resulted in prolonged stays and increased expenditure [Bates *et al.*, 1997]. Numerous contributory factors have been suggested:

- A rapid pace of development, with more powerful and technologically sophisticated medicines marketed.
- An exponential growth of knowledge that is impossible to keep up to date with and creates additional training needs.
- Pioneering advances facilitated interventions on a wider patient audience.
- Changes in healthcare provision, with hospital environments more turbulent and complex, increased workload, faster patient throughput, and 'sicker' patients.
- Demographic changes with an ageing population and a higher prevalence of acute and chronic ill health.
- Raised societal expectations with more freedom, access to education and information, increased consumerism and the development of a compensation culture.
- High profile cases stimulating media attention.
- Growing awareness that healthcare failures are not solely an organisation's failing but also impact on the government; comprehensive reform was needed. [Department of Health 1997, 1998, 2000a, 2000c; Warner *et al.*, 1998; Clinical

Initiatives Centre, 2000; Office for National Statistics, 2000; Audit Commission, 2001; Wilson, 2004].

A comprehensive report that collated the size and scale of medication errors, and identified error-prone aspects and good practice to reduce medicines risks marked an important milestone in the United Kingdom (UK) [Smith, 2004]. This contained 126 recommendations requiring combined action at local and national level.

1.4 The patient safety language

Patient safety literature uses a variety of nomenclature, misuses terminology and lacks standardisation [Chang *et al.*, 2005; Woods *et al.*, 2005].

"Idiosyncratic terminology and frameworks for the study of medical errors and related injuries have been tolerated but are an increasing problem" [Woods *et al.*, 2005;p.422].

Several groups have proposed a common taxonomy in their areas of interest e.g. paediatrics, near misses and adverse events [NPSA, 2003a; Chang *et al.*, 2005; Woods *et al.*, 2005]. The World Health Organisation (WHO) is currently developing a global patient safety terminology [Edwards, 2005a].

When evaluating medicines related issues this becomes more complex, as definitions vary depending on their use. Those developed for pharmacovigilance have been applied to health care risk management and error and safety research [Nebeker *et al.*, 2002, 2004]. Researchers have proposed methods for identifying and classifying safety issues in an attempt to create a clear and consistent approach to medicines safety research [NCC MERP, 1998; Morimoto *et al.*, 2004; Yu *et al.*, 2005]. It has been suggested that any definition needs to sit within a framework that ensures parameters are explicitly defined to ensure correct and transparent interpretation [Nebeker *et al.*, 2002]. Aronson and Ferner [2005] cite the importance of good communication combined with consistent terminology, as English is difficult to master, especially as a second language.

Yu and colleagues [2005] searched 160 medication safety websites and found 33 websites with a total of 119 definitions and 25 different medicine safety terms. They concluded that current medicines safety terminology is variable and ambiguous, for example, 'near-miss' had 12 different definitions, resulting in haphazard classification. There is an urgent need for a common nomenclature that all health professionals use in the patient safety field [Yu *et al.*, 2005].

1.4.1 Definitions

The following definitions encompass the main terms, their meanings and their inter-relationships. Where available, preference has been given to NPSA defined terms, other terms have been selected by leading experts in the field.

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".

This replaces the older term 'Clinical Risk' [NPSA, 2003a;p.97].

Patient safety incident (PSI)

"Any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving NHS-funded healthcare."

Where *"'Patient safety incident' is an umbrella term which is used to describe a single incident or a series of incidents that occur over time."*

This replaces the following older terms: adverse incident, adverse event, clinical incident, critical incident, medical error, clinical error, and medical mistake. The new term was an attempt to move away from terminology that implied individual causality and blame [NPSA, 2003a;p.97].

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" [NPSA, 2003a;p.97].

Patient safety incident (prevented)

"A patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to patients receiving NHS-funded healthcare."

This replaces the previously used terms near miss or close call [NPSA, 2003a;p.97].

Patient safety incident involving medicines

This is an umbrella term that encompasses all medication-derived patient safety incidents [Cousins, 2005a]. Therefore, it could replace the older term, 'medication misadventure', where the definition was:

"An iatrogenic hazard or incident. That is an inherent risk when medication therapy is indicated. That is created through either omission or commission by the administration of a medicine or medicines during which a patient may be harmed, with effects ranging from mild discomfort to fatality. Whose outcome may or may not be independent of the pre-existing pathology or disease process. That may be attributable to

error (human / system or both), immunologic response, or idiosyncratic response. That is always unexpected or undesirable to the patient and health professional" [Anon., 1998;p.165].

Or simply *"An incident includes any irregularity in the process of medication use"* [Morimoto *et al.*, 2004;p.306].

This encompasses medication errors, adverse drug events, adverse drug reactions and therapeutic failures [Zellmer, 1993; Morimoto *et al.*, 2004]. The NPSA has developed a new term of *'safe medication practice'* which describes attempts to minimise the risks of patient safety incidents involving medicines [Cousins, 2005a].

Medication error

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

This definition was developed by the National Co-ordinating Council for Medication Error Reporting and Prevention (NCC MERP) in the USA and has subsequently been adopted by the NPSA [Smith, 2004]. In simple terms, it is an error that occurs at any stage in the medication-use process [Ghandi *et al.*, 2000].

Adverse drug event (ADE)

"Injury resulting from medical intervention related to a drug" [Bates *et al.*, 1995a; p.29], which has subsequently been shortened to *"an injury due to medication"* [Morimoto *et al.*, 2004; p.307]. Implicit in this definition is suspicion of some causality between the injury and the drug.

ADEs can then be subdivided, as detailed below [Morimoto *et al.*, 2004;pp.306-307]:

"A **potential ADE** *is 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."*

"A **preventable ADE** *is an injury that is the result of an error at any stage in the medication use."*

"An **ameliorable ADE** *is an injury of which the severity or duration could have been substantially reduced if different actions had been taken."*

Adverse drug reaction (ADR)

"A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of the disease, or for the modification of physiological function" [WHO, 1970;p.103; Delamothe, 1992;p.465].

This excludes accidental or deliberate overdose [WHO, 2000;p.2].

There is some debate as to whether ADRs could arise from a medication error which also produces an undesirable outcome [van den Bemt *et al.*, 2000; Aronson & Ferner, 2005]. It has been argued that the WHO definition only refers to appropriate medication use, and this would exclude medication errors [Lazarou *et al.*, 1998; Ghandi *et al.*, 2000]. This is because medication errors are inappropriate use of medication and are preventable, whereas ADRs are usually not preventable and injury arises from the intrinsic properties of the medicine and not error [Otero & Schmitt, 2005]. Opponents of this argue that ADEs rely in part on the medicine's intrinsic properties, and that in time some injuries presumed to be unavoidable may be considered unacceptable and / or avoidable [Nebeker *et al.*, 2005]. This issue is currently unresolved as publications from groups that include leaders in safe medicines practice disagree [Anon., 1998; Morimoto *et al.*, 2004; Nebeker *et al.*, 2004]. ADRs are divided into type A (predictable) and type B (idiosyncratic) reactions, defined [Pirmohamed *et al.*, 1998;p.1295]:

*"**Type A reactions** represent an augmentation of the pharmacological actions of a drug. They are dose-dependent and are therefore readily reversible on reducing the dose or withdrawing the drug."*

*"**Type B reactions** are bizarre and cannot be predicted from known pharmacology of the drug."*

Type A reactions account for 80% of ADRs and are potentially preventable, since they arise from known pharmacological effects [Pirmohamed *et al.*, 1998; Wiffen *et al.*, 2002]. In contrast type B reactions *"usually occur from the initial use of a drug in a patient and are not predictable, therefore not preventable"* [Wiffen *et al.*, 2002;pp.2-3].

Side effect

"Any unintended effect of a pharmaceutical product occurring at doses normally used in man which is related to the pharmacological properties of the drug" [Delamothe, 1992; p.465].

Expected side-effects are ADEs e.g. hair loss with chemotherapy [Anon, 1998].

Medication errors are more prevalent than ADEs, but relatively few medication errors cause patient harm, and therefore an ADE [Bates *et al.*, 1995b]. The relationship between these medicines related terms is illustrated in figure 1.1. In this scheme, Bates and

colleagues, they have defined ADRs as not preventable; therefore nonpreventable ADEs are ADRs [Morimoto *et al.*, 2004].

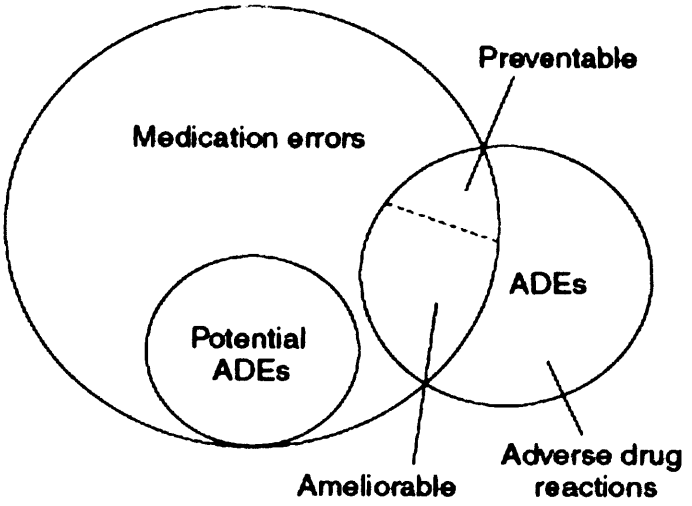


Figure 1.1. Relationships between patient safety incidents involving medication (size not to scale) [from Mortimoto *et al.*, 2004; p.307].

The causality assessment of an adverse drug reaction

The attribution of a causal link is not a prerequisite for suspecting that an adverse drug event or adverse drug reaction has taken place. It is therefore useful to attach some weight to the likelihood that an ADR was thought to be due to a suspected drug. It is also important since most pharmacovigilance work is concerned with suspected reactions [Meyboom *et al.*, 2000]. Neither definition requires certainty of causality; it has been proposed that the terms can be used interchangeably [Meyboom *et al.*, 2000]. However, as ADEs may be drug related, or totally unrelated, it is important these terms are clearly distinguished. ADEs could be considered to be a more global term that incorporates the subset of ADRs. WHO have developed a framework for assessing the causality of ADRs, which is provided below:

Certain:

"A clinical event, including laboratory test abnormality, occurring in a plausible time relationship to drug administration, and which cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the drug (dechallenge) should be clinically plausible. The event must be definitive pharmacologically or phenomenologically, using a satisfactory rechallenge if necessary e.g. penicillin anaphylaxis" [WHO, 2000; pp.3-4].

Probable/likely:

"A clinical event, including laboratory test abnormality, occurring with a reasonable time sequence to drug administration, unlikely to be attributed to concurrent disease or other drugs or chemicals, and which follows a clinically reasonable response on

withdrawal (dechallenge). Rechallenge information is not required to fulfil this definition" [WHO, 2000;p.3].

Possible:

"A clinical event, including laboratory test abnormality, with a reasonable time sequence to which more data is essential for a proper assessment or the additional data are under examination" [WHO, 2000;pp.3-4].

Unassessible/unclassifiable:

"A report suggesting an adverse reaction, which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified" [WHO, 2000;p.4].

1.4.2 Classification

There are numerous criteria employed for classifying different aspects of medication errors, adverse drug events and reactions. These are often used in combination to provide a more comprehensive picture [Ghandi *et al.,* 2000; Morimoto *et al.,* 2004].

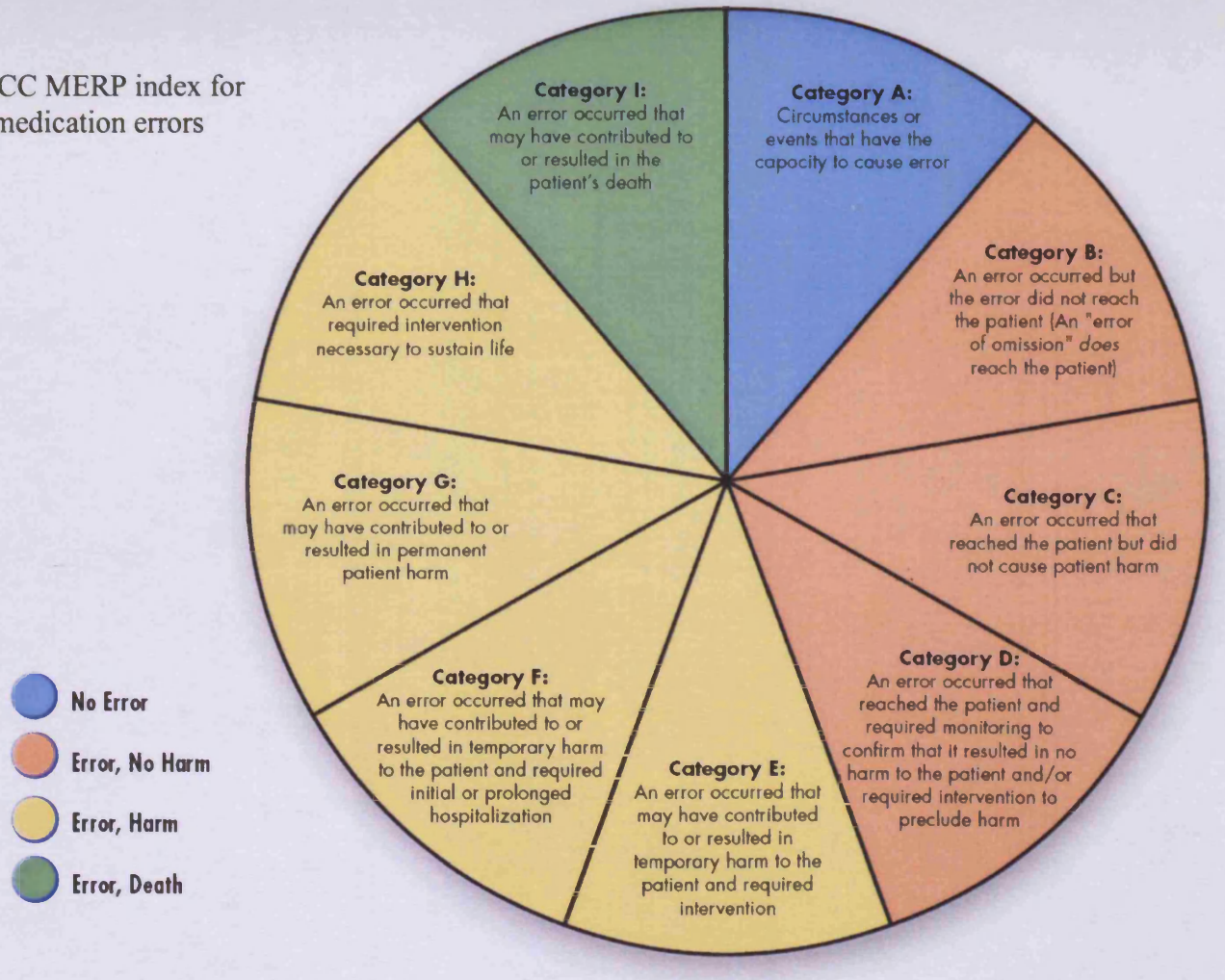
a) **Type of incident**. Incidents are independently reviewed, then classified, usually by two people as medication errors, ADE, potential ADE, or none of these [Ghandi *et al.,* 2000; Morimoto *et al.,* 2004].

b) **Preventability.** Reviewers assess the likelihood that an event could be prevented and assign weighting to this. For example: definitely preventable, probably preventable, probably not preventable and definitely not preventable [Dubois & Brook, 1988].

c) **Severity of incident.** An assessment of the seriousness or severity is assigned, often from a linear rating scale. For example, ADR severity assessment scale ranging from: an ADR occurred but did not necessitate a change in treatment to a fatal ADR [Hartwig *et al.,* 1992]. A linear rating scale has been validated for assessing the outcome of medication errors where zero represents no potential patient effect and ten would be fatal [Dean & Barber, 1999].

d) **Causality assessment**. One of the available tools to assess drug causality can be applied e.g. Kramer or Naranjo algorithm for ADRs [Kramer *et al.,* 1979; Naranjo *et al.,* 1981], or the TRIP system for detrimental drug related events [Wills & Brown, 2000]. Alternatively, a rating scale that assesses the researcher's level of certainty that an event was drug induced rather than due to an underlying disease process. An example of the scale would be i) virtually no evidence, ii) slight to moderate evidence, iii) unlikely causality, less than 50:50 but close call; up to vi) virtually certain evidence of causation [Wilson *et al.,* 1995].

Figure 1.2 NCC MERP index for categorising medication errors



Definitions

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

PSF0306

The NCC MERP has adapted the Hartwig *et al.,* [1991] error classification index. Their index, promoted to help achieve standardisation and consistency in error reporting, uses patient outcome as the prime focus [Dunn & Wolfe, 1997]. An overview of how medication errors are categorised by the NCC MERP is provided in figure 1.2. It has subsequently been updated to distinguish between Category C errors reaching the patient that are administered and those that are not [NCC MERP, 1998].

1.4.3 Safety culture

The NPSA [2003a] identified that a cultural shift from blame to openness was vital to improve patient safety; organisations needed to embed safety as a core belief, encouraging mistakes to be shared.

> *"A safety culture is where staff within an organisation have a constant and active awareness of the potential for things to go wrong. Both the staff and the organisation are able to acknowledge mistakes, learn from them, and take action to put things right"* [NPSA, 2003a;p.17].

A key principle in achieving this is the creation of an 'open and fair environment'. This entails acting openly and honestly in all matters, including the fair treatment of those involved in patient safety incidents. Staff remain professionally accountable, but insight from human error theory shows that in nearly all cases incidents are unintentional. This understanding underpins a shift from the 'blame' culture to one where staff share information on incidents. This is coupled with the awareness that organisations need to understand what is happening and, to identify issues that contribute to incidents before steps can be taken to address them, and so improve safety.

1.4.3.1 Why errors occur

There are two approaches to human error, systems-based and person-based. In the persons approach all attention from an error is focused on an individual, where they are blamed for forgetfulness, inattention or moral weakness [Reason, 2000]. This arises from two fictitious myths [NPSA, 2003a;p.22]:

> *"**The perfection myth**: if people try hard enough, they will not make any errors.*
> ***The punishment myth**: if we punish people when they make errors, they will make fewer of them; that remedial and disciplinary action will lead to improvement by channelling or increasing motivation."*

The persons based approach is deeply embedded within healthcare. This 'blame culture' creates a vicious cycle where incidents are hidden; organisations remain unaware of the

risks and error prone areas and so do not take corrective actions. This is summarised in figure 1.3.

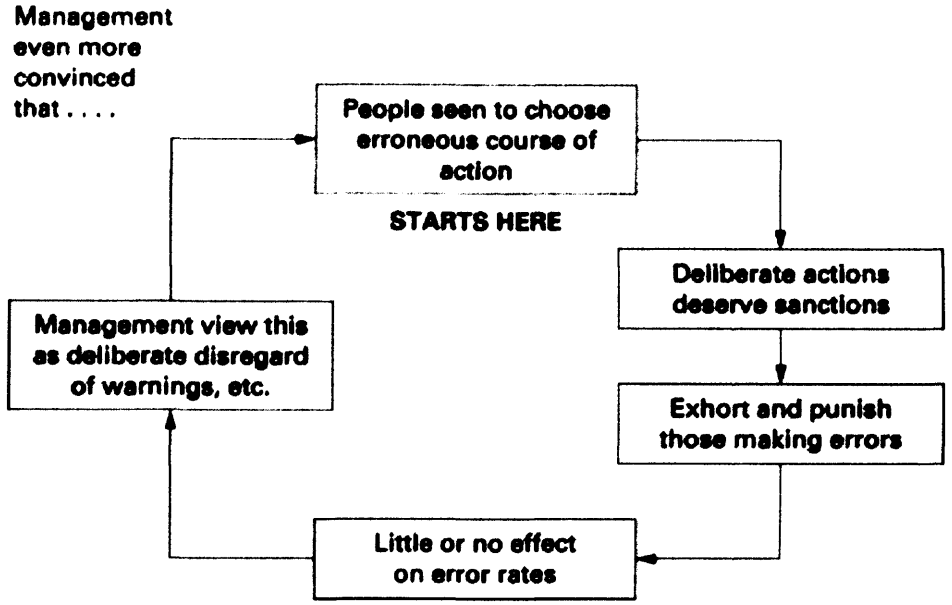


Figure 1.3 The blame cycle [from Reason *et al.*, 2001;p.ii22]

The systems approach is based upon the assumption that people are not machines; they are fallible and will make mistakes, even in the safest organisations. It focuses more widely; errors are seen as consequences not causes, and consideration is given to the environment and organisational factors contributing to an incident. This is based on the assumption that the human condition cannot be changed, but the environment in which they work can be. The NPSA have adopted this systems approach to safety [NPSA, 2003a]. This can be illustrated by the 'Swiss cheese model' of system failure, where healthcare, with its numerous inbuilt safe guards, is described as slices of Swiss cheese, and each slice equates to a defence, barrier or safeguard that protects the patient from error. Each hole indicates a flaw (active failure or latent condition) that would fail to prevent an error passing on to the next slice of cheese. In an ideal world, these slices would have no holes in them; but in reality the holes appear in different shapes and sizes and different places within the cheese at different times. An error occurs when defences fail and a whole series of holes are all aligned, shown in figure 1.4 [Reason, 2000].

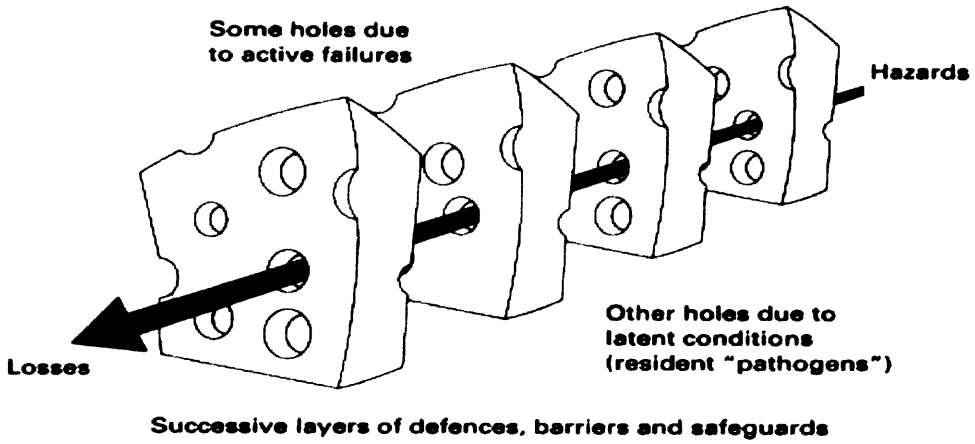


Figure 1.4 The "Swiss cheese" model of accident causation [from Reason *et al.*, 2001;p.ii21]

Reason suggested that to understand organisational accidents, an understanding of four domains is required. These were:

1. Latent failures –management decisions and organisational processes and culture.
2. Trigger factors - local work, task and environmental conditions.
3. Individual unsafe acts.
4. Failed defenses.

Latent conditions have been described as *"the inevitable 'resident pathogens' within the system."* [Reason, 2000;p.769] These are created by strategic decisions at management and organisational level from designers, builders, procedure writers, top level management and Government strategies. Latent conditions can be manifest in two ways:

- Local work and task conditions give rise to error-provoking conditions in the working area, such as understaffing, time pressures, and fatigue at ward level.
- Long lasting holes or weaknesses in the systems' defences such as unworkable procedures and equipment failure.

Fallible decisions may create latent failures within the system, which are transmitted down the departmental pathway into the workplace where they give rise to task and environmental precursors likely to promote unsafe acts [Taylor-Adams *et al.*, 1999]. Latent failures may lie undetected for a many years, before they are aligned with a local trigger and active failure creates an incident [Reason, 2000].

Active failures can be divided into violations, which are intentional rule bending, and errors, which are unintentional. Errors can be subdivided into:

- Slips arising from lack of concentration.

- Lapses caused by 'memory block'.
- Mistakes, either rule-based where rules are forgotten or get confused, or memory-based associated with insufficient knowledge [Anon., 2006a].

Active failures have been 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].

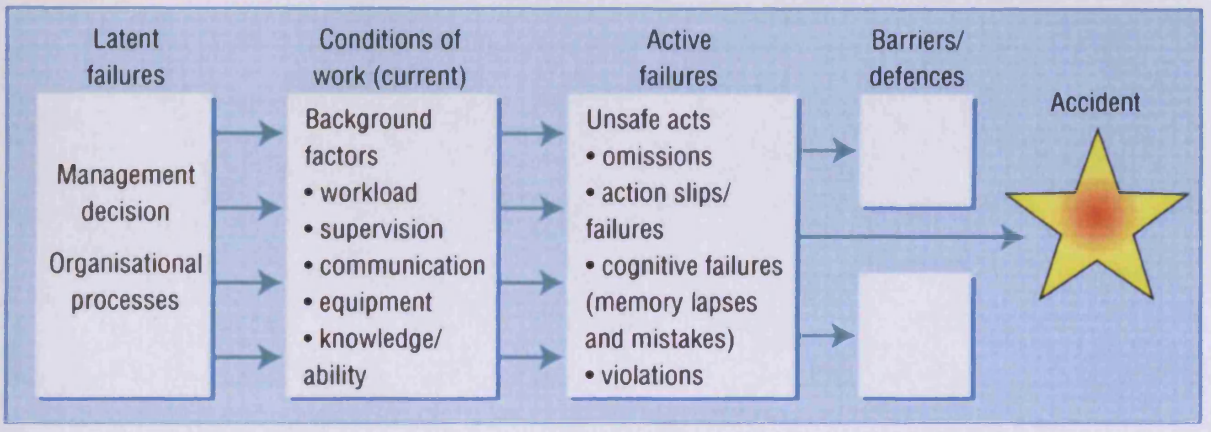


Figure 1.5 Organisational accident model based on work by Reason [as Vincent *et al.*,1998; p.778]

Learning from other safety critical industries such as aviation, oil and nuclear power has shown the importance of a holistic understanding of how an incident occurred; one that includes the organisational and environmental factors in place at that time. Knowledge that human actions and decisions play a major role in virtually all accidents through latent active failures has altered understanding [Taylor Adams *et al.*, 1999]. This interest has shaped the way in which patient safety incidents are investigated, so that the systems factors in operation when an incident occurred form part of the inquiry. The key questions that need identifying are how and why the defences failed [Reason, 2000]. A summary how patient safety incidents (equivalent to accident) arise, and should therefore be investigated is given in figure 1.5, with systems factors identified in table 1. 1.

Another lesson from safety critical industries has been the importance of design to improve 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].

It has been suggested that the NHS has *"not grasped the value and significance of design to patient safety"* [The Department of Health and The Design Council, 2003;p.18].

Design could be applied across healthcare to create products, processes and environments that are intuitive, simple to understand, convenient and comfortable and therefore, reduce the likelihood of accidental misuse and errors. Following a scoping study to identify areas where design could improve patient safety in the NHS, a number of projects were proposed that used a system design approach [The Department of Health and The Design Council, 2003].

Table 1.1 Framework of factors influencing clinical practice [from Vincent *et al.*, 2000;p.778]

Factor types	Influencing contributory factors	Examples
Institutional context	Economic and regulatory context; national health service executive; clinical negligence scheme for trusts	Inconsistent policies, funding problems
Organisational and management factors	Financial resources and constraints; organisational structure; policy standards and goals; safety culture and priorities	Lacking senior management procedure for risk reduction
Work environment factors	Staffing levels and skills mix; workload and shift patterns; design, availability, and maintenance of equipment; administrative and managerial support	High workload, inadequate staffing, or limited access to essential equipment
Team factors	Verbal communication; written communication; supervision and seeking help; team structure (consistency, leadership, etc)	Poor communication between staff
Individual (staff) factors	Knowledge and skills; competence; physical and mental health	Lack of knowledge or experience of specific staff
Task factors	Task design and clarity of structure; availability and use of protocols; availability and accuracy of test results	Non-availability of test results or protocols
Patient factors	Condition (complexity and seriousness); language and communication; personality and social factors	Distressed patient or language problem

1.4.4 Background to research methods

Before looking at the findings of medication error and adverse drug event or reaction studies, it is paramount to understand exactly how the research was conducted. Any associated methodological limitations need to be considered as this affects the usefulness and applicability of a study's findings [Allan & Barker 1990; Meyboom *et al.*, 2000]. Studies have tended to either focus on outcomes from within a global scenario, such as a period of hospitalisation; or have addressed smaller process steps within this bigger picture, particularly in the non-research setting e.g. prescribing errors, and then examined potential outcome that could arise from errors in the process [Dean *et al.*, 2002a].

The first observational studies of the medication administration process were undertaken in the 1960s, with a great diversity of results. A review of 18 observation based studies published between 1962 and 1987 found that the total opportunities for error (a statistical correction to prevent the reported error rate exceeding 100%) ranged from 1.7% to 59.1% [Allan & Barker, 1990]. Caution has been advised in interpretation or generalisation of these results due to variations in the clinical setting, methods employed and error category definitions. For example, Allan and Barker's [1990] review illustrated that the 14 observational studies had used between three to ten medication error categories from a possible 17 different categories. One of the early definitions of a medication error was *"deviation from the physician's medication order as written on the patient's chart"* which therefore excluded prescribing errors [Allan & Barker, 1990;p.558]. This early research failed to include 'wrong time' errors, or displayed the results with and without this category. With advances in therapeutics and pharmacokinetics the importance of timely administration has been realised. When Allan and Barker's [1990] review is reported excluding 'wrong time' this reduces the error rate to 0.4 - 24.7%. The authors concluded that the lack of consistency made comparison of individual studies difficult, and that the data gathered might only be applicable to the establishment studied [Allan & Barker, 1990].

A more recent review of 11 studies published between 1991 and 1999 found similar huge variations in reported findings. Total medication error rates varied from 0.04% with spontaneous reporting of all medication error types to 26.9% with disguised observation of transcription, dispensing and administration errors, including 'wrong time' errors [van de Bemt *et al.*, 2000]. Again, there was a lack of consistency in the way definitions were employed. For example, the term ADE has been used by some where injury was drug related, whilst others used this term when it is unknown whether medication is the cause [Ghandi *et al.*, 2000; van den Bemt *et al.*, 2000]. Van den Bemt and colleagues [2000;p.323] summarise the situation,

> *"Drug-related problems are an important problem in hospitalised patients, although the exact magnitude of the problem is difficult to estimate from the studies presented in our review."*

The recently published methodology for the identification and classification of patient safety incidents involving medication [Morimoto *et al.*, 2004] provides opportunity for standardisation but it would take several years to become established.

Having considered these limitations, it is useful to review the findings of some of the landmark studies of adverse events and errors in the hospital inpatient setting.

1.4.5 Prevalence and consequences of hospital adverse events

1.4.5.1 Adverse healthcare events

Incidence of adverse healthcare events

In 1984 the Harvard Medical Practice Study (HMPS) was undertaken, from a medical injury, litigation and malpractice stance, in 51 non-psychiatric acute hospitals in New York State, involving 30,121 patients. It reported adverse healthcare events, which therefore included, but were not restricted to, medication related events, and employed very strict inclusion criteria. Adverse events were defined as

> *"An injury that was caused by medical management (rather than underlying disease) and that prolonged the hospitalisation, produced a disability at the time of discharge or both"* [Brennan *et al.*, 1991;p.370].

This would therefore encompass both ADR and medication errors which resulted in patient harm. Adverse events occurred in 3.7% of hospitalisations. 'Drug complications' were the single most frequently reported type of adverse event, constituting 19.4% of adverse events, which translates into an overall 0.7% study incidence of adverse drug events. Of these 14.1% were associated with severe disability and 17.7% were considered to a result of negligence [Leape *et al.*, 1991].

The Quality in Australian Healthcare study (QAHCS), modelled on the HMPS methodology, was undertaken in 28 hospitals in two Australian states in 1992, screening 14,179 admissions. Adverse events were reported in 16.6%, which after adjustment to mirror the HMPS criteria accounted for 13% of admissions [Wilson *et al.*, 1995]. Temporary disability, fully resolved within 12 months, was associated with 12.52% of adverse events. These were responsible for nearly two thirds of increased hospital stays.

The researchers found 51.2% of the adverse events had a high degree of preventability and the preventable events were associated with greater disability. *'Injuries, poisonings and toxic effects of drugs'* [Wilson *et al.*, 1995;p.467] comprised 30.9% of the adverse events; which produced an overall 5.1% ADE rate. Of these 13.8% were associated with permanent disability and 46% judged highly preventable.

A pilot study employing similar methods to both the HMPS and QAHCS was undertaken at two London hospitals using data from 1998. The case notes of 1,014 patients from general medical, surgical, obstetrics and orthopaedics were retrospectively analysed for adverse events. An adverse event was experienced by 10.8% of patients; with an overall adverse event rate of 11.7% including multiple adverse events. The researchers judged that 48% of the adverse events were preventable. Adverse events produced impairment ranging from moderate severity to death in one third of patients [Vincent *et al.*, 2001]. The authors have advised caution in interpreting or extrapolating the results due to the sample size, restriction to two study sites and non-generalisability of the case mix to general hospital practice. In addition, concern has been raised about the subjectivity of retrospective analysis:

"What appeared to be clinically reasonable at the time may be second guessed if an adverse event occurs" [Alberti, 2001;p.502].

A novel research methodology was employed by Andrews and co-workers [1997]. This was a prospective observational study where the researchers observed practitioners' discussion of adverse events that had occurred during the care of 1,047 surgical and intensive care patients. An adverse event was defined as

"An 'inappropriate decision' was made, when at the time an appropriate alternative could have been chosen" [Andrews *et al.*, 1997;p.310].

They identified adverse events in 45.8% of patients, with an average 4.5 events per patient; 9.3% of total adverse events were attributed to medication. At least one serious adverse event was reported in 17.7% of patients, ranging from temporary disability that increased the duration of hospitalisation to death, 5.8% of the errors were due to medication. Adverse events were associated with an increased average length of hospitalisation, 23.8 days vs. 8.8 days [Andrews *et al.*, 1997]. It has been suggested the use of this observational research method was inappropriate to determine prevalence for various reasons. For example, 'inappropriate decisions' were directly equated to adverse events and are subjective [Poses, 1997].

Costs of adverse healthcare events

The QAHCS reported that an adverse event was found to be responsible for an average additional 7.1 days hospitalisation [Wilson *et al.*, 1995]. The UK pilot study found each adverse event caused an additional average 8.5 days hospitalisation, and cost £290,268. It was estimated that if approximately 5% of the annual 8,500,000 England and Wales

hospital admissions suffered a preventable adverse event this would require three million additional 'bed days' at an annual cost of £1 billion [Vincent *et al.*, 2001].

1.4.5.2 Adverse drug events

Incidence of adverse drug events

The USA ADE prevention study recruited 4,031 non-obstetric adults over six months from two tertiary hospitals incorporating medical and surgical units. Data were collected by chart review combined with prompted practitioner reporting. According to their definitions, an ADE was *"An injury resulting from medical intervention related to a drug"* [Bates *et al.*, 1995a;p.30]. These were classed preventable if they had arisen from an error. Drug errors intercepted before they were carried out were potential ADE, *"incidents with potential for injury related to a drug"* [Bates *et al.*, 1995a;p.30]. All potential ADEs were medication errors [Bates *et al.*, 1995a]. They found ADEs in 6.5% of patient admissions and potential ADEs in 5.5%. Twenty eight percent of the ADEs were judged preventable, therefore arising from errors. If potential ADEs are combined with preventable ADEs a medication error rate of 7.3% was calculated. ADEs associated with a severe level of disability were significantly more likely to be preventable than less severe events. Errors producing preventable ADEs (n=70) occurred early on in the medication process, 56% at the prescribing and 34% at the administration stage. Amongst preventable and potential ADEs (n=264) errors were less likely to be detected in the later stages of the medication process. All administration errors reached the patient, but 48% of prescribing errors were intercepted. Of the ADEs 7.7% fulfilled the HMPS criteria. This correlated with a total study ADE rate of 0.5% [Bates *et al.*, 1995a].

Leape and colleagues [1995] performed a study in an identical setting and time frame to Bates and co-workers [1995a]. Medication errors were investigated to identify defects in the 'system' that allowed the errors to occur. A system was defined as

> *"An interdependent group of items, people, or processes with a common purpose"* [Leape *et al.*, 1995;p.36].

Again, the focus was restricted to errors associated with ADE or judged potential ADE, so excluding the many errors not associated with harm [Leape *et al.*, 1995]. An ADE or potential ADE was promptly investigated using a structured form to gather information on the circumstances and causes of the event.

A total of 334 errors were detected from 264 preventable events (194 potential ADE and 70 [28%] of the ADE were attributed to errors). Events were categorised according to the stage in the medication process at which they occurred. Errors were identified in more then one stage of the prescribing process in 55 (21%) cases. Errors occurred most often at the prescribing (39%) and administration (38%) stage. Details of the type of error and when in the medication process they occurred is shown in figure 1.6.

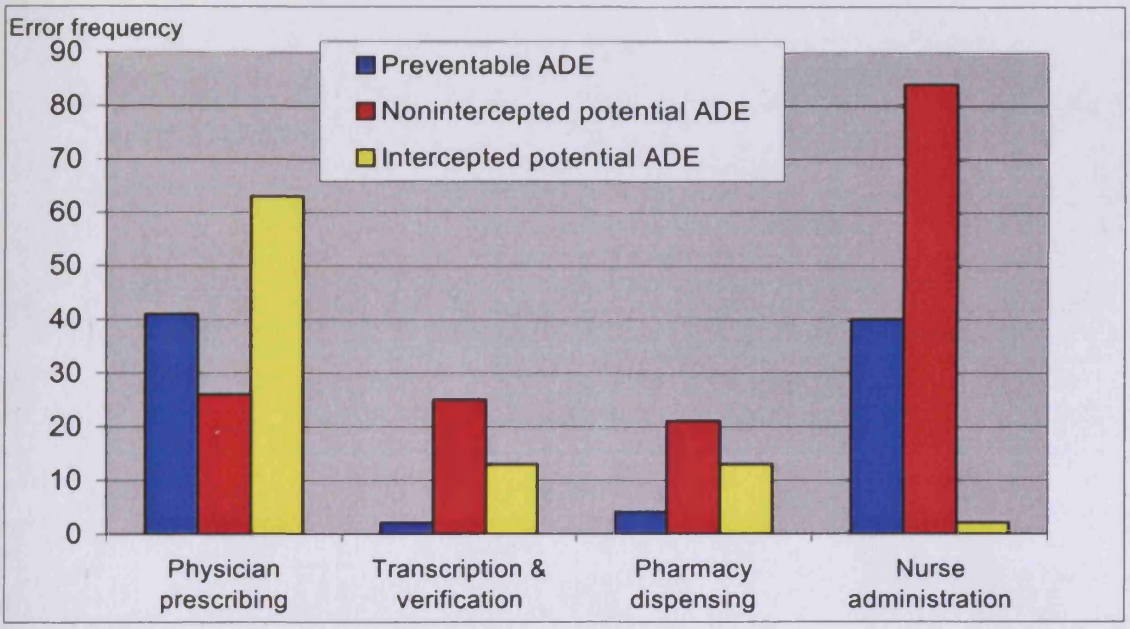


Figure 1.6 Types of medication error according to the stage of the medication process (n=334 errors) [Leape *et al.*, 1995].

Amongst common errors those most likely to cause injury were wrong choice and wrong dose errors accounting for 42% of all ADEs. Frequency and administration errors were rarely associated with ADEs.

Costs of adverse drug events

Analyses of the ADE prevention data for the effect an ADE had on healthcare resources demonstrated an increase in hospital stay and associated costs. Paired regression analysis, adjusted for multiple factors including severity, co-morbidity and length of stay showed that an ADE created an additional 2.2 days of hospitalisation and a preventable ADE 4.6 days. After adjustment for the sampling method, Bates and colleagues [1997] estimated the post event costs due to the adverse event was $2,595 per ADE and $4,685 per preventable ADE.

1.4.5.3 Adverse drug reactions

Incidence of adverse drug reactions

A retrospective analysis of coroner's inquest reports over six years, from an UK district serving 1.19 million, attributed 36 fatalities from a total 3,277 inquests to ADRs. These occurred more frequently in the elderly and were associated with a limited number of drugs [Ferner & Whittington, 1994].

Data were collected from a tertiary referral hospital between 1990-1993 using practitioner reports and computerised surveillance for ADEs cases, with matched controls. From the methodology it is clear these data in fact referred to adverse drug reactions, since the standard WHO definition of an ADR was employed. ADRs were found to complicate 2.43% of admissions [Classen *et al.*, 1997].

A meta-analysis of 39 prospective USA studies published from 1966-1996 attempted to estimate the overall incidence of ADRs in hospital patients. The researchers adhered to the WHO definition of an ADR and excluded medication errors and possible ADR in their analysis. The overall incidence of ADRs causing admission to hospital and occurring during hospitalisation was 15.1%. They found the incidence of serious ADR to be 6.7% (2.1% experienced during hospitalisation, 4.7% the reason for admission) and fatal ADRs were 0.32% (0.19% during hospitalisation and 0.13% causing hospital admission). They reported a stable incidence of ADRs over the 30 years analysed. Accepting the heterogeneity of the sample, and potential bias, this still illustrates the importance of ADRs as a key health care issue [Lazarou *et al.*, 1998].

A large systematic review of global ADR studies published prior to 1999 [Wiffen *et al.*, 2002] found the incidence of ADRs was lower since 1985 than before this date. There was little UK data, but that which was available suggested UK and European data were comparable, where ADRs affected 7% patients or hospital admissions. It is of interest that the rates reported were twice those of North America.

UK researchers prospectively studied 18,820 adult hospital admissions to two hospitals and found ADRs in 6.5%. In 80% of these the ADR was the causal reason for admission [Pirmohamed *et al.*, 2004]. It is concerning that 72% of ADRs were either definitely or possibly avoidable. Comparing their findings with the published literature, the authors state

"many of the studies included in recent systematic reviews, however, are more than 20 years old, and it is disappointing that the burden of ADRs has not decreased"

Further they suggest that

"many may be preventable through simple improvements in prescribing" [Pirmohamed *et al.*, 2004;pp.17-18].

Costs of adverse drug reactions

The study by Classen and co-workers [1997] study showed ADRs were associated with increased mortality, longer hospitalisation and greater hospital bills. The average length of stay was 4.46 days for control patients compared with 7.69 days for ADR case patients, with the crude mortality rate 1.05% and 3.5% respectively. This translated into an increased risk of death of 1.88 (odds ratio) for those experiencing an ADR. After linear regression analysis for duration of hospitalisation and cost control of matching variables, an ADR was found to be associated with an additional 1.91 days hospitalisation and $2,262 in hospital fees.

The Pirmohamed and colleagues study found that ADRs were associated with a median bed stay of 8 days, equivalent to 4% of hospital bed capacity. They estimated that the NHS spent £466 million per annum on such admissions [Pirmohamed *et al.*, 2004].

1.4.5.4 The link between adverse drug events and medication errors

Data on medication errors, and their contribution to actual or potential ADEs were gathered for 1,704 patient days over a 51 day period at a tertiary care hospital on medical Intensive Care Unit and ward areas. From 10,070 new medication orders (prescriptions) had a 5.3% medication error rate. This equated to a mean of 0.3 errors per patient per day, or 1.4 errors per admission. During the study period 25 ADEs were identified, of which five were judged preventable as they were due to errors. Overall, 0.9% of medication errors resulting in an ADE, and 6.7% a potential ADE [Bates *et al.*, 1995b]. Medication errors also cost numerous hours repeating work previously done, and 92% of errors needed direct practitioner communication to resolve them [Bates *et al.*, 1995b].

1.5 The medicines-use process

This complex process covers all stages surrounding medicines use, from the initial decision to prescribe a medicine through its administration to monitoring its effects on an individual patient. It can be split into innumerable small steps, and involves a continuum of communication between the various parties involved [Ferner & Upton, 1999; Andersen *et al.*, 2001]. When such multifaceted and interdependent processes are performed, it remains inevitable that this will incorporate an element of error. Each stage contributing to the medicines process is prone to error [Department of Health, 2000a]. An outline of this process is given in figure 1.7.

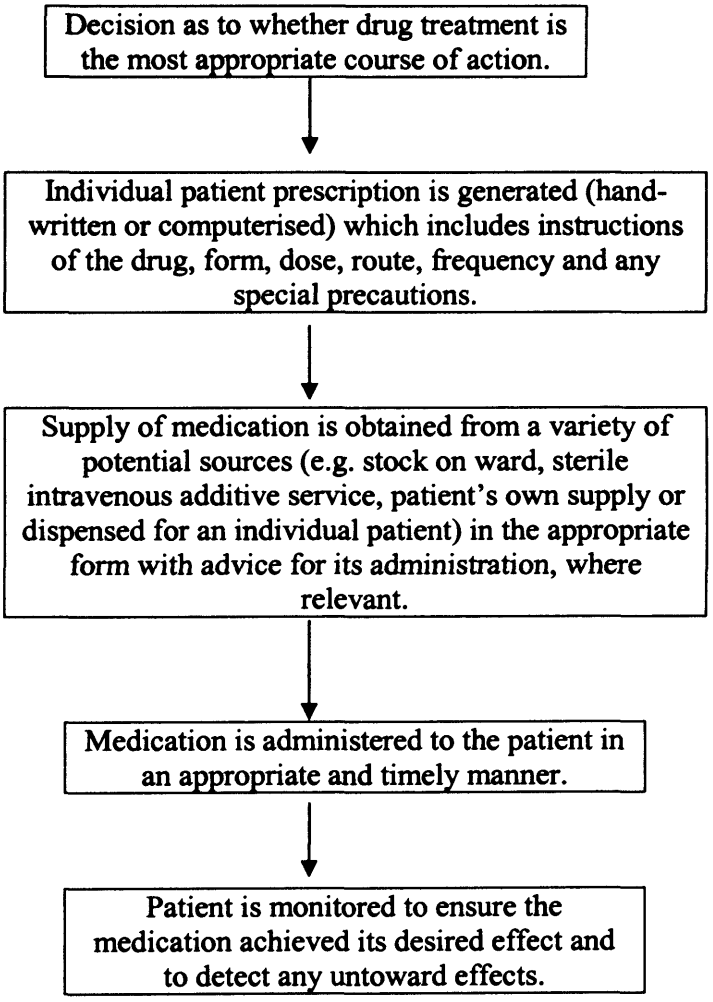


Figure 1.7 An overview of the medicines-use process [adapted from Ferner & Upton, 1999]

The outline is skeletal in nature, as many different routes can to be taken through the pathway; advice or additional input may be needed before proceeding to the next step [Hepler & Strand, 1990; Davies *et al.*, 1994; Ferner & Upton, 1999]. For example, the patient may need counselling on the use of an inhaler.

Traditionally, the medicines-use process (MUP) is subdivided and described as a series of repetitive and non-repetitive steps; the component stages of the inpatient medication process have been described as:

a) Prescribing (or ordering in American literature [Bates, 1996]),
b) Transcription,
c) Dispensing (may be referred to as filling in American literature [Bates, 1996]),
d) Administration to the patient,
e) Monitoring [Ghandi *et al.*, 2000; Andersen *et al.*, 2001].

However, medication use is not divorced from other healthcare interventions and processes that run in parallel or are often combined [Andersen *et al.*, 2001]. A sound understanding of the system is necessary to examine how errors can arise, and what can be done to minimise their occurrence. Although the definition of a medication error includes all stages in this process, research has often focused on a single stage [Bates, 1996].

1.5.1 Medication errors

Medication errors hit the headlines in the 1960s when it became apparent the problem was rife in hospitals [Vere, 1965]. Research from the UK and USA revealed that on average, a nurse made approximately one error for every 6 medicines given [Barker & McConnell, 1962; Hill & Wigmore, 1967]. Attention was focused on the unsatisfactory systems that existed for drug supply and control, and from this starting point ward pharmacy was born. Two different approaches were adapted in the UK: the combined patient prescription and drug administration record was established [Crooks *et al.*, 1965], and pharmacists began leaving a centralised pharmacy to review patients' treatment at ward level [Calder & Barnett, 1967]. In the USA unit dose dispensing and decentralised pharmacy workstations in close proximity to patient areas were established. The wheel has turned full circle since the late 1960s, and medication errors are in the limelight once again [Department of Health, 2000a]. Much has since been learned, however it is accepted that the measures introduced to control the errors have been only partially successful and there is no research base detailing the current state of play in the UK [Cousins & Luscombe, 1995; Department of Health, 2000a].

Errors can arise at any stage within the medicines-use process, each step following an error provides an opportunity for detecting the error and correcting it e.g. a prescribing error

may be noticed by a pharmacist supplying a medicine, or a nurse administering one. The administration stage provides fewest opportunities for error interception. Different stages in the MUP generate different errors.

The Bates and colleagues [1995a] and Leape and colleagues [1995] studies of preventable and potential ADE, highlighted that medication errors most often occurred in the prescribing stage (39% when error is the denominator). Forty eight percent (n=63) of these errors were intercepted, most by nurses (55 cases) and the remainder by pharmacists (8 cases) [Leape *et al.*, 1995]. The most common errors were wrong dose, wrong drug choice, wrong frequency, and prescribing a drug to which the patient was known to be allergic. The second most error prone stage was administration (38% when error is the denominator used). The majority of errors were due to wrong medicine, wrong dose, wrong technique, missed doses and wrong time. However, by contrast, only two percent of these errors were intercepted. The authors reported that errors were significantly more likely to be intercepted the earlier they occurred within the MUP. The research methodology used did not include observational techniques, yet these are considered the optimum method to detect administration errors [Dean & Barber, 2001]. Therefore, it is likely that many administration errors went undetected, and that administration is the most error prone stage of the MUP.

There are currently no corresponding large scale studies available for the UK; most researchers have focused on a single stage in the MUP. In 2001 it was estimated that half a million prescriptions were generated each day in English hospitals [Department of Health, 2001b] but the prevalence of injury caused by medication errors in the NHS was not known [Smith, 2004].

As there are fundamental differences between the USA and UK MUPs, an overview of medication errors in the UK adult inpatient setting is described below. Dean Franklin and colleagues [2005] reminded readers of the need for a clear understanding of the terminology, denominator and methodology used when evaluating a study's findings.

1.5.1.1 Prescribing errors

Dean and colleagues [2002a] undertook a large UK pilot study to determine the incidence of hospital prescribing errors. Pharmacists prospectively detected prescribing errors over

four weeks from non-obstetric patients in a large teaching hospital. The results revealed a 1.5% error rate in all the 36,168 prescriptions written, with 0.4% potentially serious errors [Dean *et al.*, 2002a]. The majority were dosing errors (54%) and arose at prescription writing (61%) rather than cognitive decision to prescribe stage [Dean *et al.*, 2002a].
Two key factors contributing to prescribing errors have been identified [Leape *et al.*, 1995; Lesar *et al.*, 1997]. These were:

a. Inadequate or poorly applied knowledge of drug therapy. Prescribing errors attributed to deficits in doctors' knowledge included wrong dose, form, frequency, route and choice of drug.
b. Failure to tailor treatment according to individual patient characteristics, such as renal impairment or documented allergies.

Semi-structured interviews of 41 prescribers who made 44 potentially serious errors revealed that most were slips in attention, and prescribers were unable to explain why. Contributory risk factors identified included work environment, workload, team communication, prescribing for another team's patient, physical and mental well being, lack of knowledge, inadequate training, team hierarchy, low perceived importance of prescribing, and lack of error awareness [Dean *et al.*, 2002b].

1.5.1.2 Dispensing errors

There are few large scale UK hospital dispensing error studies. Beso and colleagues [2005] investigated the frequency of inpatient, outpatient and discharge items errors detected at the final check stage within the pharmacy. One or more errors were found in 2.1% of items. This compared with 0.02% items reported as errors to pharmacy from dispensed items that had left the pharmacy department.

Similarly, an average error rate of 0.018% of dispensed items from 19 hospital dispensaries has been reported [Spencer & Smith, 1993]. A total of 7,158 dispensing errors were reported as part of an unofficial scheme between 1991-2001 from 89 UK hospitals [Roberts *et al.*, 2002]. No denominator was given, so the percentage error rate cannot be determined. The most frequently reported errors were wrong medicine and wrong strength of the correct medicine (both 23%). Several contributory factors were identified, these were: look-alike and sound-alike medicines (33%), high workload and, or low staffing (23%), inexperienced staff (20%) and transcriptions errors (14%) [Roberts *et al.*, 2002].

1.5.1.3 Administration errors

Anaesthetics, paediatrics, critical care and intravenous medicines carry a high risk of administration errors, and were critically dependent on the previous MUP stages [Smith, 2004]. With oral doses, a 5.5% error rate has been reported [Barber & Dean, 1998]. Studies investigating parenteral, primarily intravenous, error rates have detected between 25-49% errors with 1% potentially serious errors [Bruce & Wong, 2001; Taxis & Barber, 2003a]. The error rate for injectable medicine administration is much higher than for enteral routes. Further work is required to elucidate the reasons why and propose ways to minimise or eradicate these errors [Cousins, 2005a].

Causes of administration errors include verbal orders, illegible prescriptions, transcription errors, inadequate labelling, lack of knowledge, fatigue, illness, stress and distractions [Smith, 2004].

1.6 Research methodology

Research into medication errors is vital for quality improvement because of the unique interplay of contributory factors. However, any generalisability beyond the study setting has been questioned [NCC MERP, 2002].

> *"Interorganisational comparisons of rates are not likely to be meaningful and may be counterproductive"* [van Leeuwen, 1994;p.193].

Cousins [2005b] elaborated further, stressing the importance of understanding the context of the health care system, medicines used, MUP, pharmacy duties and staffing when interpreting studies from other countries. One example he cited from national survey data was that nurses prepare intravenous (IV) medicines in 19% of hospitals in the USA compared with Europe where pharmacies prepared only 9% of IVs (excluding parenteral nutrition and chemotherapy). Yet it was not until recently that stringent standards for pharmacy preparation and quality control have become widespread in the USA and compliance with these was still not universal in 2002 [Hunt & Rapp, 1996; Morris *et al.*, 2003].

In this field, combining more than one research method for detecting patient safety incident involving medication has been advocated [Allan & Barker, 1990; Ghandi *et al.*, 2000; Morimoto *et al.*, 2004]. Further, the research methodologies for adverse drug event detection have been considered so resource intensive that they may not be generally

applicable for adaptation into routine practice [Ghandi *et al.*, 2000]. The advantages and disadvantages of the main research methods employed are summarised in table 1.2. Some methods are more applicable to one research setting than another. Depending on the aims of the study any of the methods described could be used in combination to identify patient safety incidents. There are ongoing developments seeking to refine these methodologies, or move to more prospective methods [Murff *et al.*, 2003; Neale & Woloshynowych, 2003; Woloshynowych *et al.*, 2003; Morimoto *et al.*, 2004; Phillipe *et al.*, 2004; Dean Fanklin *et al.*, 2005; Lisby *et al.*, 2005].

Table 1.2 Methods for detecting medication errors and adverse drug reactions [adapted from Allan & Barker, 1990; Jha *et al.*, 1998; Gandhi *et al.*, 2000; Barker *et al.*, 2002a; Morimoto *et al.*, 2004].

Method	**Advantages**	**Disadvantages**
Spontaneous voluntary reporting (includes both anonymous and incident reports)	• Inexpensive. • Ongoing process (not confined to snapshot review). • Least time consuming • If anonymous, removes disciplinary concerns. • Strategies can be employed to enhance response rate e.g. prompting. • Useful for inpatient settings	• Awareness an error occurred needed to submit an error report. • Poor reporting rate, especially if concerned about disciplinary consequences. • Less likely to be reported if no harm to patient, or doctor advises against reporting. • Not representative. • Under reporting may lead to a false sense of security. • Less sensitive for omission or wrong time medication errors. • Safety culture needed to maximise data collection. • Likely to underestimate true incidence as reliant on documentation to identify potential incidents.
Pharmacy intervention records	• High data yield. • Inconsistent recording due to part time nature of pharmacy contact time. • Process rather than outcome measure. • Immensely practical. • Inexpensive.	• Doesn't pick up administration errors. • Dependant upon pharmacist's skills and subsequent documentation. • Sensitive for both ADE and potential ADE. • Process rather than outcome measure.
Critical incident technique (by participant observation or interview)	• Useful to identify cause of errors. • Facilitates targeting of major issues.	• Very large sample required. • Large volume of data generated. • Data interpretation difficult. • Problems eliminating many sources of bias. • Operationalising into a practical solution is hard. • Interview techniques rely on memory.

Table 1.2 continued... Methods for detecting medication errors and adverse drug reactions [adapted from Allan & Barker, 1990; Jha *et al.*, 1998; Gandhi *et al.*, 2000; Barker *et al.*, 2002a; Morimoto *et al.*, 2004].

Method	Advantages	Disadvantages
Direct observation of subject by trained observer	• Most sensitive and reliable for administration errors. • Moderately sensitive for ADE. • Observer gains insight into possible causes. • Objectivity preserved as subject not involved in reporting. • High yield of results. • Highly accurate, especially for dispensing and administration errors. • Useful in inpatient setting • Disguised method limits effect of interference from the researcher.	• Expensive, especially if ADE detecting as larger data set is required. • Time consuming. • Only feasible to do for short periods. • Requires skilled staff or extensive training. • Observer fatigue. • Care must be taken to minimise the observer's presence affecting results. • Risk the observer could misconstrue observations. • Useful for detecting administration errors, but these have a low chance of patient harm. • Administration studies are only valid if observer actually sees dose consumed, cannot rely on prescription record. • Observer must be unfamiliar with prescription to protect against liability.
Case data review (of prescriptions, laboratory tests, multi-disciplinary notes etc.)	• Best detection rate for inpatient setting. • Moderate detection rate for outpatient setting. • Been modified for prospective use.	• Only suitable for areas with good prescription records e.g. unsuitable for outpatients. • Not very sensitive for administration errors. • Subjective • Expensive method for collecting ADEs. • Time consuming. • Reliant on appropriate documentation of events. • Process rather than outcome measure. • Data collectors require careful training; despite this result still affected by reviewers skills.
Computerised surveillance	• Reasonably sensitive. • Inexpensive. • Can create a 'rules-based' computer programme to gather data e.g. identify 'triggers' • Good at identifying ADEs, especially numerical ones. • Can be used routinely where computerised physician order entry or electronic medication records are the norm. • Less resource intensive and more focused than manual data review	• Poor at detecting potential ADEs • Requires an electronic based system prescribing or patient data system to be in use. • Dependent upon technology in use. • Further refinement required as current methods create too many false positives (ADEs and errors).
Patient Surveys	• Detects incidents not recorded in the notes. • Important for outpatient settings • Sensitive and effective for outpatient ADE detection.	• Interviews and phone surveys are resource intensive.

Another method that has been employed is searching legal claims data, but this should generally be disregarded, as it is insensitive and expensive with independent verification of the report required [Ghandi *et al.*, 2000]. Focus groups are considered a useful tool for gathering data on key issues [Ghandi *et al.*, 2000]. Other workers have used unannounced visits for quality control purposes to determine the true incidence of dispensing errors reaching the ward [Lisby *et al.*, 2005].

Over the last decade Bates and colleagues have developed a comprehensive methodology for identifying and classifying medication safety research. This has been published for other researchers to adopt [Morimoto *et al.*, 2004]. Their data collection has focused on a combination of three methods:

1. Retrospective data review
2. Stimulated reporting from healthcare professionals
3. Patient surveys

Each incident identified is the classified, and an assessment of reliability performed. This methodology remains valid for classifying all types of patient safety incidents involving medicines. This process for classifying a verified incident is summarised in figure 1.8 below.

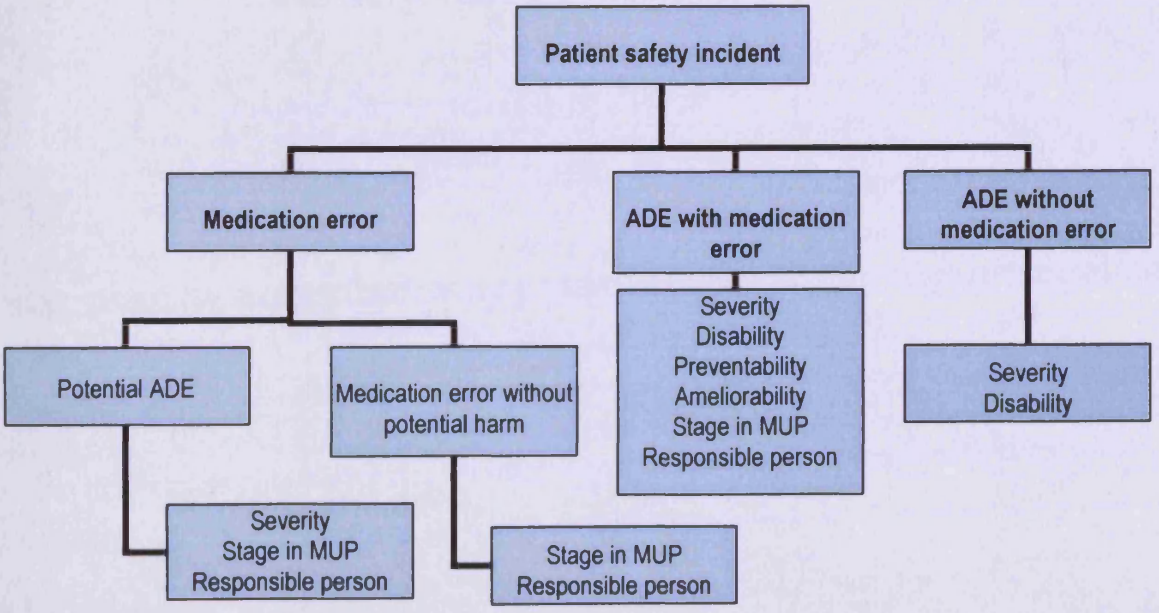


Figure 1.8 Overview of the process for the classification of medication errors and ADEs [from Morimoto *et al.*, 2004;p.312.]

The main limitation of this approach is the lack of observation to detect incidents. Key workers in the field of patient safety have validated the robustness of observational

methods, especially for patient safety incidents occurring during administration [Dean & Barber, 2001].

1.7 Conclusions

Medicines use is an increasingly complex process. Along with other processes, such as aviation and the nuclear industry, the risks are high and any service failure is highly undesirable. The Government has commissioned a review to inspect the lessons learned from prior misadventures to minimise patient harm. The findings were that rare but exceedingly serious incidents occur repeatedly. For example, there have been 13 reported cases of inadvertent spinal drug administration since 1985, some with fatal consequences. A key Government recommendation was to reduce this number to zero by the end of 2001 [Department of Health, 2000a, 2001b]. Despite this target another case of spinal maladministration of vincristine occurred in 2001 [Harris, 2001].

The Government described:

- The lack of an UK research base from which to start addressing medical and medication incidents,
- Poor organisational culture,
- Inadequate reporting systems for both actual incidents and 'near-misses',
- No central collation and distribution of information on incidents.

It recognised that in very complex, high throughput, technologically advanced areas it may not be feasible to completely eliminate errors, but that efforts to minimise them are vital [Department of Health, 2000a]:

> *"...to a great extent high-risk medicine is bound to be eventful"* and *"serious errors and complications will never be eradicated, simply because there is a level of risk for which no system can fully compensate"* [Department of Health, 2000a;pp.27-28].

ADEs are of concern because of their prevalence and the human and fiscal consequences associated with them. However as not all ADEs are preventable, initial efforts have focused on those medication errors causing harm. This is because they are preventable and investigation and analysis of errors provide means to prevent future occurrences. Amongst a pharmacist's main duties, is the promotion of safe, effective medication use, and therefore this becomes a key concern.

Chapter 2

Intravenous medication administration errors

2.1 Background

Within Europe intravenous medicines are routinely manipulated from their constituent ingredients into a form ready to administer to the patient in clinical areas [Tilleul, 2003; Turner *et al.*, 2003; Cousins *et al.*, 2005]. Intravenous medication administration errors are of particular concern as they are more complex than simple oral administration, and the result of an error is often more serious, with immediate consequences [Cadman & Park, 1999]. Many fatal medication errors in hospital patients have been attributed to hypertonic solutions or injectable medicines with narrow therapeutic ranges [Argo *et al.*, 2000]. In addition the NPSAs first patient safety alert concerned a hypertonic injectable medicine [NPSA, 2002].

Numerous case reports in the literature have highlighted problems that have arisen during IV medicines preparation and administration, some with fatal results [Anon., 1994; Vissers & Purssell, 1996; Cousins & Upton 1997, 1998, 1999; Cohen & Milo, 2000]. Examples are described in figure 2.1.

- Hydrocortisone omitted postoperatively in a patient who had been on long-term steroid therapy for Crohn's disease.
- Insulin 0.5ml was added to sodium chloride 0.9% and not mixed before administration.
- A heparin infusion was prepared using the entire contents of a 125,000 unit vial, an 8-fold overdose.
- Cidomycin® 600mg (brand of gentamicin) administered unchecked to a patient instead of the intended 600mg clindamycin.
- Phenytoin syrup drawn up in an IV syringe was administered IV rather than orally.

Figure 2.1 *Some* examples of errors reported in the literature [Cousins & Upton 1997, 1998; Hartley & Dhillon, 1998; Bruce & Wong, 2001; Taxis, 2001].

Recent studies have shown that mistakes during IV medicines preparation are common, preventable, and pose a substantial risk to patients [see section 2.6 and O'Hare *et al.*, 1995; Hartley & Dhillon, 1998; Hoppe-Tichy *et al.*, 2002; Taxis & Barber, 2003a; Wirtz *et al.*, 2003; Cousins *et al.*, 2005].

2.2 The intravenous medicines administration process

The intravenous medicines administration process can be subdivided into several stages. These can be classified as:

i. *Interpretation of the prescription* (the administrator, usually a nurse, must identify that a dose of intravenous medicine is due, mentally process the details, and act).

ii. *Intravenous medicines selection and preparation* (the product, or components required to prepare the product must be located and transformed into a ready to administer form). This process may be one or more stages leading to wide variation. This range is shown in figure 2.2:

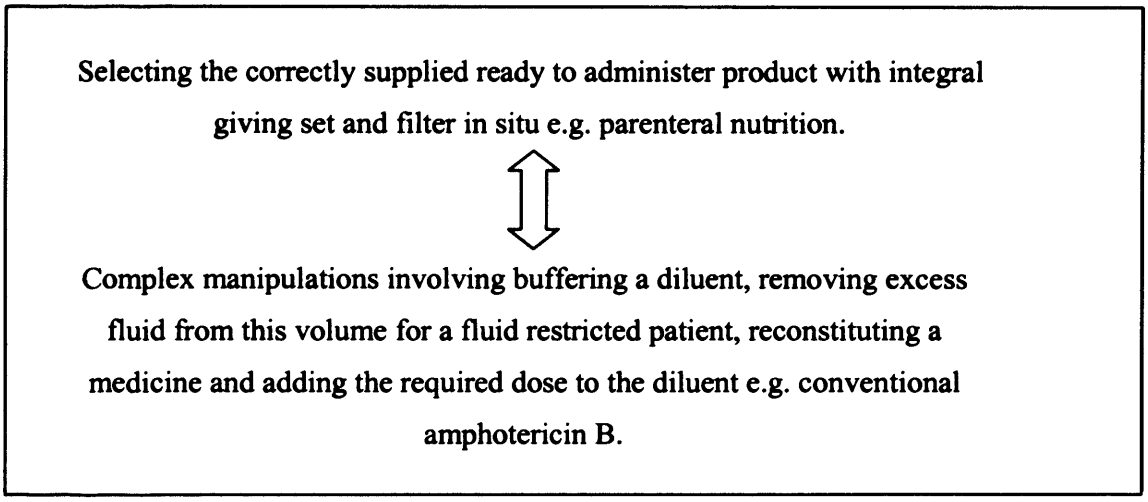


Figure 2.2 Illustration of variance in manipulation required to prepare an IV medicine

Taxis [2001] overcame this by dividing preparation into five mutually exclusive categories, described below:

- Ready to administer.
- Medicine solution.
- Dilution of medicine.
- Reconstitution.
- Reconstitution and dilution.

Specific product information from the manufacturers is contained within many intravenous products. In addition, most hospitals also have intravenous guidelines which outline how the medicine should be prepared, often called IV monographs or IV guidelines. These contain instructions for all general IV medicines in the formulary. Specialist areas with differing needs or practices for their patients care, e.g. fluid restriction, neonates also have guidance

for their specific setting. This may be restricted to the clinical area or contained within the general guidelines. Operationalisation varies between hospitals, with some producing in-house guidelines, whilst others adopt published guidelines. Some employ a combination of these [Schulman *et al.*, 1998; Anon., 2002]. Published guidelines are also commonly available for the neonatal and paediatric settings.

iii. *Patient identification* (locating the patient, and performing the safety checks to determine the patient prescribed the IV medicine has been correctly identified).

iv. *IV administration* (administering the medicine to the patient by bolus, intermittent or continuous infusion. This may include the need to insert, a giving set, in line filter, piggyback or select and correctly programme a pump).

However, these five subdivisions of IV preparation have limited use in practice as they do not take into account more than a two-step task. For example, to administer the medicine Pabrinex™ requires two solutions to be mixed together in a syringe. The mixture can either then be administered directly, or subsequently diluted. If the mixture is diluted it becomes a two-stage process.

2.3 Aseptic preparation: a historical perspective

In the late 1970s the situation with respect to IV therapy and additions to IV fluids differed greatly from today. It has been said that there was:

- Scare data on IV fluid stability and compatibility.
- Little pharmacist involvement in fluid additions.
- A lack of nurse training.
- An expansion in the use of continuous infusions.
- A lack of awareness of technical issues by prescribing doctors.
- No definition of nursing responsibilities surrounding IV addition and administration.
- Inadequate information on the ward.
- No possibility of assuring asepsis in clinical areas [Anon., 2005a; Zavery *et al.*, 2005].

Following an NHS IV fluid catastrophe, a report was commissioned to review IV medicines additions practice. Key recommendations from this 'Breckenridge Report' were that:

- IV medicines additions were aseptic procedures and ideally should be prepared in pharmacy–run facilities.
- Where this was impossible, pharmacists should be available in clinical areas to advise about IV additions, and should be heavily involved in medical and nurse training on these issues.
- Additions should be made only when supported by compatibility and stability data.
- Maximum use should be made of ready to administer preparations [Anon., 2005a; Beaney, 2001].

When the Medicines Act (1968) was written it had little applicability to hospital practice, focusing mainly on community and industrial practice. At this time the NHS was protected from prosecution by Crown Immunity. Decades later, Crown Immunity was lifted and NHS hospitals were required to comply with the provisions of the Medicines Act (1968). By the 1990s there had been a growth in pharmacy controlled aseptic medicines preparation which took place in near-patient areas and within the pharmacy department. Reductions in preparation of other hospital items meant hospital pharmacy manufacturing units were increasingly involved solely in aseptic preparation [Farwell, 1995].

The range of commercially produced licensed medicines is inadequate to provide essential patient care. Therefore, to overcome this problem unlicensed injectable products were available from two hospital pharmacy sources. These were: MHRA inspected and licensed NHS manufacturing units in compliance with the Medicines Act (1968), or through non-licensed units run exclusively under the control of a pharmacist. Where,

*"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].

Non-licensed units provided aseptically dispensed items under section 10 of the Medicines Act (1968) according to defined NHS guidelines [Zavery *et al.,* 2005]. Products are prepared for individual patients, often with short shelf lives. The supervising pharmacist is responsible for the quality of these products. Unlicensed facilities should meet the same standards as licensed facilities, although not MHRA assessed are subject to 12 -18 monthly audits including Quality Assurance Pharmacists. Regular internal audits are required, and the external audit findings are shared with commissioning bodies and the NHS Chief Executive, so ensuring standards are maintained [NHSE, 1999b].

The NHS Pharmaceutical Quality Control Committee published standards for aseptic preparation in 1993. However, these were superceded by the 'Farwell Report' in 1995. Concerns about monitoring, availability of services, consistency and application of practice standards led to the production of *'Guidance for aseptic dispensing for NHS patients'* [Farwell, 1994]. These applied to aseptic dispensing, parenteral nutrition preparation, central IV additive services, dispensed cytotoxics and radiopharmaceuticals. Aseptic preparation provides the least assurance of sterility of the injectable product, and is only used when more robust sterilisation methods are not possible [Farwell, 1995]. Assurance of the product quality relies on robust, clearly defined policies, facilities, design, equipment, process validation, training, capacity planning, competency and service audit. Consequently, pharmacy aseptic preparation is rigorously controlled, with explicit national guidance to ensure the quality of the product [Beaney, 2001].

This contrasts sharply with IV medicines prepared by healthcare staff in clinical areas where no preparation standards exist and local guidelines are rare [Audit Commission, 2001; Clinical Resource and Audit Group, NHS Scotland, 2002]. Although IV medicines preparation is generally undertaken by qualified nurses and midwives with competency in IV administration, and they subsequently administer the medication, the Chief Pharmacist remains responsible for all aspects of medicines management [NHS Executive, 1999b]. In specialist settings, other healthcare groups such as operating department assistants, perfusionists and junior medical staff may undertake IV preparation but training and competency assessment for such staff performing this task is uncertain [Marriott *et al.*, 2000; Teahon & Bateman, 1993]. Currently there is no consensus on what is appropriate aseptic technique in the ward environment [Taxis, 2001]. Nursing guidelines have been published in 'The Royal Marsden Hospital Manual of Clinical Nursing Procedures' [Mallet & Dougherty, 2000] but these differ from pharmacy practice.

2.3.1 Controls assurance for unlicensed aseptic dispensing in the NHS

Introduced in 1999, Controls Assurance was

> *"a process designed to provide evidence that NHS organisations are doing their "reasonable best" to manage themselves so as to meet their objectives and protect patients, staff, the public and other stakeholders against the risks of all kinds."* [NHSE, 1999c, p.2].

The pharmacy profession has retained its responsibility for ward based aseptic preparation [NHS Executive, 1999b], a view re-enforced by the Audit Commission Report [2001]. The

Chief Pharmacist's responsibility was highlighted under Controls Assurance Standards and is not expected to change with the forthcoming NHS healthcare standards [Department of Health, 2004]. The Controls Assurance medicines management standards for unlicensed aseptic dispensing required that pharmacy should risk assess ward based preparation activities. This aimed to ensure that the preparation of high risk products was transferred to pharmacy facilities, to avoid the additional risk of microbial contamination and medication error that may be associated with ward based preparation, and to ensure that appropriate controls were in place where ward based preparation continued. It has been suggested that the key requirements are that:

- Aseptic preparation is assembly under the provisions of the Medicines Act (1968).
- There should be appropriate training, authorisation, documentation and competency of staff undertaking IV medicines preparation.
- A designated area for aseptic preparation.
- Prepared medicines should be labelled in accordance with Trust policy and the Medicines Act (1968)
- Doses are prepared immediately prior to use.
- Staff are aware of their responsibilities under the Medicines Act (1968), Health and Safety at Work Act and Control of Substances Hazardous to Health Regulations [Hospital Pharmacists Group, 2002].

Risk assessment of ward based preparation was limited to a handful of NHS hospitals [Beaney & Goode, 2003; Clinical Resource and Audit Group, NHS Scotland, 2002; Joshi *et al.*, 2001; Munro *et al.*, 2003; Tunstell, 2004; Zavery *et al.*, 2005].

Zavery and colleagues [2005] surveyed parenteral medicine preparation on 71 out of 82 wards across two large UK teaching hospitals. The facilities for IV preparation in clinical areas contrasted sharply with the standards required for aseptic dispensing in pharmacies. At least one third of wards had no designated preparation area, whilst most had cluttered work surfaces and a sink in the preparation area. Other issues they identified included food or drink present, and damaged or unlaminated work surfaces in the preparation area. The researchers identified deficiencies in documentation and accessible information sources and concluded that

"wide variation in practice was evident in different clinical areas and overall standards of practice were very poor" [Zavery *et al.*, 2005;p.15].

There are scarce controls on the environment in which IV medicines are prepared in clinical areas. This contrasts sharply with pharmacy managed facilities where strict controls are mandated e.g. air quality, bio-burden [Beaney, 2003]. It could be argued that such stringent controls are unnecessary because doses prepared in clinical areas will be administered immediately. However, inadvertent contamination during preparation of continuous infusions could produce a potential reservoir for proliferation of micro-organisms and subsequent patient infection.

The importance of design and the environment has been recognised in the draft consultation of the hospital Health Building Note (HBN) on 'Facilities for medicines management'. Where clinical areas require

"a designated easily-cleanable area, away from thoroughfares, windows and sinks should be provided for the preparation of iv products" [Architects for Health, 2006;p.25].

There has been progress with all the recommendation from the 'Breckenridge Report' except the transfer of all aseptic additions to pharmacy controlled facilities [Anon., 2005a]. Although the abolition of all ward-based preparation may be the ideal situation, it has not been realised because of shortages in pharmacy manpower and funding [Crowley *et al.*, 2004]. Today, IV medicines, including those considered "high risk," continue to be routinely prepared in clinical areas [Anon., 2005a; Audit Commission, 2001]. This has caused concern as IV medication has become more complex and more common [Root, 2006]. This is a multiprofessional issue and requires input from all the disciplines involved.

2.4 Clinical audit

Audit has been defined as

"The process of reviewing the delivery of health care to identify deficiencies so that they may be remedied" [Crombie *et al.*, 1993;p.27].

Audit is usually described as a cyclical process, consisting of numerous steps; these are illustrated in figure 2.3

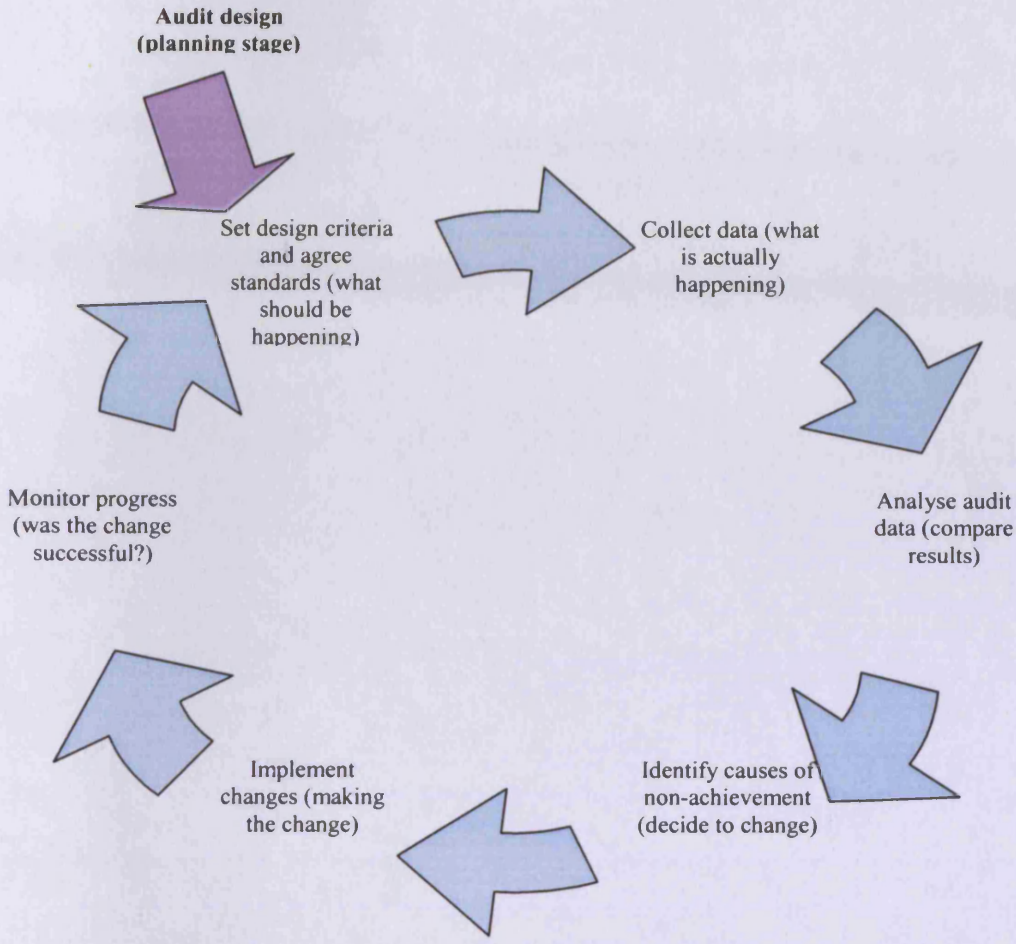


Figure 2.3 The audit cycle [Anon., 2005b;p.203]

Clinical audit is a key component of clinical governance, with all clinical staff required to participate. It has been defined as

"A quality improvement process that seeks to improve the patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structures, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual team, or service level and further monitoring is used to confirm improvement in healthcare delivery" [Copeland, 2005;p.3].

It is a tool that enables organisations to determine whether agreed or recognised standards of care are achieved, and identify areas in need of improvement. It is an ongoing process that drives quality improvements, and may be initiated locally or nationally. National audits are increasingly being used for inter-organisational comparison [Lugon, 2005].

2.5 Competency to practice

The NHS has adopted a new strategy to ensure that the workforce possess the knowledge and skills required to deliver improved patient care. Since June 2004 'Skills for Health', a

skills council for health, was licensed by the Government to develop sets of national occupational standards for staff in all healthcare areas [Edwards, 2005b]. Its key role was to prepare and disseminate national workforce competence frameworks. Where *"standards of competence describe what is required of an individual to achieve what is expected of them in their work"* [Edwards, 2005b;p.6]. Their aims have been summarised as:

- Ensuring the workforce is trained to allow patients rapid access to those with the right mix of skills to suit their needs.
- Providing staff with the opportunity to fulfil their potential.
- Skills and competencies developed in a setting are transferable and recognised with the UK [Edwards, 2005b].

An alternative description is *"a competence framework is a structured mechanism for outlining competencies and for linking individual performance to organisational performance"* [McGuire, 2005;p.144]. These competency frameworks will map out how healthcare training should be provided in the future. Initially fifty areas were identified which needed development of a competency framework, with a long term goal that competency statements will be produced for approximately 95% of the workforce [Edwards, 2005b]. An integral part of the NHS re-structuring process is the competency framework called the Knowledge and Skills Framework.

Competency frameworks can be used by individuals and managers as a tool against which to assess performance. It is envisaged that this will provide a mutual and transparent understanding of the performance required to undertake tasks [McGuire, 2005].

Competency issues have been firmly embedded within nursing practice since the profession expanded its scope of practice. In order for nurses and midwives to administer IV medicines, their regulatory body, The Nursing and Midwifery Council (NMC), requires competency in all aspects of IV therapy, validated competency in clinical judgement, and practice within their professional code of conduct. Integral to this is a personal requirement to maintain up to date knowledge and skills [Dougherty & Lister, 2005; Royal College of Nursing, 2005].

2.6 Research methods for detecting and quantifying medicines administration errors

Since medication error research began in the 1960s, researchers have come to understand that there is no single research method that is universally suitable for all situations, or stages within the MUP [Barker *et al.*, 2002b]. Four main research methods have been used to study medication administration errors. IVMPE are one stage of the IV medicines administration process, therefore similar methods have also been used in their investigation.

These methods are:

1. Observation.
2. Self reporting, such as incident forms, interviews or questionnaires.
3. Testing, such as concentration assay of the active medicine.
4. Physical evidence, such as prescription chart review [Barker *et al.*, 2002b].

Flynn and colleagues [2002] studied medication administration errors at 36 USA 'hospital and skilled-nursing facilities' comparing three methods: incidents reports, chart review and observation. In the seven month study period, 2,557 medication doses were observed. During this time, a single incident report was generated, compared with 34 errors detected by chart review and 456 through observation. The error described in the incident report was also detected by observation.

It has been suggested that observation is valid, efficient, sensitive and accurate at identifying administration errors. Self reports and physical evidence are not sufficiently sensitive. In addition discrepancies have been reported between observations of medication administration and that recorded on the prescription chart, thus providing inaccurate data for prescription charts review [Barker *et al.*, 2002b; Flynn *et al.*, 2002]. Dean and Barber [2001] investigated the reliability and validity of observational methods to detect medication administration errors in a UK hospital. High observer reliability was reported and the presence of the observer did not significantly affect the error rate. It was also established that where the observer was aware a significant error may occur, tactful intervention to prevent this error harming the patient did not alter future behaviour and thus affect error rate [Dean & Barber, 2001].

Chemical assays have been used in situations where preparation forms part of the administration process [Allen *et al.*, 1995; Ferner *et al.*, 2001; Parshuram *et al.*, 2003].

These provide valuable information from a different aspect, and have been used either as a sole method or in combination with observation during simulation [Kozer *et al.*, 2004]. All of the studies detected discrepancies between prescribed medication and that prepared, allowing quantification of the discrepancy. Parshuram and colleagues [2003] reported that over two thirds of morphine syringes prepared for use within neonatal and paediatric critical care deviated more than 10% from that prescribed. The findings from simulated scenarios may differ from 'real-life' and this raises issues of generalisation [Kozer *et al.*, 2004].

2.6.1 Intravenous medication administration error studies

Research in this area is still in its infancy, information is constantly emerging on hospital intravenous medications administration errors. The earliest originated from the USA [Thur *et al.*, 1972], but more than two decades later the Europeans have begun researching this area [O'Hare *et al.*, 1995; Hartley & Dhillon, 1998; Wirtz, 2000; Bruce & Wong, 2001; Mansfield, 2001; Taxis, 2001;Hoppe-Tichy *et al.*, 2002].

In UK hospitals, most administration data has been gathered on oral administration, with a median error rate reported as 5.5% [Barber & Dean, 1998]. IV medicines administration has been excluded from the majority of studies, possibly due to practical observation difficulties and time and resource allocations required to collect such data, especially when compared with those needed to follow a drug trolley on a routine scheduled medicines round.

Given the potential risks inherent with IV medicines use it is surprising that relatively few studies have been published in this area. This is especially so since the landmark error studies excluded observation, known to be the most sensitive method of collecting this information [Allan & Barker, 1990; Ghandi *et al.*, 2000].

2.6.2 Frequency of UK IV medication preparation and administration error studies

An extensive literature review was undertaken. It identified seven studies reporting results of IV preparation and/or administration errors, wholly or partially from UK hospitals [O'Hare *et al.*, 1995; Hartley & Dhillon, 1998; Ferner *et al.*, 2001; Mansfield, 2001; Munro *et al.*, 2003; Taxis & Barber 2003a; Wirtz *et al.*, 2003]. In addition, one study

reported parenteral error rates, which included all injectable errors, though almost all arose from the IV route [Bruce & Wong, 2001].

All seven studies used direct observation of practitioners to identify errors. Details of study settings, research methods and study findings, where provided in the original publication (for six studies), are summarised in table 2.1. All of the studies aims included quantification of the error rate. However the sample size, context and study settings varied e.g. from a single site specialist paediatric hospital to four district general hospitals. The combined number of preparation and administration errors reported ranged between 23.8 and 93.9% of doses. However, these must be interpreted in conjunction with each study's error definition (see section 2.6.3). The more recent studies have reported error rates for preparation and administration separately [Mansfield, 2001; Taxis & Barber, 2003a; Wirtz *et al.,* 2003]. The seventh study, at a single site district general hospital took a holistic approach, using questionnaires to assess the risk to staff and patients, and combined this with the direct observation of eight staff in a range of clinical areas [Munro *et al.,* 2003].

An eighth study used quantitative assays to determine the content of acetylcysteine in infusion bags employed for the management of paracetamol overdose. This study was valuable, as it did not rely on observation, but indicated what dose the patient actually received. From several large discrepancies identified, the authors reported errors in calculation, dose measurement, and mixing [Ferner *et al.,* 2001].

An observational study of 430 IV medication doses across ten wards in two UK hospitals found a combined preparation and administration error rate of 46% [Taxis & Barber, 2003a]. Their study identified preparation errors alone in 32 doses with both preparation and administration errors observed in 25 doses. The majority of preparation errors arose from medication requiring multiple-step preparation; with three potentially severe errors detected [Taxis & Barber, 2003a]. Problems with IV medication preparation were caused by a lack of staff knowledge and, or, technological difficulties associated with uncommon procedures and usual drug vial presentation, preparation process or equipment [Taxis & Barber, 2003b]. A risk rating incorporating the number and nature of manipulations, medications and doses has been developed and tested in an UK observational study. Results reveal that two thirds of IV preparations were classified as high-risk [Joshi *et al.,* 2001].

Table 2.1 UK studies of IV medicines preparation and administration errors in clinical areas

Publication reference	Study brief	Research method used	Number of IV doses observed	Study setting	Overall preparation and administration error rate	Preparation error rate	Administration error rate
O'Hare *et al.*, 1995 A	IV drug administration errors (type, rate, potential severity)	Disguised observation	179	Single site: paediatric hospital	168 doses with 291 errors. 93.9% doses	Not stated	Not stated
Hartley & Dhillon, 1998 B	IV drug prescribing and administration errors (rate, type, cause, potential harm) Implication to MUP	Disguised observation	323	Single site: 3 wards, district general hospital, drug rounds observed	79.3% morphine PCA, insulin & heparin infusions were excluded	Not stated	Not stated
Mansfield, 2001 C	Audit of the risks and resources used in ward based IV preparation and administration	Direct observation	299	Multicentre: wards from 4 district general hospitals	Not stated	0-2.35%	48.68-104.4% (exceeds 100% due to 2 extra doses)
Bruce & Wong, 2001 D	Error rate during preparation and administration of parenteral medicines.	Disguised observation	107 parenteral doses, 105 of which were IV.*	Single site: admissions ward, continual daytime observation excl PFS, med emergencies	25.2% overall (95% CI 17-33.5%), equivalent to 23.8% for solely IV doses.*	Not stated	Not stated

Table 2.1 continued... UK studies of IV medicines preparation and administration errors in clinical areas

Publication reference	Study brief	Research method used	Number of IV doses observed	Study setting	Overall preparation and administration error rate	Preparation error rate	Administration error rate
Taxis & Barber, 2003a E	Incidence & severity of IV preparation and administration errors. When errors occur.	Disguised observation & informal discussion with staff	430	Dual site study: 10 wards from a teaching and district general hospital, attended drug rounds	49% doses had errors (95%CI 45-54%) Both preparation and administration error 57.9 errors per 100 doses.	7% alone, plus 6% both preparation & administration errors	36% alone, plus 6% both preparation & administration errors
Wirtz *et al.*, 2003. F	Incidence and severity IV drug preparation and administration errors		77 preparations, 63 administration	Single UK site: 2 wards in a teaching hospital (German data excluded), attended drug rounds, 24hr infusion & PRN excluded	Not stated	22% (95% CI 13-31%)	27% (95% CI 16-38%)

* Confirmed with author (Bruce J. Personal communication, 2003)

2.6.3 Criteria used for defining IV errors employed in UK studies

The definition of errors employed has varied between studies. There appears to be no consistency in the application of the definition. One example of a comprehensive IV preparation and administration error definition is

> *"A deviation in preparation or administration of a drug from a doctor's prescription, the hospital's intravenous policy, or the manufacturer's instructions"* [Taxis & Barber, 2003a;p.684].

The criteria against which errors were determined have also varied, with up to 22 different error categories described. These details are displayed in table 2.2. Use of unclear, inconsistent or poorly described definition and error categories has prohibited comparisons between studies or extrapolation of the findings [Crowley *et al.*, 2004a]. It also raises concern about the reliability and reproducibility of studies.

Two main areas of contention have been raised. These are whether to include timing errors and poor aseptic practice within an error definition. Historically timing errors have been excluded. However the importance of timing with respect to pharmacokinetics, particularly medicines with narrow therapeutic ranges has sparked interest in these errors. It has therefore been suggested that for some medicines e.g. aminoglycosides, timing errors should be included [Allan & Barker, 1990]. In addition it is difficult to measure poor aseptic practice as there is no agreed best aseptic practice in clinical areas. However, it is likely that blatant disregard of acceptable practice in certain cases, such as the malaria transmission by contamination of a flush solution, would be considered by the majority of practitioners to be an error [Cousins & Upton, 1999; Anon., 2000].

A shift in patient safety research has emerged, from studying medication errors to a focus on those errors that cause actual harm to the patient [Resar *et al.*, 2003]. Contaminated parenteral nutrition and propofol have been reported to cause adverse events to patients [Anon., 1994; Bennett *et al.*, 1995; Kuehnert *et al.*, 1997, Langford, 1999]. It is timely to question whether a breach of asepsis should be considered an error, when patients may be harmed.

Table 2.2 Comparison of the IV error definitions employed.

Error category	Description	Study reference†					
		A	B	C	D	E	F
Dose omission	Dose not given before it's next due	x	x		x	x	x
Extra dose	Dose administered after its discontinuation or duplicated	x	x				
Unauthorised drug	An unprescribed drug is administered		x		x	x	x
Wrong drug	Preparation of drug which was not the prescribed one		(x[8])			x	x
Wrong dose	Incorrect dose given		x		x ±>10%	x	x
Wrong dosage form	Drug formulation differed from that prescribed e.g. given po ordered IV.		x		x		x
Wrong route	Formulation intended for a specific route given by the wrong route, route differs from prescription		x	x	x		x
Wrong time		x>30min	x ±>30min	x ±>1hr	x ±>1hr		
Wrong preparation technique	Dose made up incorrectly e.g. not all powder dissolved, not mixed		x		x		x
Wrong rate	Incorrect rate of administration	x	x	x	x	x	x
Deteriorated drug	Appropriate precautions not taken e.g. light protection, expired		x	x[6]	x		
Wrong diluent	Incorrect diluent	x	x[2]	x	x[4]	x	x[1]
Wrong diluent volume	Incorrect volume of diluent	x	x[3]			x	x[1]
Wrong infusion volume				x		x	x[1]
Wrong patient						x	
No second check	Failure to double check preparation or administration process			x			
No label	Product not given immediately that was inadequately or not labelled			x	x		x[7]
Inappropriate storage	Products not used immediately after preparation			x	x[2]		
Pump used but not needed				x			
Pump error	Pump not used when needed or of insufficient specification			x	x[5]		
Drug incompatible	Co-administration of two or more incompatible drugs				x	x	x
Aseptic technique				x	x		
Other						x	x

† Refers to study codes described in table 2.1; x = data collected but reported separately from error rate; x = data collected but reported under a different error category where: x[1] = wrong preparation technique, x[2] = deteriorated drug, x[3] = wrong dose preparation, x[4] = wrong base solution, x[5] = wrong rate, x[6] = inappropriate storage, x[7] = other, (x[8]) = May be in unprescribed drug category

2.7 NPSA National Learning and Reporting System data set

A standard data set was developed by the NPSA for coding all reported patient safety incidents [NPSA, 2003b]. This enabled national sharing from consistent coding at organisational level. This common taxonomy allowed incidents to be collated and analysed centrally by the NPSA [Cousins, 2003]. The advantage of pooling information was that learning from rare serious incidents could be shared throughout the NHS, allowing preventative strategies to be implemented.

One section of the NLRS related to medicines and required data in four fields. These were:

1. Stage of the MUP where the PSI involving medication occurred.
2. Details of the medicine involved.
3. In-process description of error.
4. Important factors contributing to the incident.

The NPSA Patient Safety Observatory (PSO) collects data from a variety of sources, including the NLRS and research studies [NPSA, 2005]. To maximise patient safety learning, it would be beneficial if data from medication safety research studies were collected in the NLRS format, to allow mapping onto the NLRS dataset.

2.8 Conclusions

IV medicines preparation is a multiprofessional task; therefore it requires multiprofessional agreement on what is considered acceptable practice and when this could be considered an error. In the absence of published guidance it would be useful to develop a framework which describes this. Once developed, this could be used to compare practice against the framework. This would allow a baseline assessment of practice and development of a prioritised action plan, similar to that required for quality assurance in unlicensed aseptic dispensing within pharmacies.

There is a need for prospective research to gain a deeper understanding of the issues surrounding IV medicines preparation in clinical areas and how patient safety incidents arise. It is only through elucidation of these issues that practical solutions can be developed to improve patient safety.

2.9 Summary of Aims

1. To evaluate the nature of patient safety incidents involving medication which arise within clinical areas where nurses prepare IV medicines.

Objectives:

- To describe explicitly, the composite stages involved in IV medicines preparation in 'clinical areas'.
- To develop a practical agreed international definition of an intravenous medications preparation error in hospital clinical areas, suitable for multiprofessional use
- To identify objective descriptors of situations which are considered errors and those which are not.

2. To develop and test a data collection tool to record the number and type of IV medication assembly and preparation errors in hospital clinical settings.

Objectives:

- To establish the training required to ensure observers have the necessary skills and experience for data collection.
- To assess the feasibility of using the form in clinical areas.
- To amalgamate error categories for compatibility with the NPSA medication data set of the NLRS.
- To determine what is required to develop a training pack for use of the audit tool.

3. To explore nurses' views and opinions on the practical problems they have experienced during IV medication assembly and preparation in clinical areas, and to describe the solutions they used to resolve these issues.

Objectives:

- To describe the steps in assembling and preparing IV medicines in clinical areas.
- To establish nurses' perceptions of why these problems arise and how they are resolved.
- To establish whether there are links between intravenous training, competency and experience with regards to problem identification and resolution.
- To suggest how and where Pharmacy should prioritise its resources to improve IV medicines safety.

Chapter 3

An investigation into what constitutes an intravenous medication preparation error

3.1 Introduction

An extensive literature search and informal key informant discussion failed to either locate a clear definition of an IV medicines preparation error (IVMPE) or identify such research in progress. A concurrent search for multi-disciplinary standards for IV medicines preparation in wards or departments for use as a basis for generating a definition, also failed to locate such guidance. Opportunistic questioning of key pharmacy personnel in clinical, aseptic or manufacturing practice confirmed that no guidance or standards exist in this area.

Therefore, in the UK there were no nationally agreed guidelines on how preparation should be conducted in clinical areas, no agreed training curriculum and no minimum competency required before undertaking these tasks. Small scale UK studies had shown unacceptable error rates during IV medicine preparation in clinical areas that warranted further investigation. However, the pharmacy services provided to these areas, study methodology and error definitions used have varied or not been explicitly described. This has also hindered comparison between findings. It would be useful if clear definitions of errors and good practice criteria were agreed and data collection standardised. In order to produce a universally agreed definition that would allow future study comparison and wider generalisation, international views need to be considered. It has been suggested that to development of a consensus definition would be useful and would allow researchers to use this for subsequent work. This definition must be suitable for use with direct or disguised observation methods. Such a definition could be subdivided into a preparation stage and administration stage. This study addressed the development and agreement of an IVMPE.

3.2 Study aims

To develop a practical international definition of an intravenous medications preparation error in hospital clinical areas, suitable for multiprofessional use.

Objectives

- To describe explicitly, the composite stages involved in IV medicines preparation in the 'clinical area' where clinical areas are defined as any health-care setting where direct patient care is delivered, such as wards and departments.

- To identify objective descriptors of errors which occur in the IV medication preparation process.
- To derive a definition for an IV medication preparation error.

3.3 Study methodology

3.3.1 Research strategy

The study was descriptive, as it explored people's thoughts and opinions, necessitating a qualitative research method [Smith, 2002]. This approach was used to generate data to ensure all relevant concepts were included. Development from this stage to a definition required quantification of data. Therefore, a combined technique employing both qualitative and quantitative methods was required. This can be referred to as 'multi-strategy research' by 'facilitation':

"This approach arises when one research strategy is employed in order to aid research using the other strategy" [Bryman, 2001;p.447].

Qualitative methods generated the data for the subsequent application of quantitative methods.

There were a number of qualitative techniques which could have been used to generate discussion and elucidate the issues. These included focus groups, semi- or unstructured interviews, surveys, brainstorming or committee meetings. These could yield details of the issues discussed. However to arrive at a single definition minority views would, by necessity, be disregarded. Also, the extent to which the group agreed with the emergent definition would be unknown. However, there are research methods employing multiple stages that allow the development of these ideas. Focus groups, semi- or unstructured interviews, surveys, brainstorming or committee meetings could be used to generate suggestions for inclusion in the initial stage of a consensus method [Hasson *et al.*, 2000].

3.3.2 Consensus research methods

Consensus methods are used where there is inadequate robust data and unanimity of opinion; arising from a lack of, or contradictory, evidence [Jones & Hunter, 1995; Mead & Moseley, 2001]. These methods are designed to maximise the benefits of an informed panel exploring an issue, whilst minimising the disadvantages of collective decision-making [Jones & Hunter, 1995, 1999; Bowling, 2002].

The technique allows evaluation of two types of agreement [Jones & Hunter, 1999]:

1. The extent to which participants agree with the issue being reviewed, by self-rating on a numerical or categorical scale.
2. The extent to which participants agree with each other; described in statistical terms as an average and measure of dispersion e.g. standard deviation. Where agreement is obtained, this is the consensus view.

A consensus research method was best suited to derive the definition, as it incorporated qualitative techniques, but also quantified the extent of agreement [Pope & Mays, 1999]. There are several types of consensus methods, which can be subdivided into those requiring face-to-face participant contact, and those which do not. Face to face methods include nominal group techniques or 'expert panel' and consensus development conferences [Mead & Moseley, 2001]. These methods have several limitations which preclude their effective use in this setting. These disadvantages include a limited group size. Nominal groups are usually limited to nine to twelve participants. Such groups also require expert facilitation, organisation and have financial and geographical limitations [Mead & Moseley, 2001; Bowling, 2002]. Most importantly the dynamics of direct participant interaction can influence the data obtained [Mead & Moseley, 2001]

3.3.2.1 The Delphi technique

The Delphi technique, method or process, is the only consensus method which does not require participants to meet face-to-face. As international views were required and it was impossible for participants to meet in a single location, this method was employed. A Delphi technique would allow elucidation of each respondent's views, whilst avoiding the disadvantages of direct group interaction. Participants are consulted using a mailed self-administered questionnaire. Traditionally, this had has been a postal questionnaire although widespread uptake of electronic mail has introduced other options [Beretta, 1996; Hassom *et al.*, 2000]. The traditional Delphi technique is carried out by completing a number of stages, or 'rounds' and can be defined as

"A method for the systematic collection and aggregation of informed judgements from a group of experts on specific questions or issues." [Beech, 2001;p.39].

This process continues until agreement has been reached [Hasson *et al.*, 2000]. Commonly two or three rounds are used. The process is outlined in figure 3.1.

Components of Delphi technique (in sequence)	Round
1. Selection of panel of 'experts' (respondents).	1
2. Allocation of coding numbers to each 'expert'.	
3. Construction and distribution of first questionnaire (round 1). Experts are asked to provide suggestions for possible alternative development/outcomes in a field related to their expertise or experience. Contextual information is provided introducing the study before requesting an unlimited number of comments.	
4. Completion and return of first questionnaire.	
5. Collate, order and categorise suggestions. Use to design second questionnaire (round 2).	2
6. Distribution of second questionnaire.	
7. Completion and return of second questionnaire.	3
8. Collation of score for each suggestion. Calculation of group (median) scores for each suggestion	
9. Construction of third questionnaire (similar to second questionnaire, but also including individual and group score for each suggestion).	
10. Distribution of third questionnaire (round 3).	
11. Completion and return of third questionnaire.	*Etc...*
12. Recollation of score for each suggestion. Recalculation of group (median) scores for each suggestion.	
13. Possible further rounds of voting. May request explanation and comments of extreme scores.	
14. Achievement of group consensus. Calculation of summary statistics: minimum, maximum and range of scores for each suggestion.	
15. Distribution and use.	

Figure 3.1 Typical stages in the procedure for administering the Delphi technique [adapted from Beech, 1999; Jones & Hunter, 1999].

Advantages of the Delphi technique

The advantages of this method are summarised below:

- Participants give their real opinion without concern for public scrutiny.
- Avoids hijacking of the process by dominant parties.
- Conducive to large sample sizes (10 to over 1,000).
- No geographical limitations for sample selected.
- Relatively inexpensive, although potentially time consuming.
- Iterative process of controlled anonymous feedback sharpens respondent's awareness and provides them with an opportunity for reflection.
- Good face, concurrent and content validity.

- The participants, not the researcher, decide final criteria included.
- Allows researchers to facilitate communication between previously unknown participants [Jones & Hunter, 1995; Beretta, 1996; Beech 1999, 2001; Bowles, 1999].

Therefore Delphi technique was the only method that used open-ended questioning, controlled anonymised feedback and attitudinal measurement.

Disadvantages of the Delphi technique

Concerns have been raised regarding the rigour and validity of the Delphi technique. [Beretta, 1996]. However this may originate from poor design employed in the studies, rather than the method [Jones & Hunter, 1995]. Hasson and colleagues [2000, p.1009] state

"Appropriate use of this technique requires a high degree of methodological precision and research rigour."

It is important to address these concerns throughout the study. Those areas requiring particular attention are:

- Variable attrition rates
- Variable definition of experts.
- Sample selection and comprehensive description of the participants' characteristics.
- Poor questionnaire design.
- Inconsistent definition of consensus.
- Imprecise measures of consensus.
- The potential to modify and adapt the originally verified Delphi technique.
- Deriving consensus does not mean the 'correct' answer has been reached
- The lack of opportunity to critically question the rationale for participants with potentially valid atypical views.
- Researcher bias.
- Poor response rate [Jones & Hunter, 1995; Crisp *et al.*, 1997; Bowles, 1999; Hasson *et al.*, 2000; Beech, 2001; Mead & Moseley, 2001].

The technique has been widely used in health services research, especially where more rigorous techniques are unsuitable [Jones & Hunter, 1995]. A Delphi technique was considered the most appropriate research method for this study.

3.3.2.2 Method of distribution

Electronic communication (via email) has been employed with the Delphi technique [Jones & Hunter, 1995; Hasson *et al.*, 2000]. It was anticipated that all participants would be familiar with this technology. Electronic distribution can occur rapidly, as it does not rely on a postal delivery. A delivery receipt can be requested for each message issued which is analogous to registered mail and increases reliability. Therefore, distribution via electronic mail was selected. A computer expert was approached for advice on format. A Microsoft Word file was recommended as this would be accessible to the vast majority of computer users worldwide [Tugwell, 2002].

3.4 Delphi round one – data generation stage

3.4.1 Aim

To comprehensively identify all issues involved in the IV medicines preparation process. These would then be considered in subsequent rounds.

3.4.2 Methodology

3.4.2.1 Sample recruitment

The medicine preparation process is a highly specialised field and those involved with this process would be in the best position to achieve the study objectives. A purposive sampling strategy was selected. This 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.119].

An opportunistic sample would be unlikely to provide a wide enough range of expertise because, for example, patient safety researchers are unlikely to attend a conference on advances in sterile production. However, by selecting representation from all the different perspectives of those involved in the constituent stages in IV medications preparation the definition content should be valid. Also, by approaching a range of international experts, to incorporate their views, it is hoped findings should be suitable for extrapolation to other countries. This does introduce selection bias, where the individual expert's views differ from the wider healthcare population. This was accepted as a study limitation. The expert sample selected, information on relevant expertise or experience is detailed in appendix 1.

As there is no agreement on the minimum sample required for Delphi studies, the sample size was therefore dictated by the number of subjects with relevant experience or expertise known to the researcher and two colleagues in the research team. These were referred to as the 'expert' sample. In order to avoid introducing bias by omitting key people who could help in the development of this definition a 'snowball' sample technique was also employed. Snowball sampling is used where there is no sampling frame, or other easy method of identifying participants e.g. professional groups, society memberships. The researcher contacts a small initial group of relevant participants and uses this as the basis of recruiting others potential participants from the target population [Bowling, 2002; Bryman, 2001]. Each expert approached was asked to nominate up to five others whom they felt could contribute to the study. These nominees were contacted and, if willing to participate, similarly asked to recruit others; the process continued in this fashion. This helped to minimise selection bias, although there is a tendency that one professional group can become over-represented.

Criteria for inclusion:

A wide range of healthcare professionals were considered suitable for potential selection. These included patient safety researchers, quality control and quality assurance pharmacists, manufacturing and production personnel, clinical pharmacists, representatives from the pharmaceutical industry, microbiology, nurses, nurse trainers, physicians, infection control, IV specialists and those involved in developing pharmacy practice. These people were identified collectively by the researcher and two members of the research team from publications, textbooks, strategy documents and by personal recommendation. To be considered an expert they had to meet one of the selection criteria based on a previous study [Mead & Moseley, 2001]. These criteria were: to have published papers, conducted research or presented at a conference on medications error, or be regarded by peers as an expert in the field. Therefore, healthcare staff involved in IV medicines preparation in clinical areas would be included only if their peers regarded them as experts.

Criteria for exclusion:

Co-workers and those involved in piloting the Delphi questionnaire were excluded from entry into the study to prevent 'reactive effects' [Bowling, 2002].

3.4.2.2 Developing the data collection instrument

Preliminary work

An extensive literature search of bibliographic databases and the Internet was undertaken to identify key texts on IV medicines preparation and administration. Hand searching of textbooks on intravenous therapy and professional practice in nursing, academic pharmacy and hospital libraries were also performed. Key informants from pharmacy, nursing practice, academia and those involved in delivering IV therapy teaching were also asked to identify key texts or materials.

Design of the survey material

Four documents were prepared.

A. Template

A template that contained all the composite stages in IV medicines preparation was prepared. If this definition were used as the basis for data collection, it was important to enable the composite stages involved in preparing the IV medicine to be recorded. It was envisaged that each manipulation undertaken could be recorded by ticking the relevant box on each occasion the activity was performed. This would document all the steps used for preparing a single medicine, shown in figure 3.2.

B. Definition

A proposed definition, which included an introduction to IV medicines preparation, the proposed definition of an IVMPE and a list of descriptors considered to be an IVMPE was produced, displayed in figure 3.3. This strategy was used by Dean and colleagues [2000] to develop a prescribing error definition. The descriptors were categorised and arranged under the following headings: issues arising from the prescription, contamination, health and safety issues, dose selection and preparation. The template and descriptors were developed from previous audit, with additional scenarios derived from the literature and, where lacking, generally accepted pharmacy practice [Schulman *et al.,* 1998; Springhouse Corporation, 1998; Dougherty & Lamb, 1999; Cousins, 2000; Mallet & Dougherty, 2000; Nicol *et al.,* 2000; Barker *et al.,* 2002a; Weinstein, 2001; Nursing and Midwifery Council, 2002].

An intentionally mis-worded scenario was included as a validity check.

Figure 3.2 Template

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Template of the different stages that may be involved with intravenous dose preparation in a clinical or ward setting.

The aim of this template is to describe all stages involved in the preparation of intravenous (i.v.) dose administration with one or more of the activities in the table below. The table will then become a data collection tool where the stages in preparing an i.v. product can be documented; a tick would be placed in each box that applied, where each box could contain more than one tick. Examples are given in italics.

Method of administration	**Intravenous Bolus** (direct injection)	**Intermittent Infusion** (short infusion)	**Continuous Infusion** (long infusion)
Explanation of method of administration	Administration of a small volume of medication, usually up to 10ml, directly into a vascular access device of injection site of an administration set. Unless directed otherwise, this is administered over 3-5 minutes.	Administration of a small volume infusion, usually 25-250ml, over a period of 10 minutes to several hours. This could be a one-off dose or repeated at specific time intervals.	Administration of a medication or fluid at a constant rate over a prolonged time period (often 24 hours or more). This can involve large (250-1000ml) or small volumes.
Preparation stages			
Undiluted liquid drawn into syringe	*adenosine*	*phenytoin*	*midazolam, glyceryl trinitrate*
Undiluted liquid drawn into syringe, then further diluted	*ranitidine*	*furosemide*	*soluble insulin*
Liquid added to infusion bag, glass bottle, device or volume control chamber (i.e. burette)	Not applicable	*phytomenadione*	*amiodarone, aminophylline*
Powder reconstituted used in original container	*dantrolene*	*ceftriaxone*	
Powder reconstituted and drawn into syringe	*ampicillin*	*high dose benzylpenicillin*	*hydrocortisone (continuous infusion)*
Powder reconstituted and drawn into syringe, then further diluted	*hydralazine (bolus)*	*hydralazine (infusion)*	*hydrocortisone (continuous infusion)*
Reconstituted powder added to infusion bag, glass bottle, device or volume control chamber	Not applicable	*cefuroxime*	*vancomycin (continuous infusion), thiopentone*
Liquid added to infusion bag or bottle via transfer device	Not applicable	*Abelcet®*	
Powder added to infusion bag using reconstitution device	Not applicable	*metronidazole minibag plus, imipenem,*	*vancomycin continuous infusion*
Manufacturer or pharmacy prepared ready to administer product (no additional or minimal manipulation required).	*adrenaline minijet*	*ciprofloxacin, fluconazole, mannitol*	*dopamine, propofol total parentral nutrition supplied in 2 or 3 chambers for actitivation immediately before use*
Other, please specify.....			

Figure 3.3 IV medicines preparation error and list of descriptors

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1.0 Introduction

Intravenous medication administration can been subdivided into two stages. Preparation will cover the actions from the time it is identified that a dose of intravenous medication is due from the prescription, through to the end of dose assembly. The subsequent stage of administration to the patient is not addressed by this work.

1.1 Proposed definition

The proposed definition of an 'intravenous preparation error in the clinical or ward setting' is ***a situation or act by a healthcare professional in the preparation of an intravenous medication dose that deviates from a written, verbal or computer generated prescription for an individual patient, or contravenes hospital protocol, professional or regulatory guidance.***

The 'prescription' would be considered to contain all the information that the administrator had before them. Any clarification or annotation to the prescription would be considered an integral part of the prescription.

1.2 Situations that could be considered for inclusion as an 'intravenous preparation error in the clinical or ward setting'

The texts that have been used to gather the scenarios beneath are referenced at the end of the document.

Issues arising from the prescription

- Dose omission, not preparing a dose of intravenous (i.v.) medication that is prescribed (patient refusal and compliance with hospital protocols e.g. 'nil by mouth' would not be included as an error, not would omission pending clarification of the prescription).

- Preparing a dose of medication which the patient has a documented allergy or sensitivity (this would include preparing a dose when the allergy statement is not completed on the medication chart but patient is able to communicate or is documented elsewhere; class effects e.g. penicillin allergic prescribed any penicillin; an awareness of cross reactions e.g. if anaphylaxis with penicillin or unknown reaction and prescribed a cephalosporin/carbapenem without confirmation).

- Preparing a dose of medication for a latex allergic patient without avoiding latex exposure and not adhering to hospital guidelines, where available, on the management of latex allergic patients.

- Preparing any dose of i.v. medication that is not prescribed for an individual patient (verbal orders would not be considered an error as long as the verbal instructions and documentation comply with hospital guidelines).

- Preparing a dose of i.v. medication without complying with medical guidance, or local policies that dictate how or whether the dose is administered (e.g. instructions to omit if heart rate less than 60 beats per minute, but heart rate is not known).

Figure 3.3 IV medicines preparation error and list of descriptors *continued...*

- Wrong time medication preparation (iv dose is prepared with the intention to immediately administer the dose more than 1 hour either side of when the dose is prescribed, or 1 hour before a new continuous infusion is commenced e.g. when changing an inotrope syringe for infusion. This would also include preparing the dose without intending to administer it immediately after assembly).

- Preparing a dose of i.v. medication from an invalid prescription (e.g. does not meet legal prescription requirements, discontinued prescription, incomplete or ambiguous prescription without first seeking clarification).

- Preparing a dose of i.v. medication for the wrong patient.

Contamination, health and safety issues

- Not wearing any protective clothing, such as gloves or mask, as described in the product monographs or by hospital guidelines (e.g. no goggles, gloves and apron when preparing chemotherapy).

- Not using a 23-25 gauge needle or filter needle/straw when medication is withdrawn from a glass ampoule.

- Not filtering a product when the manufacturers monograph or hospital policy state the product must be filtered (such as epoprostenol).

- Not washing hands with bactericidal soap and water and thoroughly drying, or a bactericidal alcohol hand rub and allow this to dry before preparing an i.v. dose.

- Preparation surface not cleaned before i.v. dose preparation.

- Breach of 'no touch' technique, where the operator handles critical areas such as the syringe tip or needle hub.

- Not swabbing the septum on a vial, additive port or outside of ampoule with suitable alcohol-based antiseptic, and allowing to dry before breaching or opening.

- Open windows in the vicinity of where the i.v. dose is prepared.

- Not inserting the needle through a rubber bung, with the bevel edge of the needle upwards, at a 45-60^0 angle to minimise coring.

- Not changing the needle on a syringe after medication withdrawal, before addition to an infusion bag, bottle, device or burette.

- Re-use of an intravenous medication dose that is intended for single use on a subsequent occasion, or another patient, unless there is a written hospital policy authorising this.

Figure 3.3 IV medicines preparation error and list of descriptors *continued...*

- Not discarding glass ampoules, needles etc. into an appropriate sharps container.

- Preparing a product in an unsuitable location such as the nurses' station, ward reception or patient bedside (patient beside would be accepted for doses administered via a burette).

Dose selection and preparation

- Reconstitution errors. This would include failure to fully dissolve a powder during the reconstitution phase (includes reconstitution by transfer devices); or not complying with mixing instructions stated in the product monograph or hospital guidelines e.g. vigorously shaking teicoplanin causing foaming.

- Diluent errors: using either a diluent or diluent volume unspecified in the hospital guidelines, or product monograph (also applies to infusion bags, bottles and burettes).

- Preparing a dose of i.v. medication for another practitioner, who did not witness its preparation to administer, unless there is a local guideline in place that sanctions this.

- Drug additive label either not attached to product, or one or more of the details has been incorrectly competed. The details that must be completed will be stipulated by hospital policy (does not apply to bolus doses or where delivered labelled for an individual patient e.g. Total Parentral Nutrition [TPN]).

- Expiry date error, either failure to check the expiry date of a medication, or diluent, or using a product beyond its expiry date.

- Final volume errors, this would include failing to withdraw from an infusion bag before adding a dose when concentration was important e.g. aminophylline 1mg/ml solution.

- Wrong drug selection (the substitution of a generic for branded product would not be included as an error).

- Wrong dose form (e.g. wrong form selected depot formulation; prescription or selection of a product not labelled as suitable for i.v. administration without local guidance, pharmacist or medical annotation or confirm this).

- Exclusion of displacement values in paediatrics or neonatal i.v. dose preparation, or in other situations where the product monograph or hospital policy instruct its use.

- Wrong dose or strength (where the dose due is in discrete units any deviation would be considered an error, where doses are measured any discrepancy ±10% from the prescribed dose would be considered an error).

- No second check on a manufactured item where it is required by legislation or hospital policy e.g. controlled drugs.

Figure 3.3 IV medicines preparation error and list of descriptors *continued...*

- Preparation by a practitioner who is not authorised to do this task according to local hospital policy (e.g. student nurses, healthcare support workers).
- Pharmaceutical, formulation and packaging problems, to include not rejecting a cracked emulsion or solution with obvious particles, cloudiness, discolouration; container that is damaged cracked or leaking.
- Use of products stored inappropriately for dose preparation e.g. using items that should be refrigerated but we stored at room temperature and vice versa.
- Inappropriate addition to an infusion bag, to include not mixing with inversion after additions or adding to a rigid or flexible bag hanging on an i.v. infusion stand.
- Attempting to measure accurately a dose volume to more than 1 decimal place (i.e. not using serial dilution to ensure accurate dose).
- Using a short needle, or other than 23-25 gauge needle for adding a drug to an infusion bag or burette.
- Not preparing a suitable volume of a compatible flush solution with an i.v. product where a flush is required, as guided by the hospital policy.
- Addition of medication to a blood product.
- Preparing an infusion where there is a commercially available equivalent available and this is stocked in the hospital (e.g. potassium chloride 40mmol in 1000ml glucose 5%; if there were manufacturing problems and the pharmacy had issued guidance to instruct on this, it would not be included as an error).

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C. Covering letter

An introductory covering letter was prepared, outlining the study rationale and requesting participation [appendix 2]. Participants were asked to suggest how the template, proposed definition or descriptors could be improved; and to determine if any descriptors should be removed, or added. Guidance on good questionnaire design, and particularly the total design method (TDM) advocated by Dillman, was employed throughout the survey design [Dillman, 1978; Oppenheim, 1992; Bryman, 2001; Bowling, 2002; Smith, 2002]. Language was used which was understood in a similar manner by different professions in other cultures and countries [Litwin, 1995]. Previous work employing Email had highlighted subjects concern about how their Email addresses had been obtained, so an explanation was included [Whittlesea, 2002]. The importance of participants' views was stressed, and they were encouraged to improve the material by any means. Explicit instructions on the method of reply were incorporated.

D. Introductory email

Due to concern about the risk of falling response rates with the iterative process, the first contact with participants was to request inclusion in the study. A brief introductory email was prepared encouraging participants to open the attachments. The covering letter, template, definition and list of other experts approached were sent as Microsoft Word attachments within the email, along with a request to contact the researcher if they had any problems with the documents [appendix 3].

Strategies to maximise the response rate were adopted [Dillman, 1978; Oppenheim, 1992; Bryman, 2001; Bowling, 2002; Smith, 2002]. These included:

- A covering letter explaining the rationale for the research, its importance, how participants were selected and a guarantee of confidentiality or anonymity.
- Avoiding a lengthy introduction, the letter was on a single side of A4 without appearing squashed.
- Clear instructions.
- An attractive layout. The design, text and the sequence of sentences complied with the TDM wherever possible.
- The concept of follow up of non-responders.
- A personalised greeting.
- Using a highly motivated sample with an interest in this area.

To minimise researcher bias, the researcher avoided all unnecessary contact with the participants, including those previously known to the researcher. If contact was made, the study was not discussed [Beratta, 1996]. Further information or guidance on how to complete the study would be provided verbally or in writing, but replies were only eligible for inclusion if written.

3.4.2.3 Pilot study

The covering letter and material for review was read by a lay person, to confirm face validity, and a few typographical errors detected. The self-administered questionnaire was then piloted on an opportunistic sample of eight people (5th December 2002), composed of pharmacists, nurses and academics. These were carefully selected to include a wide range of expertise and interest in patient safety, but excluded those subjects already selected for inclusion in the expert sample. As the electronic mail technique of survey distribution was a relatively new method, pilot subjects both within and outside the Trust were selected. They were also asked to indicate the time taken to review the material. Two of these participants were questioned about their understanding of the survey material and questions to ensure they were interpreted as the researcher intended. Information from the pilot indicated this method of surveying was practical, easy to complete and well accepted.

Modification of the pilot survey

Piloting revealed a problem employing Email for distribution. The hospital logo used on the electronic mail was in a font not available on computers outside the Trust and showed as Greek characters instead. Discussions with the Information Management and Technology department generated an acceptable alternative.

The wording on the covering letter was slightly amended to include instructions about the reply format participants should use and to remove any ambiguity in the text. These amendments were incorporated in the covering letter, along with an estimate of the time required to review the material based on pilot information received [appendix 4].

Two additional scenarios were suggested for inclusion and added as examples of errors. The amended definition and list of descriptors that could be considered an error is shown in figure 3.4. The face and content validity of the survey were confirmed.

Figure 3.4 Amended IV medicines preparation error definition and descriptors

Barts and The London NHS Trust
Academic Department of Pharmacy

1.0 Introduction

Intravenous medication administration can been subdivided into two stages. Preparation will cover the actions from the time it is identified that a dose of intravenous medication is due from the prescription, through to the end of dose assembly. The subsequent stage of administration to the patient is not addressed by this work.

1.1 Proposed definition

The proposed definition of an 'intravenous preparation error in the clinical or ward setting' is ***a situation or act by a healthcare professional in the preparation of an intravenous medication dose that deviates from a written, verbal or computer generated prescription for an individual patient, or contravenes hospital protocol, professional or regulatory guidance.***

The 'prescription' would be considered to contain all the information that the administrator had before them. Any clarification or annotation to the prescription would be considered an integral part of the prescription.

1.2 Situations that could be considered for inclusion as an 'intravenous preparation error in the clinical or ward setting'

The texts that have been used to gather the scenarios beneath are referenced at the end of the document.

Issues arising from the prescription

- Dose omission, not preparing a dose of intravenous (i.v.) medication that is prescribed (patient refusal and compliance with hospital protocols e.g. 'nil by mouth' would not be included as an error, nor would omission pending clarification of the prescription).

- Preparing a dose of medication which the patient has a documented allergy or sensitivity (this would include preparing a dose when the allergy statement is not completed on the medication chart but patient is able to communicate or is documented elsewhere; class effects e.g. penicillin allergic prescribed any penicillin; an awareness of cross reactions e.g. if anaphylaxis with penicillin or unknown reaction and prescribed a cephalosporin/carbapenem without confirmation).

- Preparing a dose of medication for a latex allergic patient without avoiding latex exposure and not adhering to hospital guidelines, where available, on the management of latex allergic patients.

- Preparing any dose of i.v. medication that is not prescribed for an individual patient (verbal orders would not be considered an error as long as the verbal instructions and documentation comply with hospital guidelines).

- Preparing a dose of i.v. medication without complying with medical guidance, or local policies that dictate how or whether the dose is administered (e.g. instructions to omit if heart rate less than 60 beats per minute, but heart rate is not known).

Figure 3.4 Amended IV medicines preparation error definition and descriptors *continued...*

- Wrong time medication preparation (iv dose is prepared with the intention to immediately administer the dose more than 1 hour either side of when the dose is prescribed, or 1 hour before a new continuous infusion is commenced e.g. when changing an inotrope syringe for infusion. This would also include preparing the dose without intending to administer it immediately after assembly).

- Preparing a dose of i.v. medication for the wrong patient.

- Preparing a dose of i.v. medication from an invalid prescription (e.g. does not meet legal prescription requirements, discontinued prescription, incomplete or ambiguous prescription without first seeking clarification).

- Preparing a dose for administration intravenously when it is prescribed by another route (to include prescription where route is not stated).

Contamination, health and safety issues

- Not wearing any protective clothing, such as gloves or mask, as described in the product monographs or by hospital guidelines (e.g. no goggles, gloves and apron when preparing chemotherapy).

- Not using a 23-25 gauge needle or filter needle/straw when medication is withdrawn from a glass ampoule.

- Not filtering a product when the manufacturers monograph or hospital policy state the product must be filtered (such as epoprostenol).

- Not washing hands with bactericidal soap and water and thoroughly drying, or a bactericidal alcohol hand rub and allow this to dry before preparing an i.v. dose.

- Preparation surface not cleaned before i.v. dose preparation.

- Breach of 'no touch' technique, where the operator handles critical areas such as the syringe tip or needle hub.

- Not swabbing the septum on a vial, additive port or outside of ampoule with suitable alcohol-based antiseptic, and allowing to dry before breaching or opening.

- Open windows in the vicinity of where the i.v. dose is prepared.

- Not inserting the needle through a rubber bung, with the bevel edge of the needle upwards, at a 45-60^0 angle to minimise coring.

- Not changing the needle on a syringe after medication withdrawal, before addition to an infusion bag, bottle, device or burette.

Figure 3.4 Amended IV medicines preparation error definition and descriptors *continued...*

- Re-use of an intravenous medication dose that is intended for single use on a subsequent occasion, or another patient, unless there is a written hospital policy authorising this.
- Not discarding glass ampoules, needles etc. into an appropriate sharps container.
- Preparing a product in an unsuitable location such as the nurses' station, ward reception or patient bedside (patient bedside would be accepted for doses administered via a burette).

Dose selection and preparation

- Reconstitution errors. This would include failure to fully dissolve a powder during the reconstitution phase (includes reconstitution by transfer devices); or not complying with mixing instructions stated in the product monograph or hospital guidelines e.g. vigorously shaking teicoplanin causing foaming.
- Diluent errors: using either a diluent or diluent volume unspecified in the hospital guidelines, or product monograph (also applies to infusion bags, bottles and burettes).
- Preparing a dose of i.v. medication for another practitioner, who did not witness its preparation to administer, unless there is a local guideline in place that sanctions this.
- Drug additive label either not attached to product, or one or more of the details has been incorrectly completed. The details that must be completed will be stipulated by hospital policy (does not apply to bolus doses or where delivered labelled for an individual patient e.g. Total Parentral Nutrition [TPN]).
- Expiry date error, either failure to check the expiry date of a medication, or diluent, or using a product beyond its expiry date.
- Final volume errors, this would include failing to withdraw from an infusion bag before adding a dose when concentration was important e.g. aminophylline 1mg/ml solution.
- Wrong drug selection (the substitution of a generic for branded product would not be included as an error).
- Wrong dose form (e.g. wrong form selected depot formulation; prescription or selection of a product not labelled as suitable for i.v. administration without local guidance, pharmacist or medical annotation or confirm this).
- Exclusion of displacement values in paediatrics or neonatal i.v. dose preparation, or in other situations where the product monograph or hospital policy instruct its use.
- Wrong dose or strength (where the dose due is in discrete units any deviation would be considered an error, where doses are measured any discrepancy ±10% from the prescribed dose would be considered an error).

Figure 3.4 Amended IV medicines preparation error definition and descriptors *continued...*

- No second check on a manufactured item where it is required by legislation or hospital policy e.g. controlled drugs.
- Preparation by a practitioner who is not authorised to do this task according to local hospital policy (e.g. student nurses, healthcare support workers).
- Pharmaceutical, formulation and packaging problems, to include not rejecting a cracked emulsion or solution with obvious particles, cloudiness, discolouration; container that is damaged, cracked or leaking.
- Use of products stored inappropriately for dose preparation e.g. using items that should be refrigerated but were stored at room temperature and vice versa.
- Inappropriate addition to an infusion bag, to include not mixing with inversion after additions or adding to a rigid or flexible bag hanging on an i.v. infusion stand.
- Attempting to measure accurately a dose volume to more than 1 decimal place (i.e. not using serial dilution to ensure accurate dose).
- Using a short needle, or other than 23-25 gauge needle for adding a drug to an infusion bag or burette.
- Not preparing a suitable volume of a compatible flush solution with an i.v. product where a flush is required, as guided by the hospital policy.
- Addition of medication to a blood product.
- Preparing an infusion where there is a commercially available equivalent available and this is stocked in the hospital (e.g. potassium chloride 40mmol in 1000ml glucose 5%; if there were manufacturing problems and the pharmacy had issued guidance to instruct on this, it would not be included as an error).

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3.4.2.4 Administration of the survey

The email addresses of participants were obtained from research publications, strategy documents, personal contact or by Internet search, via ABS On-line, 'Google®' (academic or general search engine for international subjects). The workplace of any UK subjects whose email address was still outstanding was telephoned and their email address requested, together with a brief explanation of why this was required. It is impossible for questionnaires to be anonymous with email technique as respondents' details are included on all electronic mail. However, as the subject material was not contentious, or asking for personal information, this was considered unlikely to affect the response rate. Respondents might nominate subjects who have already been approached and, to prevent this, a list of those contacted, and their work establishment, was attached to the survey. Respondents were assured their replies would be treated anonymously. This has been termed 'quasi-anonymity', where the respondents are known to the researcher, even each other, but their judgements and opinions remain strictly anonymous [McKenna, 1994].

Each respondent was contacted following receipt of their reply, to thank them for participating. An individualised reply was sent to participants where relevant, for example those who had supplied a reference. Those who replied but declined to be included in the study were acknowledged and asked if they wished to be included in subsequent Delphi rounds. This strategy was adopted for all subsequent rounds.

Distribution of the survey to the 'expert' sample

After the successful pilot, survey distribution was commenced. Respondents were contacted on the 12th December and asked to reply by the 24th December. Some difficulties were experienced in sending several emails; the addresses were checked, then resent on Monday 16th December with a reply requested by 31st December. In one case it proved impossible to send the email, despite verifying the address, and so the email was sent to the subject's secretary who agreed to forward it.

Surveyors usually avoid December due to the festive season. However, time constraints meant that the survey had to be sent. In addition many of the research experts travel internationally or attend conferences during the year, but might be more easily reached at this time.

Modification of the survey from the 'expert' sample

Several participants were unable to meet the proposed deadline, but indicated they wished to respond. One respondent wanted to comment by fax. Therefore all subsequent study correspondence included a fax number. A number of respondents stated that it has taken them longer to review the material than suggested in the covering letter. This information was amended in subsequent emails. This list of participants included in the Delphi was also updated to include all those that had been approached for inclusion in the study [appendix 5a & 5b].

Follow up of the expert sample

Non-responders from the 'expert' sample were sent a follow up email on 8th January 2003, with a requested reply date of 31st January. Comments from initial replies were included into a modified covering email [appendix 6] and letter [appendix 7]. The template and definition were unchanged. The covering letter followed TDM recommendations with a more assertive style to engage participants and re-enforce why their assistance was required [Dillman, 1978]. Those who had indicated an alternative date for reply were not followed up until this date had passed, after which they were sent this material, if relevant.

Distribution of the survey to the snowball sample

The rationale for these participants' selection was amended in the covering letter [appendix 8], because many participants had been identified from the snowball sample and a suitable sample size and range of professionals were already included. These participants were asked to nominate individuals only if they felt their expertise was invaluable. These participants were mailed the survey in the first fortnight in February 2003 (3rd to 14th), and given 14-21 days to respond. The dates varied as nominations for inclusion were followed up on receipt, rather than waiting until the end of the collection period.

Subsequent follow up

Participants of both the purposive and snowball sample who had not replied were sent a final follow up letter on 7th February [appendix 9]. Those who had given a date for their comments were sent a follow up immediately after their deadline had elapsed. A follow-up email was sent before categorising participants as non-responders explaining why this was important and asked participants to reply, so the researcher was aware it had been received, as this influenced the study's validity.

3.4.2.5 Data processing

A code was generated for each participant approached, so that replies were labelled to preserve anonymity during analysis. The code incorporated the type of the healthcare professional [D=doctor, N=nurse; P=pharmacist, T=pharmacy technician], an indication of where the reply originated from [U=UK, I=International] and an identifying number.

Any replies received in writing or by fax were converted into an electronic format to facilitate analysis. Each response was coded with a reply number and stored as a separate file, in text format, for qualitative analysis.

3.4.2.6 Data analysis

Replies were analysed for content using a computer-assisted programme [QSR N6]. Each reply was imported and reviewed to identify common themes. Content analysis was undertaken following the principles described by Tesch [1990], Fink [1995a] and Bryman [2001]. Emergent themes were identified and confirmed by iterative re-evaluation of the data. Independent review of the data confirmed the emergent themes, and facilitated collapsing of sub themes to create the key emergent variables. The template and any references provided were analysed separately.

3.4.3 Results of Delphi round one – data generation stage

3.4.3.1 Response rate

A total of 102 subjects were approached for participation in the study. A schematic representation of this is displayed in figure 3.5.

3.4.3.2 Demographics

Subjects were recruited from four professional backgrounds both in the UK and internationally. Replies were received from England, Wales, Scotland, Australia, USA, France, Germany and the Netherlands. Details of the respondents' background are detailed in table 3.1. The majority of respondents (74%) were from the UK. The profession most sampled were pharmacists (81% of subjects).

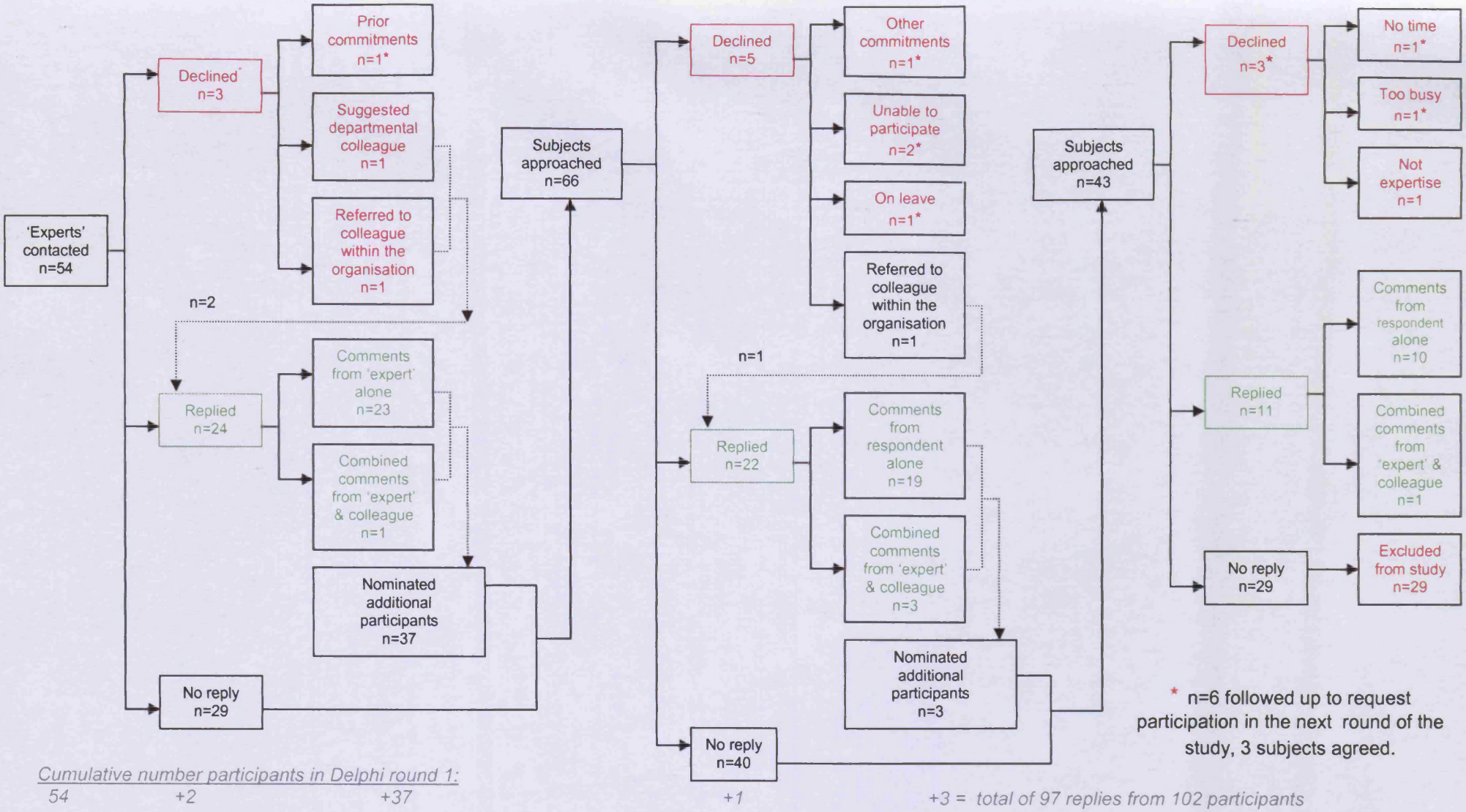

Figure 3.5 Schematic representation of sample from the Delphi round one- data generation stage (n=72 study replies, n=40 excluded from round*)

Table 3.1 Analysis of all replies received by individual respondent (n=102 subjects)

		Doctor	Pharmacist	Pharmacy technician	Nurse	**Total**
UK	Replied	2	41	1	6	50
	Referred to a colleague	1	7	0	1	9
	Declined	0	4	0	0	4
	No reply	0	19	0	2	21
International	Replied	3	8	0	1	12
	Referred to a colleague	0	0	0	0	0
	Declined	2	2	0	0	4
	No reply	1	1	0	0	2
	Total	9	82	1	10	102

Details of the replies received are described in table 3.2. Sixty-two replies (78%) were suitable for analysis. Those not analysed consisted of eight where participants declined to participate in the study and six that indicated they planned a reply but this was not received within the study deadline. A further three respondents suggested another colleague within their organisation who would be more appropriate for inclusion.

Table 3.2 Details of the study replies received (n=79 replies)

Types of reply	Doctor	Pharmacist	Pharmacy Technician	Nurse	Total	% of total replies
Suitable for analysis	5	49	1	7	62	78
Referral to a colleague	1	2	0	0	3	4
Declined	2	6	0	0	8	10
Planned to reply but not received	0	5	0	1	6	8
Total replies	8	62	1	8	79	100

The details of the respondents' professions, and whether this was an individual or joint response, are shown in table 3.3. The majority of replies were from single respondents. However four pharmacists each submitted a joint reply.

Table 3.3 Analysis of study replies suitable for analysis by authorship (n=57 replies from 62 respondents)

Author(s) profession	UK	International	Total
Doctor	2	3	5
Pharmacist	35	5	40
Pharmacy Technician	1	0	1
Nurse	6	0	6
Pharmacist & pharmacist	3	1	4
Pharmacist & nurse	0	1	1
Total	47	10	57

3.4.3.3 Validity check

Only nine of the 57 replies (16%), commented on the scenario used as a validity check. These included...

"I don't think 'nil by mouth' is a good example of a valid reason for omitting a dose of an IV." [Reply 43].

"Dose omission is not a preparation error. Why would an IV dose be withheld when a patient was "nil by mouth"?" [Reply 50].

3.4.3.4 Survey administration

The time when the survey was distributed was not ideal as 12 study replies from 54 questionnaires had been received from by the initial 24Th December deadline which was then extended until 31st December. The timing was problematic for participants employed within the NHS, shown by

"This is too short a notice to comment constructively on these papers... it may only take 20 minutes to read through but the thinking around the approach being taken here would be considerably longer and the last two weeks of December are not the quietest for the NHS." [Reply 45].

Nine of the 15 replies received came from those involved in NHS service delivery. This was resolved by lengthening the time between survey distribution and reply deadline. The response rate for round one, including both expert and snowball participants was 70.6% (n=72) from 102 participants contacted.

3.4.3.5 Content analysis – key emergent themes

Four key themes were identified from the replies. These were:

- *Perspective.* To whom the definition was directed e.g. patient, staff etc.
- *Scope.* This included comments on where IV medicines preparation fitted within the medicines use process.
- *Operationalisation.* This concerned practical aspects of how the review material would be translated into a data collection tool.
- *Classification.* This encompassed issues regarding error definitions.

3.4.3.5.1 Perspective.

Comments received suggested that the definition should be explicit with respect to the population benefiting from error prevention. Several respondents considered the definition should be restricted to a patient safety perspective only.

"I think in error work it is essential to only call a drug error an action that has the potential to harm the patient, e.g. the administration of the wrong dose or the wrong drug." [Reply 04].

This was particularly apparent from replies to the scenario within the contamination, health and safety section concerning the operator's failure to place glass ampoules in the sharps container.

"... is this a preparation error? It is certainly highly desirable, even mandatory for the safety of operators, but not doing so is unlikely to compromise the patient, so I don't see this as an error of "preparation"." [Reply 05].

Should the definition be expanded to include operator safety, then there were additional issues that needed to be incorporated into the definition. An example was:

"What about using certain closed systems to avoid staff contamination e.g. minibag plus for penicillins to protect the staff from hazardous powders. This should be a Health and safety issue for the hospital" [Reply 08].

3.4.3.5.2 Scope

Issues pertaining to the scope of the definition were raised from a number of different aspects. These were

i. The context of 'preparation' within the medicines use process. Further clarification was required on which activities constituted solely preparation, rather than prescribing or administration.
ii. Respondents questioning the inclusion of preparation activities beyond those proposed. This ranged from expanding the definition beyond the clinical setting, or inclusion of other "ready-to-administer" IV medicines.
iii. The audience to whom the definition was targeted.

The preparation stage within the medicines use process

Erroneous prescription issues

Respondents considered the definition was lacking because it failed to address issues regarding 'an inappropriate prescription'. They raised concerns regarding deviation from this 'inappropriate prescription' constituting an error, despite it being in the patient's best interest. Examples are given below:

"Some reference should be made to the quality of prescribing in your proposed definition of an error. An error occurred here after a prescription for 'IV Vancomycin 1g bolus' was written. The nurse followed the prescription and gave it over 5 mins." [Reply 01].

"The definition could be ambiguous in so much as it refers to a deviation from what is written on the prescription only, following the prescription blindly when it is wrong can also cause an error. ...this is an important point as the responsibility in law does not just lie with the prescriber, but the person who administers it." [Reply 38]

Prescription evaluation

Respondents suggested that there was an interim step in the IV MUP between prescribing and preparation, namely prescription evaluation. This consisted of those actions taken once the prescription has been interpreted by the individual who was going to prepare the IV dose, but before physically starting the preparation.

"... the definition is lacking in so much that it does not really address the interpretation and checking of the prescription." ... "It is the responsibility of the nurse who is preparing and administering an i.v. drug, to ensure that the prescription is correct and that is complies with the stated dosage, route and method of preparation in either the BNF or local formulary or an authorised trial protocol." [Reply 38].

Respondents enquired whether prescription evaluation issues formed part of the preparation process, e.g.

" ... is evaluating the prescription part of the preparation process? If so is a prescribing error, which is missed by the nurse and subsequently an incorrect dose prepared and administered included as a preparation error (i.e. a dose prepared by adhering to incorrect instructions)". [Reply 54].

"I do feel that verification of the prescription is a major part of preparation." [Reply 38].

Respondents commented that prescription evaluation was not really part of the preparation stage. They suggested this occurred prior to preparation. Also, if it were included in the definition there were other prescription aspects to be included.

"The list of situations included in section 1.2 is quite comprehensive but inconsistent. For example I would suggest that preparing a dose for a patient with an allergy to the drug as part of the prescription evaluation, yet other aspects of the prescription evaluation are not included." [Reply 54].

Other prescribing issues

One respondent interpreted both the definition and the scenario 'preparing a dose of medicine from an incomplete or ambiguous prescription' to mean that all the instructions for IV preparation should be explicit from the prescription against which a dose was prepared. They also considered this information would not routinely be available from other documentation kept in clinical areas.

"... does not recognise that very few prescriptions for IV therapy are ever complete. That is they seldom provide details of the diluent, final volume." "...a prescription for Erythromycin 1g IV qds is written this means reconstituted in 10ml Water for Injection and added to 500ml Sodium Chloride 0.9% and infused over 4 hours. These conventions are not formally recognised or written as procedures in a Trust. Your definition does not recognise this and would categorise the majority of IV dose preparations as an 'error' ..." [Reply 20].

Boundaries of the preparation stage

Some respondents considered the definition to be ambiguous with respect to where in the MUP the preparation stage started and finished.

"Where does preparation end and administration finish?" [Reply 55].

Others felt that it would be impossible to clearly delineate preparation errors from errors at other stages in the medicines use process.

"The scope of this definition EXCLUDES (or overlaps with) other points in the medication use system that can result in errors - prescribing and monitoring. I assume that since you are EXCLUDING drug administration errors, that the scope of your work is limited to the preparation and dispensing steps (or "nodes"). Given the current work in this area, explaining the scope and rational for limiting it will be important to readers. There is nothing wrong with this - it just needs to be clear." [Reply 41].

Some scenarios were thought to be broader than the preparation stage and therefore fell beyond the boundary of a preparation error. For example, this error may belong to the prescribing stage:

"... I'd prefer this scenario to be a "medication error", not a "Preparation" error. It is not an error in the preparation, but is an error in the interpretation of the prescription.

...the preparation might be perfect" [Reply 05].

Certain circumstances included in the questionnaire were considered to be part of the administration, rather than the preparation stage:

"Preparing a dose of digoxin when the patient has a low heart rate. Clinical monitoring is often undertaken prior to drug administration and so preparing the dose would not be an error, but administering the dose would." [Reply 20]

Clarification of the preparation stage

Replies indicated that more information was required to re-enforce the aim of the study focusing on the preparation stage.

"... I hope that it is clear that preparation is separate from administration." [Reply 05].

Some respondents suggested that the preparation process could be subdivided in different ways. These included:

" *... three possible stages are: prescription evaluation, assembly of ingredients, preparation of the dose."* [Reply 54]

"Administration of medication does not include preparation. This section should be reworded to make it clear that the paper refers specifically to preparation and not administration. [Reply 28].

"I accept your separation into preparation and administration stages, for ease of analysis. I would however suggest that you consider 'preparation for administration' as part of the preparation of doses." ... "I feel these 'preparation for administration' errors should be dealt with in the preparation analysis stage of your work because most of these must be sorted before preparation is started if patient care is not to be compromised later in the same process." [Reply 44].

Additional features of the preparation stage

It was suggested that some activities were required before the preparation process began. Examples included:

"Not having suitable instructions for preparation before beginning". "Not gathering all equipment required before beginning." [Reply 35].

Several respondents considered that issues related to IV administration equipment needed to be incorporated into the preparation stage.

"Are they using the right piece of electrical equipment? This refers back to the Brian Auty report on classification of infusion pumps. High risk pump for a high risk drug". [Reply 08].

A reason for this inclusion was that availability of infusion equipment might influence product preparation. This is exemplified by the following comments:

"Critical medication e.g. inotropes should be prepared so that they can be used on the most appropriate piece of IV equipment and to allow the service to be given efficiently. If a dose is prepared for use on a syringe driver it may mean the syringe has to be changed several times per day. Each time there is a change the patient receives no treatment for the period of the change. This break is unacceptable with inotropes, therefore, better to make in an infusion bag to maintain continuity of this critical treatment." [Reply 08].

Participants also questioned whether pharmaceutical issues relevant to the preparation should be included. These issues encompassed a variety of areas, described below.

"I couldn't find something that covered the situation where there should have been a filter and it was omitted." [Reply 19].

"Could drug-container and drug-giving set interactions be given here? I'm thinking of drugs such as nitrates, paclitaxel, and ergocalciferol." [Reply 25].

Other respondents advised that other equipment would be required before administration should commence. For example:

"... availability of spill kits prior to administering chemotherapy?" [Reply 29]

Examples were also supplied regarding additional error-prone tasks performed by the operator.

"If operator injures themselves (needlestick or opening vial)" [Reply 19].

" If operator creates opportunity for subsequent error (puts vial back in wrong box or in a loose ampoule bin)." [Reply 19].

It was recommended that compliance with regulations should also be included. For example

"Failure to keep required records e.g.CDs, KCl etc" [Reply 48].

Settings outside the clinical area

Respondents requested clarification of how errors in IV preparation originating in settings other than the clinical or ward area would be viewed.

This ranged from products prepared in the pharmacy department to errors outside hospital care.

"What if the product is CIVAS'd and there is an error in the pharmacy?" [Reply 19].

"Are you just covering IV medication prepared in hospital? A number of IV medications are given in the community setting and the issues related to IV medication preparation are just as relevant in that setting." [Reply 09].

Queries were also raised relating to the scope of settings. For example:

"Why not replace "IV" with "Parenteral"? that would mean that ALL parenteral drug medication preparation errors could be counted." [Reply 26].

"The proposed definition was good but does this definition cover IV medication prescribed under a PGD [patient group direction]*?"* [Reply 09].

"Emergency administration at cardiac arrest, or for anaphylaxis etc (Medicines Act permits this for saving life.)" [Reply 56].

Respondents also wanted clarification of healthcare personnel included in the definition. For example:

"The definition seems confined to healthcare professionals. Can we completely rule out any circumstances when a patient may self-administer?" [Reply 07].

"I have known patients/relatives administer." [Reply 56].

"... we are unclear whether this is aimed at pharmacy, nursing or medical staff – or all!" [Reply 12].

Issues related to the definition

Numerous comments were received about the use of reference material in addition to the prescription during medicines preparation. Participants explained that deviation from the manufacturers' instructions should be included.

"I was also wondering whether or not 'regulatory guidance' would include deviation from a package insert?" [Reply 14].

"You need to include deviation from the manufacturers' instructions for preparation as defined in the specific product characteristics (SPC)." [Reply 50].

In addition to the prescription respondents suggested referring to other documentation used at most hospitals.

"In our hospital, as in many others there is info specified in the hospital's 'Control of Medicines' policy etc. as being our standard texts that are made available by the hospital in all wards and clinical areas. I would, for example, expect anyone preparing an IV medication to consult the BNF and the manufacturers' package inserts as a matter of routine. I would further expect them to consult any other hospital-approved guidance on prep and admin of IV drugs ..." [Reply 44].

"Where do texts such as Trissel and Medicines for Children fit within this definition?" [Reply 07].

Respondents highlighted that information might vary between reference sources, and that consideration should be given to how this would be resolved. These included:

"What would happen in practice if guidance from different sources is not fully consistent, because of the long time scales required to change some documents e.g. guidance from UKCC/NMC on Administration of Medicines vs. recent guidance from DoH on intrathecal administration of vinca alkaloids, or guidance in the Duthie Report on The Safe and Secure Handling of Medicines (1988 and still not superseded) vs. NPSA guidance on concentrated potassium solutions' management." [Reply 44].

"What is the position if a situation deviates from an SPC with good reason? One example might be intravenous administration for injections to children. Many of these would deviate from regulatory guidance (at least in the form of the SPC) and yet not be covered by hospital protocols, professional or regulatory guidance." [Reply 07].

3.4.3.5.3 Operationalisation

Respondents debated how the definition would be applied in practice, and also questioned the practicality of some scenarios:

"I'm used to using definitions specifically for measuring numbers of errors, so I tend to avoid including anything you can't measure....." [Reply 14].

"...in "issues arising from the prescription": could be difficult to measure/detect all these since details may not be documented/reported.... Depends, I suppose, on how you plan to collect data." [Reply 02].

"I would not include this, since nurses may draw up a flush just by the bedside. If they do not prepare one may not mean they do not use one later on." [Reply 04].

"Preparing an IV dose not prescribed: how often is WFI/saline 'prescribed'?" [Reply 40].

It was noted by some participants that much current ward IV preparation would be considered erroneous according to the proposed definition. Therefore this should be reviewed.

"If ALL the definitions listed are accepted as criteria aginst (sic) any one of which failure would be classified as an error, I suspect that the overall error rate for a typical prescription sample could be uncomfortably close to 100%. Are you prepared for this? Would it undermine the credibility/perceived relevance of your work? Perhaps there's room to use a points or weighting system? [Reply 02].

Some respondents gave practical advice on the potential use of the definition as an audit or research tool. This included.

"As far as I am aware there is no standard validated for the safe preparation of medicines for parenteral use at ward level. There will, therefore, be much local variation. It will be impossible to achieve a wide consensus for this in the absence of such a standard." [Reply 50].

"What you have is pretty complete, but it may be either too unwieldy to use as a research tool, or need to be categorised to delineate errors from causes of errors." [Reply 41].

3.4.3.5.4 Classification of error

Several replies focused on the concept to be classified as an error. It was suggested that the incident must incorporate the potential for patient harm. Therefore, if such a stance was adopted the definition and scenarios currently addressed a broader scope than just errors. Some refinement to focus on errors was proposed.

"I think your definition is of an 'IV preparation INCIDENT' (not error)". [Reply 40].

"Ultimately in terms of patient safety the terms inappropriate medication and patient harm needs to be incorporated." [Reply 32].

Respondents proposed a number of different classification methods, some of which are described below:

"I would separate out the different issues around IV drug preparation and recommend to use the following categories:

- *Drug errors*
- *Actions that are deviations from recommended practice/guidelines or good quality practice.*
- *Deviations from recommended aseptic technique. There is hardly any evidence what constitutes safe aseptic techniques and which techniques have the potential to harm patients."* [Reply 04].

"This leads to an issue of taxonomy - are you interested in the error itself, or the root cause of the error (or, perhaps both). Some of the "errors" fall into one category (wrong dose) and some the other (attempting to measure a dose to more than one decimal place...) Perhaps the list needs to define the actual errors and another list needs to assess the root cause of the error." [Reply 41].

The respondents were most concerned about the statements in the section, contamination and health and safety. These included aseptic technique issues.

"I thought overall these were very comprehensive but under Contamination, health and safety issues, I did wonder whether the scenarios number 5, 7, 8, 9, 10, could really be considered an 'intravenous preparation error'." [Reply 09].

"You may be accused of being rather (impractically) purist in your definitions in the section, Contamination, health and safety issues. I would suggest that you stick with it, but ensure that you acknowledge this view in your discussion." [Reply 51].

3.4.3.5.5 Content analysis – other themes

Three additional supporting themes were identified. These were:

- Supportive statements regarding the utility of the study, despite its complex nature.
- Concern that the respondent possessed suitable expertise to contribute to the study.
- Comments on the comprehensiveness of the documentation.

These are illustrated by the following comments.

"I commend your choices – I think pharmacy has a key role in this area both in terms of technical advice and the ethos of error management." [Reply 26].

"It is difficult for me to really make any informed comments as these are all about giving the service without pharmacy's CIVA service." [Reply 08].

3.4.3.6 Template

The introductory paragraph to the template appeared to confuse several respondents. Some experienced difficulty understanding how the template related to the range of scenarios proposed as erroneous.

"I'm not entirely sure how you will use this, it currently does not allow you to document all the potential errors in preparation you have listed, purely the method of preparation – is that all you need to use it for?" [Reply 43].

Comments received indicated the template needed to incorporate issues relating to IV paediatric practice. Additional minor revisions to improve its clarity were proposed. For example

"I would add graphic to help people understand the process" [Reply 46].

Generally, it was well received:

"I have considered this closely, but cannot add or comment further, this seems fine to me." [Reply 05].

3.4.3.7 Reference material

Respondents supplied numerous reference sources, and references. The investigator was already familiar with some of these but others were new and included an IV guide chapter, thesis reference, draft audit guidelines and publications. In addition three respondents sent 'The Good Practice Statement for the Preparation of Injections in near-patient areas', including clinical and home environments [Clinical Resource and Audit Group, NHS Scotland, 2002].

3.4.3.8 Language issues

A number of comments were received concerning grammar, typographical errors and rephrasing statements to improve clarity.

Some replies indicated that some wording was unfamiliar to a specific professional group (e.g. vial septum), or was not internationally transferable. Clarification was required for the US medicines use process to distinguish between activities undertaken by pharmacy and those performed in clinical areas.

Nomenclatures used for the preparation process required clarification to ensure respondents were clear that the administration stage was not considered part of the preparation process.

3.4.4 Discussion

3.4.4.1 Response rate

A good response rate was obtained, 78% (n=62). Mail surveys traditionally have a lower response rate than investigator-administered techniques [Bryman, 2004]. Several respondents commented that the questions posed, and review material supplied was both complex and time-consuming. The high response rate therefore indicated the suitability of purposive sampling to target subjects particularly motivated in the study area. Attention was paid in the survey design to maximise response rate through careful construction, following the TDM method [Dillman, 1978] and this was justified by the response rate achieved. Reported response rates from similar Delphi studies were consistent with these. Dean and colleagues [2000] approached 43 potential respondents before round one to request participation in the study, and from the 34 that agreed to participate received replies from 30, equivalent to a 70% response rate.

An additional method of increasing response rate in this study would have been to contact potential participants in advance to request their participation. This is appropriate for surveys administered on a single occasion. However, one of the disadvantages of the Delphi technique is falling response rate with the iterative process. Therefore no advance warning was considered best for this study and was accepted as a study limitation.

No problems were experienced with the electronic distribution of the survey material. This also facilitated data analysis, and reduced potential researcher transcription errors. As the majority of responses were received electronically, texts could be downloaded in QSR N6 without the need for transcription. This confirmed the electronic method of administration as a convenient and suitable method for use throughout this study.

The study recruited a predominantly UK based sample, with a majority of pharmacists. Pharmacists were intentionally over-sampled because of their experience in quality control and aseptic production. This bias was increased during snowball sampling as UK pharmacists were most likely to nominate other UK pharmacists. However, the range and scope of comments received suggested than this was not a problem. Replies were varied and many contained new material. Some of the pharmacists had niche expertise. The international sample was not fully representative; instead it contained comments from those countries where authors publish on patient safety. Representation from Europe,

Australia and USA were included to ensure the study produced an internationally transferable definition.

3.4.4.2 Study limitations

No expert medical microbiologist or infection control nurse was identified. It was hoped these might be generated through nominations, but this did not occur. To ensure adequate representation from the pharmaceutical industry, Baxter and Macopharma could have been invited to participate. However, no industrial representatives were nominated. This would suggest that their contribution to IV medicines preparation safety in the clinical environment would be small. It was anticipated that other professionals with a deep tacit understanding of IV preparation in clinical practice would be identified by the snowballing technique e.g. theatres staff, midwives, practice development and nurse trainers. Initially selected 'experts' were asked to nominate individuals whom they felt could contribute to the definition. It is surprising that few nurses were nominated. As the initial expert sample did not include many nurses all opinions may not have been included. There is a lack of comments from nurses actively engaged in clinical practice. This was a limitation of the research methodology used and suggests the 'expert' sample inclusion criteria would benefit from refinement.

The timing of survey distribution could have been improved to avoid Christmas. As the survey was complex respondents also appeared to need at least four weeks to reply and by incorporating this time-scale respondent fatigue was minimised.

In some cases an administrative assistant had sent the response on respondent's behalf. This was not a limitation in this initial round. However, it could be problematical in subsequent rounds as it would be uncertain who had completed the survey.

3.4.4.3 Validity check

The scenario mis-worded to suggest that 'nil by mouth' was an acceptable reason for omitting an IV dose, was overlooked by most of the respondents. Those who did comment on this appeared to have constructed their replies in systematic format, several of whom commented on every scenario. With hindsight, this was probably a poor choice of validity scenario. Some respondents may have skimmed over the scenario as they thought it was a prescribing rather than preparation issue. A few respondents appeared to think that it was

an error, or unintentional slip. However as the work required by respondents to comment on the definition was complex, it cannot be assumed that this validity check was not noted. Participants may have decided not to specifically comment on this issue.

3.4.4.4 General summary

The material generated for review was valuable. Many respondents had taken considerable time and effort in constructing their replies. However some participants may have been deterred by some of the subjects and therefore did not respond. The majority considered that this area of inquiry was incredibly complex and hampered by the lack of agreed standards. Although the researcher was aware of many of these issues, additional insight was gained.

Replies indicated that the area was broader and more contentious than originally foreseen. Therefore this needed to be addressed in the next Delphi round, to ensure the topics selected were tightly focused, and to minimise the time required for completing the questionnaire. Some scenarios drew long and detailed answers from some respondents, whilst others accepted the same scenarios without comment. Therefore, the majority of decisions reached from interpreting the results were included in the second study round [Delphi-stage two], to ensure that group consensus was achieved, rather than the opinion of vocal subgroup.

3.4.4.5 Perspective

During the next stage it was important to explain to respondents which group of people would benefit from the study undertaken. The main focus was to improve patient safety, by minimising the likelihood or consequence of an error. Therefore, adopting a patient safety focused stance would be useful. This would allow refinement of the scope of the project, as all scenarios designed to protect solely the operator were removed from subsequent rounds. Agreement was sought from the respondents in round two about restricting the focus to solely patient safety. Those scenarios which addressed both patient and operator safety issues were not be excluded from the study until this agreement had been evaluated.

3.4.4.6 Scope

Clarification of the preparation stage

Respondents held different views on the boundaries of the preparation stage within the medicines use process. Some acknowledged that there would be overlap between these constituent parts, whilst other felt it could be clearly delineated. Most respondents thought that the issues arising from the prescription section contained predominantly prescribing issues, which if erroneous should be classified as prescribing errors. Those issues which were clearly prescribing errors were excluded from the item pool generated from this analysis. In addition, respondents' agreement that these should be classified as prescribing errors was sought.

Respondents considered the definition failed to address preparation from an erroneous prescription. Therefore for the purposes of further Delphi rounds, it was assumed that the prescription was both valid and appropriate. A definition was added into the opening statement. This compares with other work where the appropriateness of the prescription was not assessed [Taxis & Barber, 2003a].

Comments explaining that hand-written prescriptions rarely contain all the instructions for preparation were addressed by altering the opening statement. Participants were informed that information available when preparing injections includes the prescription, and those texts recommended by the hospital (e.g. an IV guide and British National Formulary).

Many respondents appeared to have conflicting opinions about where the preparation stage finished and administration began. This was exemplified by some suggesting scenarios be excluded as they were administration errors, whilst other proposed the inclusion of administration issues such as the availability of extravasation kits. The main areas requiring clarification were: whether the addition of a giving set or extension set, and the use of an infusion device fell into preparation or administration. This was highlighted by two different definitions identified by respondents.

Gandy and colleagues [2002] proposed that preparation was,

> *"Preparation follows assembly. It is the procedure of using all of the assembled items in drawing up, mixing, combining or reconstituting the pharmaceutical agents, diluents and/or infusion fluids into the right form, combination and strength according to the patient's prescription sheet, and via the correct delivery vehicle/administration device. Preparation includes following clinical guidelines for the correct use of equipment"* [p.244].

This contrasted with the alternative definition:

"The manipulation of ingredients and components to make the final product" [Clinical Resource and Audit Group/NHS Scotland, 2002;p.6].

The first definition incorporated the giving set within the preparation stage whereas the second did not.

Respondents highlighted that preparation is in fact a two or three component process. These were defined as prescription evaluation, assembly and preparation. Prescription evaluation was aligned with prescribing errors and therefore was not considered in this study. The subcomponent stages of assembly and preparation were adopted for this study. Respondents were asked for their views on published definitions for these terms in round two. Rephrasing the review material would also improve clarity as 'administration' could be removed from the definition.

Settings outside the clinical area

Several respondents commented on IV preparation issues that fell beyond the study area e.g. pharmacy dispensing and central intravenous additive service (CIVAS) errors. Studies had been undertaken in these areas; therefore no amendments were made to the study remit. Preparation in community hospitals would be included, but all areas outside the hospital clinical environment such as preparation in patients' homes were beyond the scope of this study.

There was no reason to exclude patient group directions from the definition, as they are actioned following explicit hospital approved and documented guidelines. Although these are commonly used in the UK their incorporation for international use would need agreement in round two.

Literature review had revealed different preparation recommendations for different types of parenteral injections (e.g. intrathecal, intramuscular injection) and showed the risk was greater with the IV compared to the intramuscular route. Therefore, it was decided to restrict the study to the IV route. All comments received outside the IV scope were disregarded. The intention was to focus on products that required manipulation in the clinical setting so fluid replacement without any ward based additions would also be excluded.

One interesting point raised in the Delphi was whether the definition should include preparation of medicines in an emergency setting, as this is often done by verbal order and documented retrospectively. The 1968 Medicines Act does make provision for administration without prescription in such settings. Therefore, respondents were asked for their views in round two.

Target groups for definition

The definition was intended to apply to healthcare professionals who prepared IV medicines. Several respondents indicated that on occasions, patients or relatives would administer IV medicines. If patients prepared and administered their own IV medicines at home and continued to do so in hospital it was considered they should be included. Therefore the definition would include any one who assembled and/or prepared IV medicines in the clinical setting.

3.4.4.7 Operationalisation

Some suggestions were made to ensure the emergent definition would be useful in the practical setting. Therefore, it was advised that issues which could not be measured should be excluded from the definition. It was anticipated that the definition needed to be suitable for observational research methods. This issue was clarified in round two.

There were concerns that the definition would be unwieldy for practice use or that the majority of preparation would be considered erroneous if the definition was applied. Therefore in round two respondents were explicitly informed about the scope of the definition.

3.4.4.8 Classification of error

Some respondents considered that potential for patient harm was a prerequisite for defining an incident as an error. This would be concordant with the emerging patient safety stance and would narrow the definition. Therefore, the respondents' views were sought on this in round two. This mirrored other researchers stance where errors were required to have the potential to adversely affect the patient [Taxis & Barber, 2003a] or increase the risk of harm [Dean *et al.*, 2000].

Respondents raised most concern over the inclusion of aseptic techniques derived from standard nursing texts. These were often viewed as deviations from standard practice or poor quality practice and not errors. Respondents' views on this were explored further in round two.

Certain respondents cited error classification from other research publications or local policies [van den Bemt *et al.*, 2002]. None of these were suitable for adoption verbatim as they were intended for general medicines error research, or failed to address specific preparation issues.

3.4.4.9 Template

It was apparent that, despite piloting, the introductory statement caused confusion and required clarification. The main issue was that respondents did not appear to understand the link between the template, error definition and scenarios. Many respondents realised that the template described the component stages of preparation and suggestions highlighted the wide variation in practice. The main omission identified by respondents was the lack of paediatric practice issues, where the delivery of medicines may differ substantially from adults. The comments received suggested actions to rectify this point. Following minor modifications to improve clarity, the template was redrafted for use in a clinical setting.

3.4.4.10 Reference material

'The Good Practice Statement for the Preparation of Injections in Near-patient areas, including Clinical and Home Environments' [Clinical Resource and Audit Group, NHS Scotland, 2002], was published during this study and added to this research. However these guidelines do not contain explicit guidance on preparation, but instead promote a philosophy of risk assessment and the production of local standard operating procedures. The document made some definite recommendations, including that parenteral nutrition and cytotoxics should only be issued from a pharmacy in a patient ready-to-administer form [Clinical Resource and Audit Group, NHS Scotland, 2002]. Therefore in round two respondents were asked whether this was routine practice in their clinical setting, to allow generation of a precise definition.

It appeared that terminology was understood in different ways by respondents. This problem had already been highlighted by other researchers who studied aseptic nomenclature issues with a multiprofessional group [Gandy *et al.*, 2002]. Wherever possible, the current research employed the terminology proposed by Gandy and colleagues, and the glossary of terms from the 'Good practice statement on injection preparation' [Clinical Resource and Audit Group, NHS Scotland, 2002; Gandy *et al.*, 2002]. However there was still discrepancy between these recent publications on the definition of 'preparation'. The disparity arose over the transition from preparation to the administration stage. The Gandy and co-worker [2002] definition included the use of the correct administration device, whereas that produced by the Clinical Resource and Audit Group and NHS Scotland [2002] indicated that preparation finished before connection to a needle or giving set. Therefore further work aimed to reach an agreement on this issue.

3.4.4.11 Language and study design

The comments about grammar and typographical errors were noted. Suggestions for rephrasing were adopted where the scenarios was transferred into the second round. In other cases these were incorporated, where feasible into reworded scenarios transferred into the second round. Comments where a potential for misunderstanding exists were also addressed.

The main area of concern was confusion about what UK professionals' term 'preparation' and USA participants term 'dispensing'. This may have occurred because virtually all IV doses in the USA are supplied to the ward in patient ready form from the central or satellite pharmacy [Cousins 2005b; Schneider, 2002a]. Although not commented on by all the USA respondents, it was addressed in round two by incorporating clear explanation of the study's scope.

3.4.5 Conclusions

A high response rate (78%) from the motivated UK and international multiprofessional sample yielded valuable comments and debate about the proposed definition.

The key issues identified following analysis of the round one-data generation stage were:

1. The need for a precisely defined scope for the study. It was suggested that it should focus solely on the assembly and preparation of IV medicines requiring manipulation in clinical areas. Greater attention to terminology and restriction of

this research to this area should minimise respondents commenting outside the study setting.

2. An explicit statement of to whom the definition was directed was required. It was proposed the focus would be patient safety. Any individual involved in the preparation of an injection was included.
3. The respondents advised that for practical application the definition should only include issues readily measured during preparation.
4. Error classification; some respondents suggested the work was broader than errors and addressed IV incidents. They suggested restricting errors to preventable actions with the potential for patient harm, enabling other deviations to be classed poor practice.

Application of these recommendations generated an item pool of statements for potential inclusion in round two. Allowing the respondents to be asked to agree and clarify the definition and its operationalisation.

3.5 Delphi round two – working towards a consensus

3.5.1 Aim

To seek quantification and agreement of the definition of an IV medication preparation error in clinical areas.

3.5.2 Methodology

3.5.2.1 Survey distribution

Survey distribution was performed in an identical manner to round one [see section 3.4.2.4].

3.5.2.2 Sample recruitment

All respondents from the first round sample who had submitted a study reply (n=62), as well as those who had not participated in round one but had agreed to participate in subsequent study rounds (n=3). The five respondents who had expressed an interest in the study, but did not submit a valid reply in round one were approached to participate in this round. Four agreed to take part. Therefore, the sample contained 69 participants.

3.5.2.3 Data collection instrument

Analysis of round one replies had generated an item pool of statements for potential inclusion in round two. These were incorporated into an electronic self-administered survey. The survey was constructed following guidance on appropriate question construction [Oppenheim, 1992; Fink 1995b] and the TDM format for design [Dillman, 1978]. Specialist electronic design input was provided [Tugwell, 2003]. A draft survey was prepared consisting of predominantly closed questions, employing a rank scale or categorical answers. Additional space, in the form of a free text box, was provided alongside each question to allow respondent to add comments as this had been cited as a limitation of the Delphi method [Murphy *et al.*, 1998].

Not all the scenarios generated were included, because of the amount of respondents' time required for completion might result in a low response rate. Therefore, a draft of statements for inclusion was circulated to two other researchers and agreed. This was important as it has been suggested that judgements made on scenarios which rarely occur in practice may be less reliable [Murphy *et al.*, 1998]. The format for similar question types was amended to shorten the length of the questionnaire. Questions related to specialist issues were removed to avoid respondent fatigue. The covering letter included the key findings from the first stage of the study, and provided a clear focus for the definition.

Attitudinal measurement

Use of a categorical scale would have made it impossible to quantify the degree of consensus because without an underlying scale replies cannot be ranked [Oppenheim, 1992]. Therefore, to facilitate statistical analysis, a numerical scale was used. As the variables studied required attitudinal measurement, Likert scales were used to rate agreement [Oppenheim, 1992]. Use of Likert scales is established in survey research as they provide good reliability, and robustness [Oppenheim, 1992]. The choice of Likert scale mirrors that selected by Dean and colleagues [2000] for the consensus study of a prescribing error. However, Dean and colleagues used the RAND nine point Likert scale. This was not used in this study as it can be confusing and complex and therefore lead to item redundancy [Oppenheim, 1992].

The Likert scale required all the respondents to rank how much they agreed with a proposed statement on a five-point scale: strongly agree, agree, uncertain, disagree,

strongly disagree. For questions where respondents were asked to rate potential errors, a simple three-point scale was selected.

Defining consensus

For each statement included in Delphi round two, all respondents' attitudinal scores required evaluation to ascertain whether consensus has been gained for the each statement.

"'There seems to be no firm rules for establishing when consensus is reached ..." [Powell, 2003 p.379]. There is no unity on how agreement is defined when consensus is reached for Delphi studies in general [Murphy *et al.*, 1998]. Agreement can be demonstrated in two different ways [Jones & Hunter, 2000]:

1. An individual participants agreement with a statement, usually described by the median of all replies.
2. Agreement consistent with the other study participants i.e. consensus, usually described by the interquartile range.

Powell [2003] cited failure to provide a suitable description of consensus as a common failing of Delphi studies. In her commentary, she found that the percentage of participants agreeing with a statement was a common choice for group consensus but the rigour with which it was applied varied considerably, from 55-100%.

Therefore, prior to data analysis, consensus was defined by the researcher and three research experts following review of the RAND nine-point scale developed for nominal groups [Jones & Hunter, 2000]. Figure 3.6 describes the definitions employed.

Category	Definition†
Consensus	Widespread agreement, where 90% or more of the group's replies fell within two adjacent attitudinal categories on the five-point scale, or one category on the three-point scale.
Equivocal	Uncertain agreement, where between 80-89% of the group's replies fell within two adjacent attitudinal categories on the five-point scale, or one category on the three-point scale.
No consensus	Widespread or polarised views, less than 80% of the group's replies fell within two adjacent attitudinal categories on the five-point scale, or one category on the three-point scale.

† all values were rounded to the nearest whole number

Figure 3.6 Consensus categories employed

If the data were distributed such that the group's replies fell equally into two or more non adjacent attitudinal categories and this prevented clear assignment to one of the above

consensus categories, then results were graded to the nearest agreement consensus category.

3.5.2.4 Study administration

An explanation was included in the covering letter about how to rate each variable on the Likert scales. The scale was added to the text, with an adjacent box for comments. Word descriptors were used, rather than a numerical scale because a common error occurs when a respondent is confused over which end of the scale is agreement and which is disagreement [DeVellis, 2003]. Respondents were requested to select the response which most reflected their opinion. It was stressed that the respondents needed to complete this stage individually rather than through discussion or formulation of a group response.

Pilot of survey

On the 28th May 2003 the covering letter [appendix 10] and electronic survey [appendix 11] were piloted on an opportunistic sample of five people (pharmacists, nurses and a member of the public) with clear instructions given [appendix 12].

Modification of the pilot survey

Several minor problems required clarification were identified during piloting. The wording of questions 5, 8d and 22 were ambiguous and were rephrased through discussion with the respondents who had identified these issues. All negatively worded statements were revised to positive statements e.g. the double negative in question 19. Although the questioning style intentionally used aimed to avoid 'yes' bias in completing the questionnaire, piloting had revealed confusion. The 'yes' bias was therefore accepted as a study limitation.

After the modifications described to the survey, two lay persons reviewed the electronic survey to ensure face validity [appendix 13]. With the above revisions incorporated, it was deemed that face and content validity had been confirmed. Details of the questions posed are shown in table 3.4.

Table 3.4 Questions in the self-completion questionnaire to develop a practical definition of an intravenous medication preparation error in the clinical setting

No.	Question posed	Reply type	Likert scale length
1a.	Medication assembly is the 'gathering together on a cleaned tray, trolley or appropriate work surface, all the items of equipment and pharmaceutical agents required for the aseptic preparation and administration of a medicine to a patient, whatever the form, route and method/technique of administration' [Br J Clin Govern 2002;7: 244].	agree, or disagree	5
1b.	Medication preparation 'is the procedure of using all the assembled items in drawing up, mixing, combining or reconstituting the pharmaceutical agents, diluents and/or infusion fluids into the right form, combination and strength according to the patient's prescription sheet, and via the correct delivery vehicle/administration device. Preparation includes following clinical guidelines for the correct use of equipment'. [Br J Clin Govern 2002; 7: 244].	agree, or disagree	5
2a.	An iv medication preparation error in the clinical setting is defined as: 'The preparation of iv medication that deviates from either: a written/computer generated prescription, or instructions for its preparation'.	agree, or disagree	5
2b	'Instructions' for preparation include those provided by: 1. The manufacturer 2. A written/electronic policy, protocol, procedure, or guideline approved by the hospital 3. A hospital adopted reference source (e.g. Medicines for Children reference book) 4. Specific documented professional advice (e.g. pharmacist annotation of suggested preparation for an unlicensed route, or fluid restricted patient)	rank in order of import-ance.	4
3.	Events without the potential to cause patient harm should NOT be classed as errors.	agree, or disagree	5
4.	For practical purposes, the error definition should exclude any actions that cannot be directly measured (e.g. verbal orders, preparation at emergencies like an arrest).	agree, or disagree	5
5.	IV medication prepared from a hospital approved patient group directive should be included in an error definition (patient group directives provide explicit guidance for the administration and documentation of approved medication by staff, in the absence of a doctor).	agree, or disagree	5
6.	Deviations from recommended practice should not be classified as errors (e.g. not obtaining a second check where required, failure to attach a medicines additive label).	agree, or disagree	5
7a	Parenteral nutrition should never be prepared in the clinical setting	agree, or disagree	3
7b	Chemotherapy preparation must never occur in general clinical areas, without additional specialist facilities (e.g. isolator)	agree, or disagree	3
7c	The preparation of medication into rate controlled delivery devices does not occur in clinical areas (e.g. implantable infusions, intimate devices)	agree, or disagree	3
7d	Errors should exclude measures to protect the operator from the product (e.g. health and safety issues)	agree, or disagree	3
8a	Preparing for an individual patient, an iv medication that is not prescribed (excludes flushes)	Is this an error?	3
8b	Preparing a medication dose for administration intravenously when it is prescribed by another route (i.e. wrong route)	Is this an error?	3
8c	Deviation from the hospital or manufacturer's instructions on either the selection, or volume used, of a diluent/solvent (applies to both initial reconstitution and/or dilution)	Is this an error?	3
8d	The selection of the wrong medication. (The substitution of a generic for a branded product where the manufacturers instructions for preparation and administration are the same is acceptable)	agree, or disagree	3
8e	Where a recommended clinical environment is available, preparing a product in any other location (Preparation at the patient bedside would be accepted for doses administered via a burette)	agree, or disagree	3

Table 3.4 Questions in the self-completion questionnaire to develop a practical definition of an intravenous medication preparation error in the clinical setting *continued*...

No.	Question posed	Reply type	Likert scale length
9	Incorrectly labelling a product. (Labels are required for all infusions. Labels for bolus doses are needed when more than one dose is prepared, or the prepared dose is stored for more than 10 minutes, put down or passed to another practitioner).	agree, or disagree	3
10	Preparing an iv dose using the incorrect medicine formulation. (e.g. selecting a depot formulation, or using a product that does not state it is suitable for iv use without instruction to confirm appropriateness, e.g. where the product is not licensed for iv administration but is routinely given iv).	agree, or disagree	3
11	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).	Is this an error?	3
12	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 minibag plus infusion device that has a vial of powder attached, or vigorously shaking a medication that foams e.g. teicoplanin).	Is this an error?	3
13	If a product is appropriately labelled, it is acceptable to prepare it in advance of its intended use, as long it is used before the instructed expiry? a. In any clinical setting?	agree, or disagree	3
	b. Where any interruption in medication delivery could affect patient care (e.g. inotrope infusion)?	agree, or disagree	3
	c. What time frame, if any, would be acceptable?	free text	n/a
14a	Adding a medicine to a syringe/infusion already containing a drug with which the medicine is incompatible, or there is unknown compatibility	Is this an error?	3
14b	Adding a medicine to a syringe/infusion already containing a medicine with which there is unknown compatibility	Is this an error?	3
14c	Adding medication to a blood product or compounded (ready to administer) parenteral nutrition without first contacting pharmacy	Is this an error?	3
14d	d. Preparing a medication, in an incompatible container (e.g. insulin, glyceryl trinitrate)	Is this an error?	3
14e	Preparing multiple doses of an iv medication for more than one patient on the same medication (e.g. bulk preparation)	Is this an error?	3
14f	Preparing more than one dose of an iv medication for more than one patient at the same time	Is this an error?	3
14g	Not filtering a product when the manufacturer's instructions or hospital policy state the product must be filtered (e.g. epoprostenol)	Is this an error?	3
14h	Withdrawing medication into a syringe through a filter needle, and not changing the needle before the medication is added to a syringe or infusion	Is this an error?	3
14i	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)	Is this an error?	3
14j	Any calculation mistake that produces a preparation (± 10% dose instructed) is an error	Is this an error?	3
15a	Preparing a medication using an expired ingredient	Is this an error?	3
15b	Using a previously opened multidose container, where the date of first use is not indicated	Is this an error?	3
15c	Preparing a medication using degraded or unsuitable ingredient (includes cracked emulsions; solutions with unintended particles or discolouration; damaged containers)	Is this an error?	3
15d	Using an ingredient that has not been stored according to instructions, unless a risk assessment has been made to verify its suitability prior to preparation (e.g. using a product that should be refrigerated and was stored at room temperature)	Is this an error?	3

Table 3.4 Questions in the self-completion questionnaire to develop a practical definition of an intravenous medication preparation error in the clinical setting *continued...*

No.	Question posed	Reply type	Likert scale length
15e	Using a single use ingredient whose tamper evident seal has been broken (e.g. use of an iv infusion previously removed from the outer wrapper)	Is this an error?	3
15f	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	Is this an error?	3
16	Deviation from appropriate aseptic technique is an error.	agree, or disagree	5
17	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).	agree, or disagree	5
18a	Not washing hands with a bactericidal soap and water and then thoroughly drying before an iv dose preparation session is an error.	agree, or disagree	5
18b	Not using a bactericidal alcohol hand rub and allowing this to dry before an iv dose preparation session is an error.	agree, or disagree	5
19	Failing to wear gloves during preparation to prevent contamination of the medication is NOT an error.	agree, or disagree	5
20a	Failing to swab the septum (rubber top) on a vial, additive port or outside of an ampoule with a suitable alcohol-based antiseptic before breaching or opening is an error.	agree, or disagree	5
20b	Failing to swab the septum (rubber top) on a vial, additive port or outside of an ampoule with a suitable alcohol-based antiseptic and not allowing it to dry before breaching or opening is an error.	agree, or disagree	5
21	Breach of 'no touch' technique, where the operator handles areas such as the syringe tip or needle hub, is NOT an error.	agree, or disagree	5
22	If the product or operator leaves the clean field they are working in this is an error.	agree, or disagree	5
23	Pouring the medication into unsterile cup to aid drawing up is NOT an error.	agree, or disagree	5
24	Failing to use a 23-25 gauge needle, or a filter needle/straw, when withdrawing medication from a glass ampoule to remove glass shards is an error.	agree, or disagree	5
25	Failing to take appropriate infection control precautions after an injury during preparation is NOT an error (e.g. continuing preparation without changing the needle after a needle-stick injury).	agree, or disagree	5

Abbreviation: n/a=not applicable, No.=number

Distribution of the survey

Data collection was commenced, using a revised opening greeting [appendix 14], in an identical manner to round one. Surveys were issued on 7 and 8th July 2003, and requested date of the 18th August 2003. Non-responders were followed up on the 19 and 20th August 2003 with another copy of the questionnaire and requested to reply by the 8th September 2003. A second follow up of non-responders was issued 10th September 2003 requesting replies by 22nd September 2003. It was apparent from comments received to the follow up email that some respondents had not registered the requested reply date contained in the covering letter. Therefore, this was added to the email introductory statement.

3.5.2.5 Data processing

Survey replies received electronically were downloaded and printed as a hard copy. These and the written replies were coded, as described in round one, to disguise the respondent's identity and stored in a secure filing cabinet pending analysis.

3.5.2.6 Data analysis

The results were entered onto SPSS version 11.5, a statistical database for analysis. A coding frame was used where: strongly agree=4, agree=3, undecided=2, disagree=1, strongly disagree=0, error=5, not an error=6, manufacturer's information=80, hospital policy=81, hospital adopted reference=82 and professional advice=83. Missing data was assigned to '99' and duplicate entries to '98'. After data entry the accuracy of data transcription was checked manually as a quality control exercise.

The data were both categorical and ranked ordinal and, for a small sample, non-parametric statistics were most appropriate [Puri, 2002]. These were analysed quantitatively for a measure of central tendency and measures of dispersion. For each descriptor, the median, range, minimum value, maximum value, interquartile range and frequency distribution were calculated. The chi-squared test (χ^2) was used to determine independence between the responses and respondents. Where there were missing data points, analysis was based on valid replies alone. Comments received in the free text boxes were analysed qualitatively for common and recurrent themes.

3.5.3 Results

3.5.3.1 Response rate

A total of 69 subjects were approached for participation in this second round of the study. One subject became a project advisor, thereby removing their eligibility for study inclusion. Therefore, all analysis was based a total of 68 subjects entering round two of the study. A schematic representation of this is displayed in figure 3.7.

3.5.3.2 Demographics

Details of the respondents' background are detailed in table 3.5. The majority of respondents (78%, n=48) were from the UK. The profession most sampled were pharmacists, with 78% (n=48) of subjects.

Table 3.5 Analysis of all replies received by individual respondent (n=68 subjects)

		Doctor	Pharmacist	Pharmacy technician	Nurse	**Total**
UK	Replied	1	38	1	6	46
	Declined	0	1	0	0	1
	Retired	0	1	0	0	1
	No reply	1	4	0	1	6
International	Replied	2	8	0	1	11
	Declined	0	0	0	0	0
	Retired	0	0	0	0	0
	No reply	2	1	0	0	3
	Total	6	53	1	8	68

Not all questionnaires were eligible for analysis; this is described in table 3.6.

Table 3.6 Details of the study replies received (n=59 replies)

Types of reply	Doctor	Pharmacist	Pharmacy Technician	Nurse	Total	% of total replies
Suitable for analysis	3	42	1	7	53	90
Promised but not received	0	4	0	0	4	7*
Declined	0	1	0	0	1	2*
Retired	0	1	0	0	1	2*
Total replies	3	48	1	7	59	100*

(* may be more than 100% due to rounding)

3.5.3.3 Validity check

Question 8d was included as a validity check, within a table where, based on comments from round one, it was anticipated most of the replies would be error. However, the question was unreliable as a validity check because some respondents were confused over the wording, for example:

"I don't quite understand Q8-d: does this apply to wrong drug or just to selecting the same generic form" [IP34].

Clarification of this statement is discussed in section 3.5.3.5.

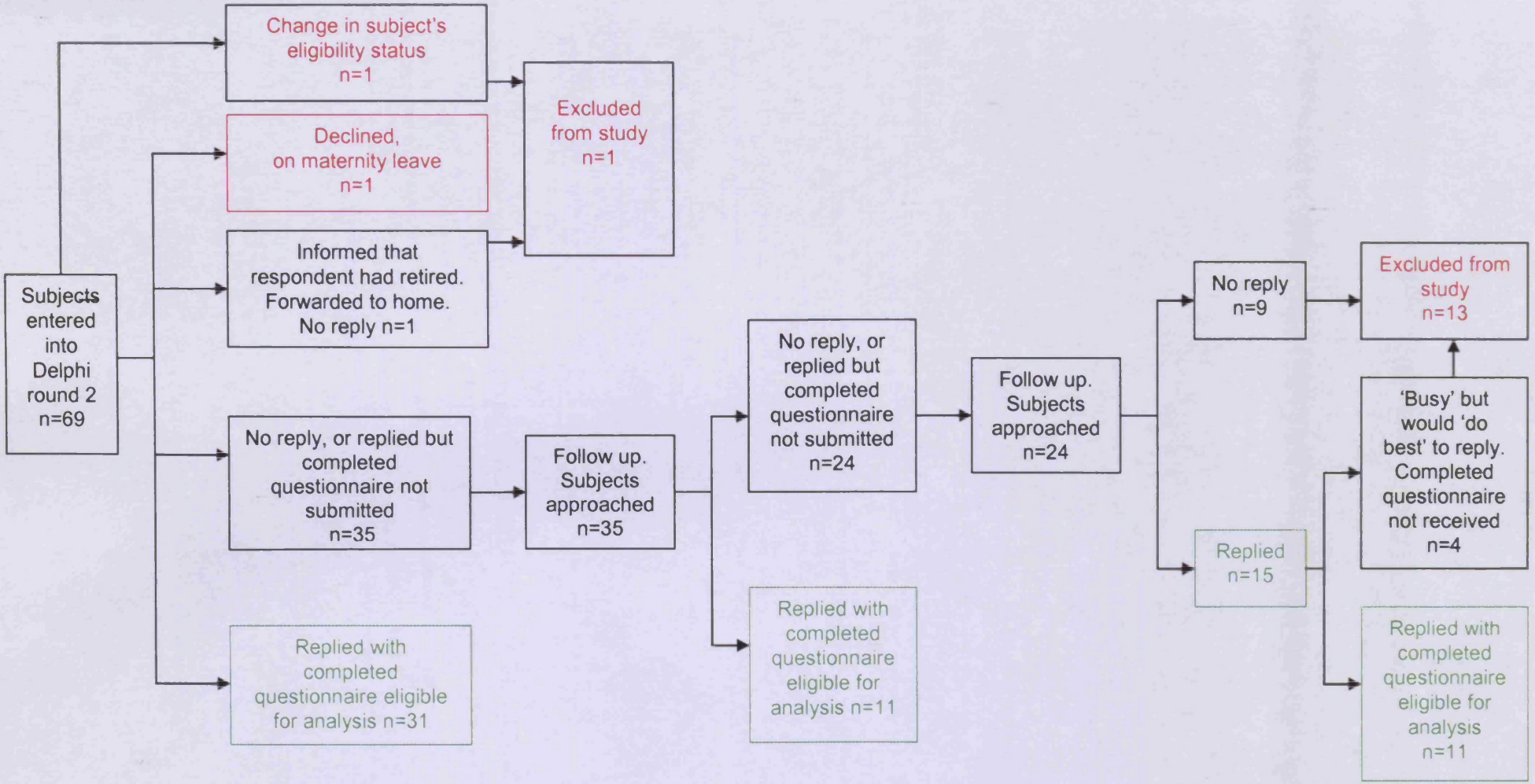

Figure 3.7 Schematic representation of sample from the Delphi round two – establishing agreement and consensus (n=53 study replies and n=16 exclusions)

3.5.3.4 Quantitative results from questions posed

A total of 48 questions were included, three of which contained subsections on a similar theme (questions 13, 18 and 20). Results were reported based on these 48 subject areas. Consensus was reached in 18 areas (37.5%), no consensus in 19 areas (39.6%) and an equivocal finding regarding 11 issues (22.9%).

3.5.3.4.1 Consensus achieved

Table 3.7 describes those statements where consensus was achieved. Respondents agreed that chemotherapy should never be prepared in clinical areas. They agreed on the definitions provided for IV medicines assembly and preparation. Patient Group Directions (PGD) should also be included within the error definition.

An example of the distribution of replies received for a scenario that reached consensus is shown in figure 3.8.

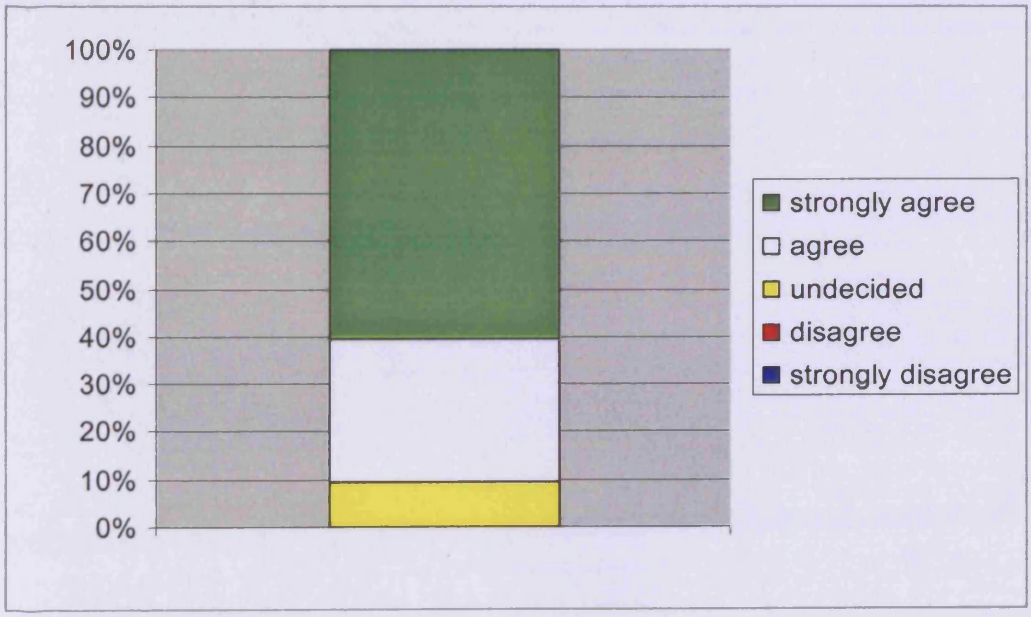

Figure 3.8 Histogram distribution of the scenario: PGDs should be included within the error definition, question 5 (n=53 replies).

Table 3.7 Analysis of statements where consensus was reached, Delphi round two (n=53 replies).

Question number	Question topic	Likert scale length	Valid response rate and attitude scale categories	Group distribution: 25%, median, 75%	No. of missing data values	Chi squared value	
						χ^2	p
1a	Medication assembly definition	5	90.4% A/SA	A,A,SA	1	34.6*	<0.0005
1b	Medication preparation definition	5	90.6% A/SA	A,A,SA	0	39.3*	<0.0005
5	Patient Group Directions should be included	5	90.6% A/SA	A,SA,SA	0	20.9**	<0.0005
7b	Chemotherapy must never occur in general areas	3	92.3% A	A,A,A	1	81.5	<0.0005
8b	Wrong route error	3	96.2% Error	n/a	0	94.3	<0.0005
11	Wrong dose or infusion concentration	3	92.5% A	A,A,A	0	83.5	<0.0005
12	Faulty reconstitution or mixing	3	96.2% A	A,A,A	0	45.3*	<0.0005
14a	Known addition incompatibility	3	96.2% Error	n/a	0	45.3*	<0.0005
14d	Incompatible container	3	96.2% Error	n/a	1	92.3	<0.0005
14g	Failure to comply with directions to filter	3	100% Error	n/a	0	#	#
14i	Inappropriate addition method	3	94.3% Error	n/a	0	41.7*	<0.0005
14j	Calculation mistake	3	94.3% Error	n/a	0	41.7*	<0.0005
15a	Using expired ingredients	3	96.2% Error	n/a	0	94.3	<0.0005
15c	Use of degraded ingredients	3	100% Error	n/a	2	#	#
15f	Latex exposure in latex allergic patient	3	96.2% Error	n/a	1	44.3*	<0.0005
17	Using a single use container more than once	5	94.1% A/SA	A,A,SA	2	31.5**	<0.0005
23	Pouring into an unsterile cup	5	94.2% A/SA	SA,SA, SA	1	105.4*	<0.0005
25	Lack of appropriate infection control follow-up	5	90.2% A/SA	A,SA,SA	2	77.5	<0.0005

Abbreviations used: A=agree, SA=strongly agree, n/a=not applicable, no.=number.
Chi-squared test not suitable as all observed data in one attitude category.
*Chi-squared test excludes one variable as no datum was observed in a one of the attitude categories; **two variables excluded as no data observed in two categories.

3.5.3.4.2 Consensus uncertain/equivocal

Table 3.8 contains those statements where there was uncertainty as to whether the issues should be included or disregarded. Both statements related to poor aseptic technique during IV preparation fell into this category. Respondents' scores showed that there was uncertainty as to whether practice deviations during IV preparation should be classed as errors.

Table 3.8 Analysis of statements where it was uncertain whether consensus was reached, Delphi round two (n=53 replies)

Quest^n number	Question topic	Likert scale length	Valid response rate and attitude scale categories	Group distribution: 25%, median, 75%	No. of missing data values	Chi squared value	
						$\chi 2$	p
6	Practice deviations should not be errors	5	81.1% SD/D	SD,D,D	0	38.2	<0.0005
8a	Unprescribed medication	3	88.7% Error	n/a	0	73.1	<0.0005
8c	Wrong diluent or solvent	3	83.0% Error	n/a	0	59.6	<0.0005
9	Labelling error	3	86.8% A	A,A,A	0	68.2	<0.0005
10	Incorrect medicines formulation	3	81.1% A	A,A,A	0	54.9	<0.0005
14h	Dose withdrawal via a filter needle which is not changed before addition	3	84.6% Error	n/a	1	24.9*	<0.0005
15b	Re-use of a multidose container with no opening date stated	3	86.5% Error	n/a	1	67.0	<0.0005
15d	Faulty storage	3	84.3% Error	n/a	2	59.6	<0.0005
15e	Use of single use medicines despite no intact tamper evident seal	3	80.4% Error	n/a	2	51.9	<0.0005
16	Deviations from appropriate aseptic technique is an error	5	86.6% A/SA	A,A,SA	1	29.1*	<0.0005
21	Breach of no-touch technique is an error	5	84.6% A/SA	A,A,SA	1	26.3*	<0.0005

Abbreviations used: SD=strongly disagree, D=disagree, A=agree, SA=strongly agree, n/a=not applicable, no.=number.

* Chi-squared test excludes one variable as no datum was observed in a one of the attitude categories.

An example of the distribution of replies received for a scenario where it was equivocal whether consensus was reached is shown in figure 3.9.

Figure 3.9 Histogram distribution of the scenario: practice deviations should not be classed as errors, question 6 (n=53 replies)

3.5.3.4.3 Consensus not achieved

Table 3.9 contains those statements that respondents did not feel should be included as IVMPEs. Respondents did not agree on the IVMPE definition provided. There was no group agreement on the acceptability of preparing an IV dose in advance of its need, even in those situations where interruption of the infusion would be important for the patient. Respondents' opinions varied on whether it was acceptable to exclude unmeasurable actions when auditing against the definition. An example of the distribution of replies received for a scenario where consensus was not reached is shown in figure 3.10.

Figure 3.10 Histogram distribution of the scenario: Errors should exclude operator safety measures within the error definition, question 7d (n=52 replies, 1=missing data)

Table 3.9 Analysis of statements where consensus was not reached, Delphi round two (n=53 replies).

Quest[a] number	Question topic	Likert scale length	Valid response rate and attitude scale categories	Group distribution: 25%, median, 75%	No. of missing data values	Chi squared value	
						$\chi 2$	p
2a	IVMPE in clinical setting definition	5	78.9% A/SA	A,A,SA	1	39.3	<0.0005
3	Errors should be potentially harmful to the patient	5	75.4% SD/D	SD,D,D	0	29.7	<0.0005
4	Unmeasurable actions can be excluded when auditing	5	71.7% SD/D	D,D,U	0	39.9	<0.0005
7a	Parenteral nutrition should never be prepared in clinical areas	3	79.2% A	A,A,A	0	50.5	<0.0005
7c	Filling of rate controlled devices does not occur in clinical areas	3	54.7% A	U,A,A	0	11.0	0.004
7d	Definition should exclude measures to protect the operator	3	46.2% D	D,U,A	1	4.3	0.116
8d	Wrong medication brand	3	75.0% Not an error	n/a	1	42.0	<0.0005
8e	Failure to use the recommended preparation area	3	51.9% Error	n/a	1	8.8	0.012
13a	Acceptable to prepare in advance	3	51.9% D	D,D,A	1	8.3	0.015
13b	Acceptable to prepare in advance where it is paramount medication delivery is uninterrupted	3	60.4% A	U,A,A	0	18.2	<0.0005
14b	Unknown addition compatibility	3	75.0% Error	n/a	1	41.3	<0.0005
14c	Addition to prepared parenteral nutrition or blood products	3	79.2% Error	n/a	0	52.6	<0.0005
14e	Preparing multiple doses of the same medicine for multiple patients	3	37.3% U	n/a	2	0.5	0.790
14f	Preparing multiple doses for multiple patients at the same time	3	42.3% Error	n/a	1	2.0	0.368
18a	Failure to wash and dry hands before preparation	5	70.6% A/SA	U,A,SA	2	10.1*	0.018

Table 3.9 Analysis of statements where consensus was not reached, Delphi round two *continued...* (n=53 replies).

Quest[n] number	Question topic	Likert scale length	Valid response rate and attitude scale categories	Group distribution: 25%, median, 75%	No. of missing data values	Chi squared value	
						$\chi 2$	p
18b	Failure to decontaminate hands with alcohol rub before preparation	5	75.0% A/SA	A,A,SA	1	28.8	<0.0005
19	Failing to wear gloves	5	63.4% A/SA	U,A,SA	1	18.0	0.001
20a	Failure to swab a vial's septum	5	78.8% A/SA	A,A,SA	1	18.6*	<0.0005
20b	Failure to let any alcohol dry after swabbing	5	70.0% A/SA	U,A,SA	3	12.2*	0.007
22	Leaving the cleaned area during preparation	5	67.3% D/U	D,U,A	1	25.3	<0.0005
24	Failing to filter or use a narrow gauge needle when withdrawing from glass ampoules	5	73.0% A/SA	U,A,SA	1	14.2*	0.003

Abbreviations used: SD=strongly disagree, D=disagree, U=undecided, A=agree, SA=strongly agree, n/a=not applicable, questn=question, no.=number.
* Chi-squared test excludes one variable as no datum was observed in a one of the attitude categories.

Respondents were asked to provide the time frame within which they felt it was acceptable to prepare an IV dose in advance of its intended time of administration (question 13c). Replies varied greatly ranging from zero to 24 hours before expiry, whilst others were unsure e.g. one replied with question marks [UP20]. It was not possible to evaluate these replies for consensus; this is supported by the earlier sections of this question also falling in the no consensus category.

Respondents were asked to rank, in priority order, the sources of information that should be used for IV medicines preparation (question 2b). This information is described in figure 3.11. Virtually all respondents used hospital approved guidance within the top three sources. Respondents were equivocal about the other sources.

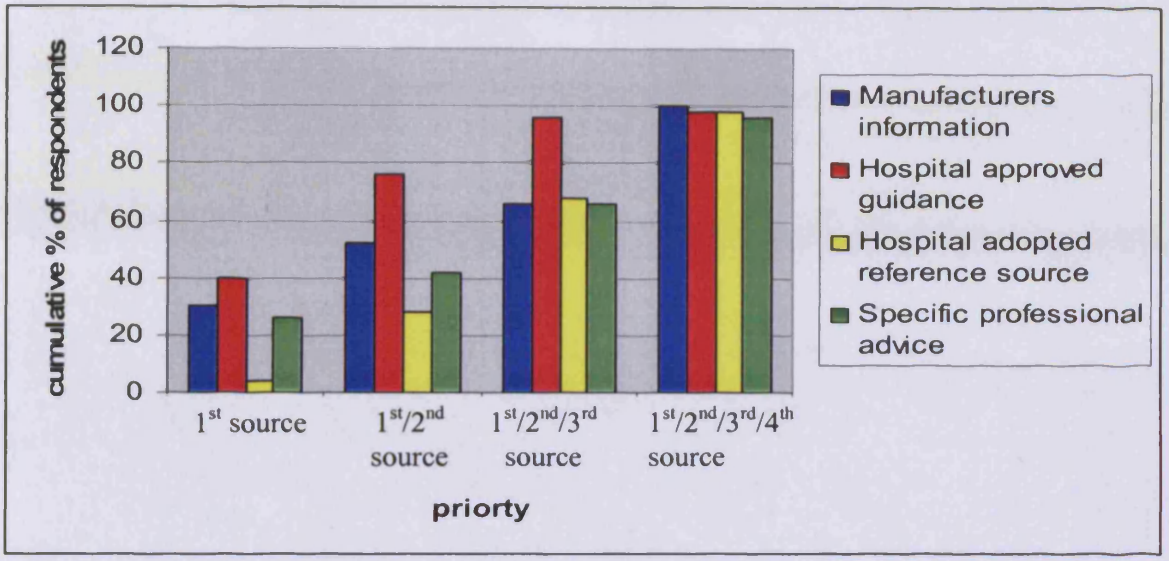

Figure 3.11 Cumulative bar chart showing priority of information sources for IV preparation

3.5.3.5 Qualitative analysis

Additional comments were received on all questions other than 14d, 14g and 14i. These comments can be categorised into the following common issues:

- Rewording.
- Rephrasing.
- Question division.
- Obscure or specialist area.
- Unrealistic scenario.

Further clarifications of the definitions were suggested; examples from each of these categories are described below.

Rewording or rephrasing

Respondents made suggestions for improving the wording of statements. Several of which focused on the clarity and scope of the definition, examples included:

"Deviation from prescription, SPC, or national or local agreed protocol or procedure or generic standard for aseptic preparation and mixing" [question 1b, UP61].

"I think that the wording is very vague as the medication could be prepared correctly according to the prescription but this could be an error" [question 2a, UN03].

"As far as the patient is concerned they couldn't care less on whose authority the medicine is given, if it's wrong it's wrong" [question 5, UP51].

"The terminology used by the Nursing & Midwifery Council is 'patient group direction'" [UN04].

A general comment received was that it was easy to stray from the study focus of IV preparation in clinical areas. Therefore it was recommended that preparation error be used throughout the questionnaire. An example was:

"I think you need to specify 'preparation error' throughout. I have tried to answer the questionnaire assuming that this is what is meant but it is easy to forget and think of drug administration errors" [UN04].

Question division

Comments received from respondents identified several statements were complex and would benefit from being divided into multiple sections allowing each section to be dealt with as a single issue. Examples of these were:

"I don't quite understand Q8-d: does this apply to wrong drug or just to selecting the same generic form (but with a different preparation instruction)? In the last case I would only judge it as an error when the preparation deviates from the manufacturer's instructions of the different brand" [question 8d, IP34].

"Should be asked separately. We have guidelines for some drugs that can be added to blood products, but nothing to parenteral nutrition" [question 14c, UP36].

"Never ever add to blood may be locally approved additions to TPN" [question 14c, UP82].

Obscure or specialist area

Some statements concerned issues where no apparent evidence-base existed to guide respondents' comments. Some of these issues were contentious and respondents' comments identified potential problems with their inclusion in the error definition framework, shown by:

"Definition of appropriate aseptic technique is essential. Nurses e.g. are trained to a different standard to pharmacy staff in many areas -standard practice must be agreed and taught" [question 16, UP57].

"Sadly we currently don't train nurses well enough in aseptic technique! Not sure whether there is sufficient literature to support the notion that infection arises from poor aseptic technique when items prepared immediately before use" [question 16, UP82].

"Highly debated in the US. Some feel that gloves create a "reservoir" of micro organisms that are more dangerous if the glove is punctured than simple and periodic hand washing" [question 19, IP23].

"Glass particles will generally be too big to pass through needle" [question 24, UP39].

"Currently there is insufficient evidence to answer this question. There is not hard evidence how dangerous preparation in clinical areas is and after what time a product should be no longer used. Providing this evidence would be a whole project on its own. Currently I would not call these deviations an error" [question 13c, IP30].

Unrealistic scenario

Respondents had been briefed that the definition and framework was intended for use in observational audit. Comments highlighted potential difficulties with some of the scenarios included, examples included:

"If aseptic is defined as 'free from bacteria' then e.g. prep of oral drugs is rarely aseptic due to the nature of the original products to be used e.g. medicine spoon, stock bottle of liquid medicine - these are unlikely to be sterile. The best we can require is that they are clean and further contamination is not introduced during the assembly/preparation process" [question 1a, UP57].

"These may be difficult to measure but methods could be developed to do so, practice may change and also the need to measure these" [question 4, UP37].

"Manufacturers instructions are difficult to obtain at ward level. A well written policy and product monographs approved by the hospital will have included that information" [question 2b, UP77].

"This is sloppy practice not a drug error" [question 18a, UN05].

"depends on policy as some hosps have taken a pragmatic view as they consider that insisting on handwashing with soap & water is impractical" [question 18a, UP11].

"Regarding parenteral nutrition: Does preparation not include breaking barriers of two bag compartments and mixing the solutions of each segment without opening the bag? I think this could be done in a clinical setting" [question 7a, UP37].

3.5.3.6 Survey administration

The main difficulty encountered receiving replies on time was partly due to distribution over the summer vacation period. However, the double follow-up and extended time frame gave most subjects an opportunity to participate. It appeared that some had pressing work commitments, which precluded their replying, for example

"I will do my best. I have been away recently and I have an unprecedented workload at present – all compounded by time lost due to computer virus/worm problems" [UP55].

3.5.4 Discussion

3.5.4.1 Response rate

A good response rate was obtained 84% (n=57). As with the first round of this study, participants were predominantly UK based (68%, n=46), with a majority of pharmacists from both the UK (n=38) and internationally (n=8). However, the proportion of non-pharmacist and international replies had increased. This may have been because purposive sampling had identified those with a specialist interest in patient safety. These replies were important as they highlighted differences between UK and USA practice.

3.5.4.2 Study limitations

The timing of survey distribution could have been improved to avoid the summer vacation period. It was apparent that the survey was time consuming to complete and this may have limited the number of replies received. This highlighted the need for the third round questions to be clear and succinct to prevent respondent fatigue.

Technical problems associated with the electronic method of communication were experienced. These included changes to respondents' Email address within their organisation, changes in respondents' circumstances e.g. on maternity leave, retired, and server failures and difficulties opening the email attachments. Some replies suggested that respondents were under the impression they had completed the questionnaire but had left missing answers, which may have been due to the electronic method of completion.

3.5.4.3 Validity check

Question 8d failed as a validity check as the question required dividing into two sections. One section dealing with IV medicines where it was important the brand was specified, and one where the branded product and generic version could be interchanged and provide an identical clinical effect. This issue had been identified by respondents in the round one replies and was believed to be addressed by the statements provided. However, the statement was ambiguous. Therefore the lack of a validity check was accepted as a study limitation.

3.5.4.4 Error definition and framework

Consensus achieved quantitatively

Consensus was achieved in 37.5% (n=18) of subject areas, mainly when a clear-cut decision of whether an error with potential to reach the patient, had occurred e.g. using

expired ingredients. This finding was anticipated. However, it was apparent that although consensus was reached, the definitions of IV medicines assembly and preparation would benefit from refinements, suggested by respondents. Therefore, these two statements were entered into round three and the 16 consensus statements retained.

Equivocal

There were eleven issues where consensus was neither agreed nor rejected. In several cases the respondents' comments suggested this may have arisen from uncertainty or ambiguous statements. In such cases the statements were clarified, by purposive questioning of a range of health-care professionals not included in the study prior to inclusion in round three. Respondents rejected the notion that practice deviations could not be called errors (81.1% strongly disagree or disagree, [n=53]). Most of these issues were included within the other scenarios and therefore this statement was excluded from the study. Ten revised statements were entered into the next study questionnaire.

Scenarios had been carefully worded in an attempt to ensure a balance between over generalised and over specific situations. However this meant some scenarios was perceived as rather bland and respondents were reluctant to answer clearly and suggested exceptions to the statement. This was addressed through careful attention to wording where these statements were retained for round three, and rejection of too-specialist scenarios. For example, statement 7c concerning the filling of rate controlled devices in clinical areas was removed from the study as it was felt to be too specialist and misunderstood by some respondents.

No consensus

The largest number of statements fell into this category, 39.6% (n=19). This was seen as widespread responses across the attitudinal categories or a bimodal distribution. In the majority of these statements respondents felt there was insufficient evidence to categorise as errors. None of these statements included key scenarios required for study robustness. Comments from respondents indicated many were areas where practice in clinical areas differed, consensus was unlikely to be achieved. Therefore statements (questions 7c, 7d, 8e, 13, 14e, 14f, 20b and 22) were removed from the study. In addition, their inclusion would risk respondent fatigue.

The remaining 11 statements and subsection 20a were rephrased, as described for the equivocal statements [section 3.5.4.4], and entered into round three.

3.5.5 Conclusions

At the end of this round the following issues had been clarified:

a. The focus of the definition and framework was patient safety issues.
b. The boundaries of the preparation stage. Prescription issues did not form part of the preparation stage, but could impact on this, therefore prescription problems should be identified and recorded separately. Where preparation was remote from the patient bedside this included all activities undertaken before the patient was approached, including inserting and priming the giving set.
c. The definition applied solely to hospital clinical areas. Therefore, non hospital settings and preparation within the pharmacy department were excluded.
d. It was difficult for respondents to remain focused on IV preparation. Therefore, reference to administration should be avoided, and IV route should be stated throughout.
e. To prevent the audit tool being too unwieldy priority for scenarios retained in round three was given to issues clinically important to the patient and amenable to detection through observation.

Consensus had been achieved for 16 statements. One statement required dividing into two questions. A further 23.5 statements were retained for entry into round three of the study.

3.6 Delphi round three - reaching a consensus

3.6.1 Aim

To seek quantification and agreement of the definition of an IV medication preparation error in clinical areas on those issues with the potential to gain consensus, and those issues rephrased from round two.

3.6.2 Methods

3.6.2.1 Sample recruitment

The sample consisted of all respondents from the second round sample who had submitted a study reply (n=53),

3.6.2.2 Data collection instrument

Where there had been consensus in round two, variables that would not benefit from rewording were excluded from further participant rating. Those variables where consensus had been reached, but would benefit from re-wording, as well as those variables where it was possible consensus might be achieved, were resubmitted to the subjects. Subjects were supplied with their previous response to each statement and a description of how this had compared with the group responses. Group distribution was described by the median, 25% and 75% quartile values. Subjects were asked to consider their previous reply, along with the group view and select their opinion. There was a potential risk of subject bias, where respondents might alter their view in line with majority view. So careful instructions in the covering letter attempted to guard against this phenomenon. Subjects were asked to select the most appropriate attitudinal response for all new statements.

A major concern was loss of subjects due to the iterative nature of this study. It was important that the questionnaire was both succinct and easy to complete. Therefore, for the third round the self-completion questionnaire format was revised to minimise respondent fatigue. Statements were tabulated and replies selected from a drop down menu.

3.6.2.3 Study administration

The opening statement on the electronic mail was similar to round two, but included the reply date, as comments from previous respondents suggested this would help. In order to motivate the sample a clear covering letter explaining the study findings to date and purpose of the final round was developed [appendix 15]. Clear guidance on how to complete the survey was included in the opening statement and at the top of each table.

Pilot of survey

The covering letter [appendix 15] and electronic survey [appendix 16] were piloted on a purposive sample of twelve people, incorporating pharmacists, pharmacy technicians, nurses and members of the public on 22nd December 2003. The pilot sample was amended to include those who had provided constructive comments in earlier rounds, as well as recruiting new members with specialist skills in IV therapy and aseptics to ensure validity and robustness. Clear instructions were given to the piloters as the revised survey format also required testing in practice.

Modification of pilot survey

The electronic survey and format were well received. Minor grammar and layout amendments to the covering letter were accepted [appendix 17]. The following key revisions were incorporated into the survey:

- Clarification of the green colour for a 19-gauge needle to apply to UK practice, as it was uncertain whether this was an international standard.
- Clarification in the 'looking for agreement' section that all statements may be considered errors e.g. faulty labelling amended to faulty labelling is an error.
- Rewording of the instructions for participants on how to complete each of the tables.
- Substituting the word error for not acceptable in the 'are these potential errors' to ensure consistency.

The survey is displayed in figure 3.12 overleaf. Additional questions that were added are shown within figure 3.12 with a grey background.

Distribution of the survey

Data collection was commenced; in an identical manner to rounds one and two [see section 3.4.2.4]. Surveys were issued on 12 and 13th January 2004, and participants requested to return these by 2nd February 2004. Non-responders were followed up on the 11th February 2004 with responses required by 27th February 2004. A second follow up of non-responders was issued 8th March 2004 requesting replies by 22nd March 2004.

3.6.2.4 Data processing

Data processing was performed in an identical manner to round two [see section 3.4.2.5].

3.6.2.5 Data analysis

Data analysis was performed in an identical manner to round two [see section 3.4.2.6].

3.6.3 Results

3.6.3.1 Response rate

A total of 53 subjects were approached for participation in this round of the study. A schematic representation of this is displayed in figure 3.13.

Figure 3.12 Round three survey

Self-completion questionnaire to develop a practical audit tool for detecting potential medication errors arising during intravenous medication assembly and preparation in clinical settings

The audit tool will address **only** potential medication errors arising during intravenous medication assembly and preparation in hospital clinical environments. **Therefore the following issues fall outside of the study remit and should not be considered whilst reaching your opinion**:

- Issues arising during the prescribing (ordering), or dispensing stage of the medicines use process.
- Issues arising after the preparation stage of the medicines use process e.g. administration.
- All non-intravenous routes of administration.
- Medication that requires no manipulation in clinical settings e.g. pre-filled syringes.
- Those activities that occur outside of the hospital areas providing direct patient care, e.g. in pharmacy.

This revised and shortened questionnaire is based on the group's earlier responses and has been designed for electronic completion. There are no right or wrong answers, so please give your personal views.

Your reply will be treated confidentially. If you have any problems or queries, please contact me by e-mail (crowleycv@cardiff.ac.uk), or telephone on +44 (0)2920 875535.

The questions are tabulated for ease of completion. Your reply from the last questionnaire is displayed in the column titled 'your previous reply'. The group's reply is described by the lower limit of the interquartile range, the median (in bold) and the upper limit of the interquartile range.

For each statement, please consider the revised scenario and the group's opinion, then choose the ONE answer that most represents your views by selecting the appropriate reply box. If you wish to alter your reply, click on the box and it will unselect that reply.

Figure 3.12 Round three survey *continued...*

Definition issues

The following statements have been revised in light of the group's comments. For **each** statement, please consider the revised definition and your previous reply in relation to that of the rest of the group. Then click on the word "select" to choose the statement that most closely represents your views and thus rank the extent to which you agree, or disagree.

Proposed definitions:	Your previous reply	Group reply: 25%, **median**, 75%	**Your revised opinion**
Intravenous medication assembly is *'the gathering together on a cleaned tray, trolley or appropriate work surface; the items of equipment and pharmaceutical agents required for the preparation of a medicinal product for a patient.'*	agree	Agree, **Agree**, Strongly agree.	**select**
Intravenous medication preparation is *'the procedure for using the assembled items in drawing up, mixing, combining or reconstituting the pharmaceutical agents, diluents and/or infusion fluids into the right form, combination, and strength according to the patient's prescription sheet. Preparation includes using relevant documentation for preparing the medicinal product, calculations, and labelling.'*	agree	Agree, **Agree**, Strongly agree.	**select**
The exclusion of actions that cannot be measured by direct observation would be an acceptable study limitation (e.g. actions at emergencies like a cardiac arrest.)	agree	Disagree, **Disagree**, Undecided.	**select**
An intravenous medication assembly or preparation error in the clinical setting is defined as *'the preparation of iv medication that deviates from the prescription, manufacturer's guidance, national or locally agreed policy, procedure or guidance, or generic standards for clean or aseptic preparation.'*	agree	Agree, **Agree**, Strongly agree.	**select**
Bates et al., (1995) defined potential adverse drug events (ADEs) as *'incidents with the potential for injury related to a drug'*. Therefore clinically relevant medication errors arising during intravenous medication assembly and preparation may be called potential ADEs.			**select**
Parenteral nutrition should not be compounded in clinical areas.	Un-decided	Agree, **Agree**, Agree.	**select**

Figure 3.12 Round three survey *continued...*

Looking for agreement

It has been suggested that each of the following statements, represents an error. For **each statement,** please rank the extent to which you agree, or disagree.

Statement:	Your previous reply	Group reply: 25%, **median**, 75%	Your revised opinion
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.)	Un-decided	Agree, **Agree**, Agree.	**select**
Preparing an iv dose using the incorrect medicine formulation is an error, e.g. a depot formulation is given iv. (Where the product is unlicensed for iv use but is a documented accepted practice, this is acceptable.)	agree	Agree, **Agree**, Agree.	**select**
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.			**select**
Failing to swab the septum (rubber top) on a vial or additive port with a suitable alcohol-based antiseptic before breaching the septum is an error.	Un-decided	Agree, **Agree**, Strongly agree.	**select**
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.	Un-decided	Agree, **Agree**, Strongly agree.	**select**
Failure to do at least one of the following before an iv dose preparation session is an error ▪ Wash hands with soap and water and dry thoroughly, ▪ Wash hands with bactericidal soap and water and dry thoroughly, ▪ Use a bactericidal alcohol hand rub and allow to dry, ▪ Wear gloves.			**select**
Where it is imperative a named brand is used, use of any other brand (e.g. conventional amphotericin B vs. lipid based amphotericin) is an error			**select**
Where manufacturers' instructions for preparation of a branded or generic product are identical, use of either is acceptable (i.e. not an error).			**select**
Failure to use a 19 gauge (green in the UK) needle or narrower, or a filter needle/straw, to prevent particulate contamination when drawing medication from a glass ampoule is an error.	disagree	Undecided, **Agree**, Strongly agree.	**select**

Figure 3.12 Round three survey *continued...*

Are these potential errors?

For **each** statement, please rank whether you think the scenario is an error.

Scenario:	Your previous reply	Grp reply: 25%, **median**, 75%.	Your revised opinion
Preparing for an individual patient, an iv medication that is not prescribed (excludes flushes.)	error	Error, **Error**, Error.	**select**
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.	error	Error, **Error**, Error.	**select**
Adding an iv medicine to a syringe/infusion already containing an iv medicine where there is not documented compatibility.			**select**
Adding an iv medicine to a blood product or compounded (ready to administer) parenteral nutrition where there is not locally documented acceptability.			**select**
Using a previously opened iv multidose container, where the date of first use is not documented.	error	Error, **Error**, Error.	**select**
Using a single use iv ingredient whose tamper-evident seal has been broken (e.g. an iv infusion previously removed from the outer wrapper.)	undecided	Error, **Error**, Error.	**select**
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.)	error	Error, **Error**, Error.	**select**
Filtering a product whose stability may be adversely affected by this process (e.g. using a 0.22micron filter with a lipid.)			**select**
Decanting iv medication into a sterile container to aid drawing up in clinical areas.			**select**
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.	error	Error, **Error**, Error.	**select**

If there are any other comments you wish to make I would be pleased to receive them

Thank you for your assistance, it is greatly appreciated. Now please review the document and check that you have answered **all** the questions. For each question the 'select' comment on the drop down menu should now contain your reply. If it still reads 'select', then re-enter your reply. Then **SAVE** the document under a different file name to save your responses and e-mail the newly saved file to crowleycy@cardiff.ac.uk by **Monday 2nd February 2004**.

Alternatively, send the completed form to: Clare Crowley, Welsh School of Pharmacy, Cardiff University, Redwood Building, King Edward VII Avenue, Cardiff CF10 3XF, UK.

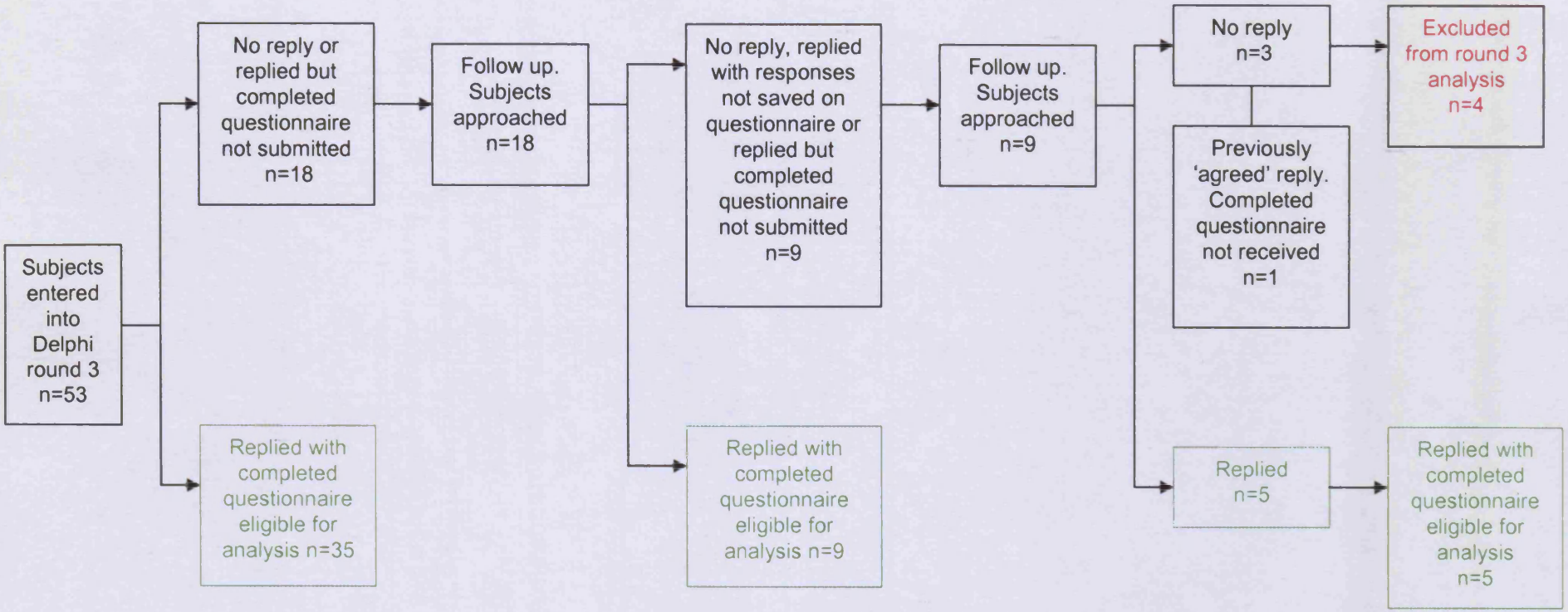

Figure 3.13 Schematic representation of sample from the Delphi round three – establishing agreement and consensus (n=49 study replies, n=4 exclusions).

3.6.3.2 Demographics

Details of the respondents' background are detailed in table 3.10. The majority of respondents (81%) were from the UK. The profession most sampled were pharmacists (79%).

Table 3.10 Analysis of all replies received by individual respondent (n=53 subjects)

		Doctor	Pharmacist	Pharmacy technician	Nurse	**Total**
UK	Replied	1	32	1	6	40
	Declined	0	0	0	0	0
	No reply	0	3	0	0	3
International	Replied	2	7	0	1	10
	Declined	0	0	0	0	0
	No reply	0	0	0	0	0
	Total	3	42	1	7	53

Forty-none replies (98%) were suitable for analysis including two received after the study deadline. One pharmacist had agreed to reply, but this was not received by the deadline. The distribution of this is shown in table 3.11.

Table 3.11 Details of the study replies received (n=50 replies)

Types of reply	Doctor	Pharmacist	Pharmacy Technician	Nurse	Total	% of total replies
Suitable for analysis	3	38	1	7	49	98
Promised but not received	0	1	0	0	1	2
Total replies	3	39	1	7	50	100

3.6.3.3 Quantitative results to questions posed

In this round, twenty five questions were posed. One question was combined (18a,b &19), two new subject areas were added to those already considered in round two, and 'wrong medication brand' was split into two subject areas, increasing the overall study total to 51 subject areas.

Consensus was reached on 17 statements (68%), equivocal findings regarding six statements (24%) and no consensus on two statements (8%).

3.6.3.3.1 Consensus achieved

Consensus was reached on the definitions of IV medicines assembly, preparation and an error. It was agreed that parenteral nutrition should not be prepared in clinical areas, but that it was acceptable to manipulate multi-compartment formulations within a sealed

system. Both statements on aseptic technique were agreed, including the more stringent version where breach of no touch technique was an error. Statements where consensus was not achieved are shown in table 3.12.

Table 3.12 Statements where consensus was reached, Delphi round three (n=49 replies).

Adapted from 2nd round quest^{n} no.	Question topic	Likert scale length	Valid response rate and attitude scale groups	Group distribution 25%, median, 75%	No. of missing data values	Chi squared value	
						$\chi 2$	p
1a	IV medication assembly definition	5	93.5% A/SA	A,A,SA	3	59.2	<0.0005
1b	IV medication preparation definition	5	97.8% A/SA	A,A,SA	2	22.6**	<0.0005
2a	IV medication assembly or preparation error definition	5	95.8% A/SA	A,A,SA	2	51.6*	<0.0005
7a	Parenteral nutrition should not be prepared in clinical areas	3	95.7% A	A,A,A	3	38.3*	<0.0005
8a	Unprescribed medicines	3	100% Error	n/a	3	#	#
8c	Diluent, solvent or infusion fluid error	3	93.3% Error	n/a	4	33.8*	<0.0005
8d	Where imperative a named brand is used, deviation is an error	3	91.1% A	A,A,A	4	67.7	<0.0005
9	Incorrect labelling	3	100% A	A,A,A	2	#	#
10	Incorrect medicines formulation	3	100% A	A,A,A	2	#	#
14c	Addition to prepared parenteral nutrition or blood products	3	93.5% Error	n/a	3	74.9	<0.0005
14h	Dose withdrawn via a filter needle which is not changed before addition	3	97.8% Error	n/a	4	41.1*	<0.0005
15b	Using multidose container where no date of opening is recorded	3	97.8% Error	n/a	3	42.1*	<0.0005
15d	Faulty storage	3	95.6% Error	n/a	4	37.4*	<0.0005
15e	Using of single use container where tamper evident seal is broken	3	95.6% Error	n/a	4	37.3*	<0.0005
16	Gross disregard for aseptic technique	5	97.9% A/SA	A,SA,SA	2	21.1**	<0.0005
21	Breach of no-touch technique	5	95.6% A/SA	A,A,SA	3	18.6**	<0.0005
new	Filtering where this may adversely affect stability	3	100% Error	n/a	3	#	#

Abbreviations used: A=agree, SA=strongly agree, n/a=not applicable, no.=number.
Chi-squared test not suitable as all observed data in one attitude category
* Chi-squared test excludes one variable as no datum was observed in a one of the attitude categories; **two variables excluded as no data observed in two categories.

3.6.3.3.2 Equivocal findings

There were two statements that fell on the boundary for inclusion in this equivocal category, question 8d and 24 (shown in italics in table 3.13). In question 8d most respondents considered interchange of generic and branded IV medicines acceptable. This was demonstrated by 89.1% of respondents who chose 'agree' and that all replies within the interquartile range were within the agree category. Therefore, with clear evidence that the majority of participants agreed with this statement, this was construed as consensus achieved.

By contrast, in question 24 the replies are more widely dispersed across the strongly agree and agree categories with 80.9% of respondents in agreement. When this is combined with the smaller sample size retained to the third round this fall on the boundary between no consensuses and equivocal. Therefore, this category was reassigned to the no consensus group.

Table 3.13 Statements where it was uncertain whether consensus was reached, Delphi round three (n=49 replies).

Adapted from 2nd round question no.	**Question topic**	Likert scale length	Valid response rate and attitude scale groups	Group distribution: 25%, median, 75%	No. of missing data values	Chi squared value	
						χ^2	p
3	Clinically relevant medication errors are potential ADEs	5	86.4% A/SA	A,A,SA	5	35.6*	<0.0005
8d	*Where acceptable, interchange of generic or branded medicine is acceptable*	*3*	*89.1% A*	*A,A,A*	*3*	*64.5*	*<0.0005*
14b	Additions where compatibility are not documented	3	87.0% Error	n/a	3	25.1*	<0.0005
18a&b, 19	Failure to clean hands before preparation, or wear gloves	5	87.2% A/SA	A,A,SA	2	29.7*	<0.0005
20a	Failure to swab an additive port or vial septum	5	87.0% A/SA	A,A,SA	3	28.1*	<0.0005
24	*Withdrawal from glass ampoules must be via a filter needle, or 19-gauge or narrower needle*	*5*	*80.9% A/SA*	*A,A,A*	*2*	*33.8**	*<0.0005*

Abbreviations used: A=agree, SA=strongly agree, n/a=not applicable, no.=number.
* Chi-squared test excludes one variable as no datum was observed in a one of the attitude categories.

3.6.3.3.3 Consensus not reached

Consensus was not achieved in two areas. One was decanting of medicine into a sterile cup, also known as 'open bowl technique'. The other area was whether it is acceptable to exclude unmeasurable issues during observational audit. These are shown in table 3.14.

Table 3.14 Statements where consensus was not reached, Delphi round three (n=49 replies).

Adapted from 2nd round question no.	Question topic	Likert scale length	Valid response rate and attitude scale groups	Group distribution: 25%, median, 75%	Number of missing data values	Chi squared value	
						$\chi 2$	P
4	Excluding unmeasurables is an acceptable study limitation	5	78.7% D/U	D,D,U	2	33.6*	<0.0005
new	Decanting into a sterile cup	3	66.7% Error	n/a	4	25.2	<0.0005

Abbreviations used: D=disagree, U=undecided, n/a=not applicable, no.=number
* Chi-squared test excludes one variable as no datum was observed in a one of the attitude categories

3.6.4 Discussion

3.6.4.1 Response rate

A good response rate was obtained for this round (n=50), with 92% (n=49) suitable for study inclusion. As with the first and second round of this study, participants were predominantly UK based (80%, n=40), with a majority of pharmacists from both the UK 64% (n=32) and internationally 14% (n=7). However, the proportion of international replies had increased to 20% (n=10). This may have been because purposive sampling had identified those with a specialist interest in patient safety, particularly international respondents.

3.6.4.2 Study limitations

Questions to test for alternate form reliability would ideally have been included. This was not possible because if the survey had been longer response rate may have been jeopardised. Some idea of test-retest reliability would become apparent from comparing the results from round two and three had it proved possible to include identically worded scenarios in both rounds. However, to minimise attrition and panel fatigue this was not undertaken. Although not formally assessed, reliability is suggested by the number of respondents with similar replies and convergence towards agreement in round three, where statements were succinctly clarified.

The main problem with survey administration and analysis was poor remote access to Cardiff University computing services. There were server problems with their so that it was not possible to communicate at all. It also took at least five minutes to download each respondent's reply using remote access. These problems had not previously been experienced as the researcher had used a local NHS account that was no longer available.

3.6.5 Conclusions

The result of round three was an agreed definition of an IVMPE and list of inclusion criteria, criteria to be excluded and some uncertainties when considering an IVMPE were also achieved.

3.7 Results of Delphi study – rounds one to three

The recruitment and responses to all stages in this study are summarised in flowchart figure 3.14. From a total potential sample of 102 subjects, 49 (48%) remained to submit analysable replies in the final round.

Replies to questions posed

Overall 51 questions were included, three of which contained subsections on similar themes (questions 13, 18 and 20). Results were reported based on these subject areas.

Consensus was reached in 34 areas (66.7%), with equivocal findings for five areas and a sixth sub issue, septum swabbing (10.8%). Statements which should not be included in the error definition consisted of 11 areas (one composed of questions 18 & 19) and a subsection of a twelfth area: failure to let the alcohol dry after swabbing.

3.7.1 Consensus issues

Definitions for IV medicines assembly, preparation, and errors have been agreed. The scope of the definition and a range of scenarios that should be considered errors for use when operationalising the definition have also been agreed. These are shown in table 3.15.

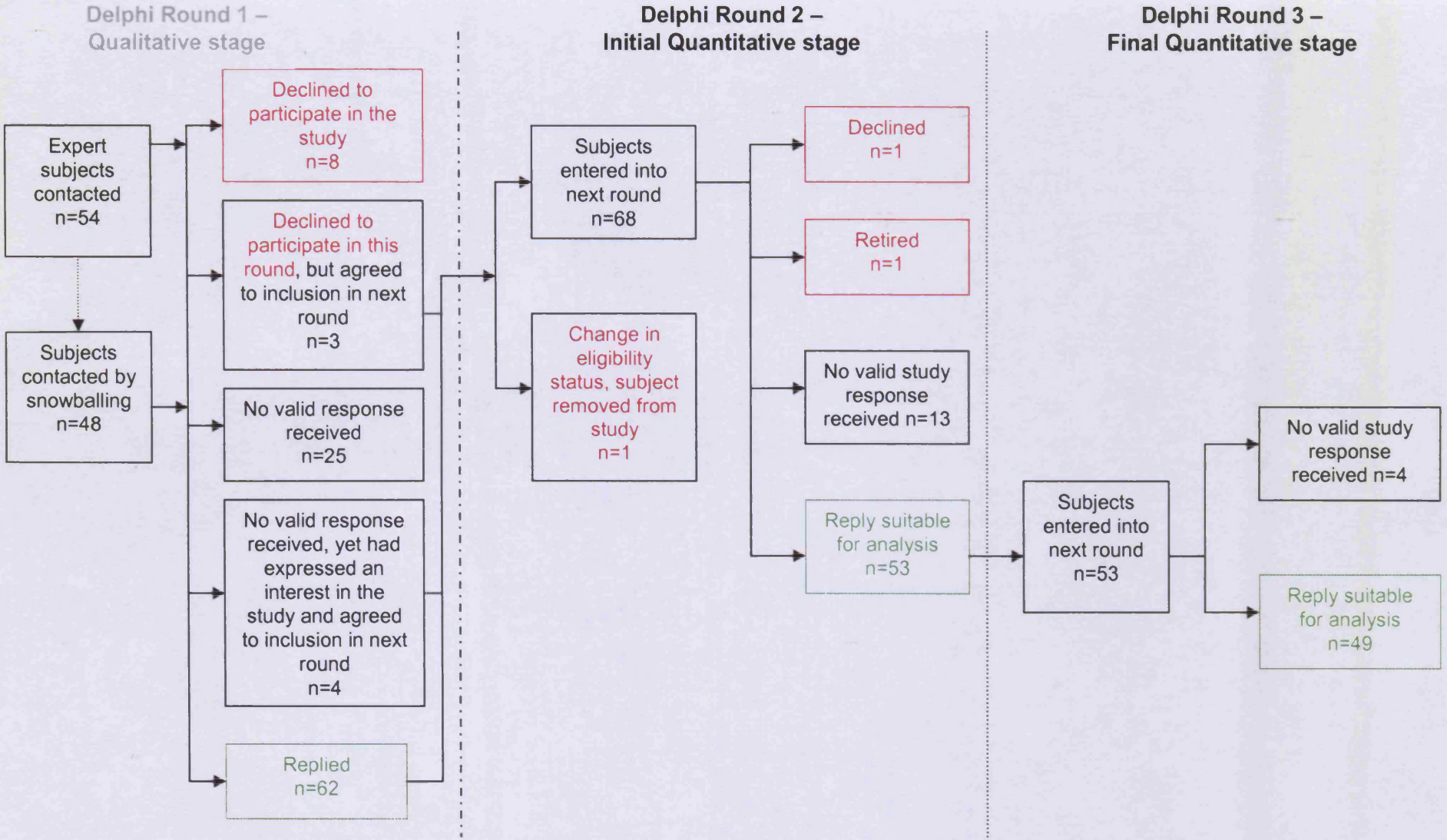

Figure 3.14 Schematic overview of the Delphi study on an intention to recruit basis (102 subjects entered study, n=49 completing all rounds, n=53 exclusions).

Table 3.15 Statements where consensus was achieved overall.

Adopted from 2nd round question	Question topic	Likert scale length	Valid response rate and attitude scale groups	Group distribution: 25%, median, 75%.
1a	IV medication assembly definition –r3	5	93.5% A/SA	A,A,SA
1b	IV medication preparation definition –r3	5	97.8% A/SA	A,A,SA
2a	IV medication assembly or preparation error definition-r3	5	95.8% A/SA	A,A,SA
5	Patient Group Directions should be included	5	90.6% A/SA	A,SA,SA
7b	Chemotherapy must never occur in general areas	3	92.3% A	A,A,A
7a	Parenteral nutrition should not be prepared in clinical areas	3	95.7% A	A,A,A
8a	Unprescribed medicines	3	100% Error	n/a
8b	Wrong route error	3	96.2% Error	n/a
8c	Diluent, solvent or infusion fluid error	3	93.3% Error	n/a
New	Filtering where this may adversely affect stability	3	100% Error	n/a
14c	Addition to prepared parenteral nutrition or blood products	3	93.5% Error	n/a
14h	Dose withdrawn via a filter needle which is not changed before addition	3	97.8% Error	n/a
15b	Using multidose container where no date of opening is recorded	3	97.8% Error	n/a
15d	Faulty storage	3	95.6% Error	n/a
15e	Using of single use container where tamper evident seal is broken	3	95.6% Error	n/a
14a	Known addition incompatibility	3	96.2% Error	n/a
14d	Incompatible container	3	96.2% Error	n/a
14g	Failure to comply with directions to filter	3	100% Error	n/a
14i	Inappropriate addition method	3	94.3% Error	n/a
14j	Calculation mistake	3	94.3% Error	n/a
15a	Using expired ingredients	3	96.2% Error	n/a
15c	Use of degraded ingredients	3	100% Error	n/a
15f	Latex exposure in latex allergic patient	3	96.2% Error	n/a
16	Gross disregard for aseptic technique	5	97.9% A/SA	A,SA,SA
21	Breach of no-touch technique	5	95.6% A/SA	A,A,SA
8d	Where imperative a named brand is used, deviation is an error	3	91.1% A	A,A,A
8d	Where acceptable, interchange of generic or branded medicine is acceptable	3	89.1% A	A,A,A
9	Incorrect labelling	3	100% A	A,A,A
10	Incorrect medicines formulation	3	100% A	A,A,A
11	Wrong dose or infusion concentration	3	92.5% A	A,A,A
12	Faulty reconstitution or mixing	3	96.2% A	A,A,A
17	Using a single use container more than once	5	94.1% A/SA	A,A,SA
23	Pouring into an unsterile cup	5	94.2% A/SA	SA,SA, SA
25	Lack of appropriate infection control follow-up	5	90.2% A/SA	A,SA,SA

(Abbreviations used: SD=strongly disagree, D=disagree, U=undecided, A=agree, SA=strongly agree, n/a=not applicable, no.=number)

3.7.2 Issues where consensus was equivocal

Within the error framework there were areas where there was uncertainty that the situations should be labelled errors. These scenarios are described in table 3.16. When auditing these scenarios could either be discarded, or reported separately.

Table 3.16 Overall statements where it was uncertain whether consensus was reached.

Adopted from 2nd round question	Question topic	Likert scale length	Valid response rate and attitude scale groups	Group distribution: 25%, median, 75%.
3	Clinically relevant medication errors are potential ADEs	5	86.4% A/SA	A,A,SA
14b	Additions where compatibility are not documented	3	87.0% Error	n/a
18a&b, 19	Failure to clean hands before preparation, or wear gloves	5	87.2% A/SA	A,A,SA
20a	Failure to swab an additive port or vial septum	5	87.0% A/SA	A,A,SA
6	Practice deviations should not be errors	5	81.1% SD/D	SD,D,D
16	Deviations from appropriate aseptic technique is an error	5	86.6% A/SA	A,A,SA

Abbreviations used: SD=strongly disagree, D=disagree, U=undecided, A=agree, SA=strongly agree, n/a=not applicable, no.=number

Analysis of pharmacy staff replies compared with all other staff groups showed that pharmacy staff were more concerned with sterility, aseptic and poor practice issues. This is described in table 3.17.

Table 3.17 Analysis of responses by profession: pharmacy staff (n=43) vs. non-pharmacy staff (n=10 respondents)

Delphi round	Question no.	Question topic	Mann-Whitney U value	p[a]
2	7d	Definition should exclude measures to protect the operator	118.0	0.021
2	12	Faulty reconstitution or mixing	172.0	0.003
2	14a	Known addition incompatibility	172.0	0.003
2	14h	Dose withdrawn via a filter needle which is not changed before addition	125.5	0.009
2	14i	Inappropriate addition method	150.5	<0.0005
2	15b	Using multidose container where no date of opening is recorded	133.0	0.003
2	15e	Use of single use medicines despite no intact tamper evident seal	137.0	0.019
2	20a	Failure to swab a vial's septum	125.0	0.036
2	20b	Failure to let any alcohol dry after swabbing the septum	117.5	0.034
2	22	Leaving the cleaned area during preparation	125.0	0.037

a Asymptotic significance (2-tailed values)

3.7.3 Issues to exclude

A range of statements that should not be considered errors are shown in table 3.18. These areas were either where there was little agreement, or areas withdrawn after round two showed that consensus was unlikely to be achieved.

Table 3.18 Overall statements where consensus was not reached.

Adopted from 2nd round question	Question topic	Likert scale length	Valid response rate and attitude scale groups	Group distribution: 25%,median, 75%.
4	Excluding unmeasurables is an acceptable study limitation	5	78.7% D/U	D,D,U
24	Withdrawal from glass vials must be via a filter needle, or 19-gauge or narrower needle	5	80.9% A/SA	A,A,A
New	Decanting into a sterile cup	3	66.7% Error	n/a
7c	Filling of rate controlled devices does not occur in clinical areas	3	54.7% A	U,A,A
7d	Definition should exclude measures to protect the operator	3	46.2% D	D,U,A
8e	Failure to use the recommended preparation area	3	51.9% Error	n/a
13a	Acceptable to prepare in advance	3	51.9% D	D,D,A
13b	Acceptable to prepare in advance where it is paramount medication delivery is uninterrupted	3	60.4% A	U,A,A
20b	Failure to let any alcohol dry after swabbing	5	70.0% A/SA	U,A,SA
22	Leaving the cleaned area during preparation	5	67.3% D/U	D,U,A
14e	Preparing multiple doses of the same medicine for multiple patients	3	37.3% U	n/a
14f	Preparing multiple doses for multiple patients at the same time	3	42.3% Error	n/a

3.8 Overall discussion

3.8.1 Response rate

The overall response rate of 48% (n=49) was acceptable, but would ideally this would be higher. Possible explanations for this were panel fatigue and attrition because this was a multiple round study. International respondents were more likely to complete the study (10/18 respondents) than those recruited from the UK (40/84 respondents). This could be because international subjects were identified by publications in patient safety, so were likely to be highly motivated, in contrast to UK nominations included those nominated by UK 'experts' who may be less patient safety focused.

Participants were not contacted in advance of the study to request inclusion, which may also result in a lower response rate [Oppenheim, 1992]. If response rate were calculated based on positive participants replies this would be greater at 79% (n=62). This is consistent with reported response rates from similar Delphi studies. Dean and colleagues

[2000] approached 43 potential respondents before a two round Delphi to request participation in their postal study, and from the 34 that agreed to participate received replies to both rounds from 26, equivalent to a 60% response rate. In a similar study, Ghaleb and co-workers [2005] approached 60 potential subjects, 50 of whom agreed to participate in their two round Delphi, with 40 completing both rounds, equivalent to a 67% response rate. The response rate achieved in the study was sufficient to be confident in the validity of the study findings. However, it is not known whether non responders had different views from study participants, this remains a potential source of bias.

3.8.2 Study limitations

The purposive sampling technique is not random or representative, therefore the findings of the study are not automatically generalisable, or possess external validity. The Delphi technique intentionally samples those with expertise and experience in the study area [Hasson *et al.*, 2000]. Sample selection is important to ensure that all fields of expertise are included; one method of ensuring this is a large sample size. The sample approached for inclusion in this study was larger than other safety focused Delphi studies [Dean *et al.*, 2000; Avery *et al.*, 2005; Ghaleb *et al.*, 2005]. In contrast with previous studies, participants were also recruited from outside the UK. The large sample size approached for inclusion in this study was chosen to ensure that sufficient participants were recruited for the study to be valid.

Snowball sampling was used as there was no easy method of ensuring all relevant participants had been identified. This helps to minimise selection bias within the sample and has been previously been used in Delphi studies [Mead & Moseley, 2001]. However one disadvantage of this recruitment method is that a profession can become over-represented. As the majority of participants were pharmacists, they were more likely to be over represented. It was anticipated that there would be a large proportion of pharmacists as different pharmacists contributed to academic, clinical, aseptic and safety expertise. However it was anticipated that the snowball technique would have identified other pharmacy technicians, nurses, doctors, practice development and infection control staff. This method succeeded in gathering only a few nominations from clinical practitioners. This resulted in limited comments from clinical staff currently preparing IV medicines as part of their job. The inclusion of nurses, midwives and doctors would have added an extra dimension to this study.

One criticism, often cited of previous Delphi studies, is that the methods are not described in sufficient detail to permit replication. This does not apply to the study, which could be replicated. Studies using a Delphi process to establish consensus on prescribing error do not adequately describe how their sample was selected and contacted to allow replication [Dean *et al.*, 2000; Ghaleb *at el.*, 2005]

Electronic communications have been used in qualitative and Delphi studies [Beretta, 1996; Alexander, 2000; Avery *et al.*, 2005]. A number of issues specific to this method of communication were experienced e.g. advice from an expert in information technology would have prevented some of these, and would be advisable for similar future studies.

Some of the known disadvantages of using a self completion questionnaire were apparent in this study. These included the inability to probe or clarify issues, lower response rate compared to a researcher administered questionnaire and missing data not remedied by researcher prompting [Bryman, 2004]. In addition, although respondents were asked to complete Delphi round two and three themselves and not discuss their views with others, this could have occurred [Beretta, 1996; Bryman, 2004].

Limited piloting prior to round two may have prevented the detection of ambiguous or unclear issues. The majority of the pilot sample were identical to those that commented on the pilot for round one. Time constraints limited the inclusion of all those used in round one. However, on balance it was decided that it was more important to issue the survey to the study participants before the summer vacation, especially as the piloters who provide detailed feedback in round one were all included. The time between rounds should be as short as possible to prevent panel members losing interest [Mead & Moseley, 2001]. There were months between rounds in this study, this may have reduced response rate to the subsequent round.

Consensus was achieved following three successive rounds with a panel of experts which provided high face, content and concurrent validity [Beretta, 1996].

Reliability of the study findings are usually considered to be the consistency or dependability with which the instrument measures the attribute it was designed to measure [Beretta, 1996]. As there is no evidence of the reliability of Delphi studies, alternative

criteria have been suggested to ensure credible interpretation of findings. These are credibility, applicability (or fittingness), auditability (or consistency) and confirmability [Hasson *et al.*, 2000]. Credibility was achieved and demonstrated by the consensus process using the panel's expertise. The other parameters would be confirmed when the IVMPE and framework was used (chapter 4) and definitions explored with nursing staff (chapter 5). These additional steps are needed to validate the findings.

3.8.3 Error definition and framework

The initial definition proposed of an intravenous medication assembly or preparation error in the clinical setting was

"a situation or act by a healthcare professional in the preparation of an intravenous medication dose that deviates from a written, verbal or computer generated prescription for an individual patient, or contravenes hospital protocol, professional or regulatory guidance."

This was refined and agreed as

"The preparation of IV medication that deviates from the prescription, manufacturer's guidance, nationally or locally agreed policy, procedure or guidance or generic standards for clean or aseptic preparation."

It is interesting that respondents rejected the initial definitions provided in round one and two as these were similar to those previously employed in published studies [Taxis & Barber, 2003a; Wirtz *et al.*, 2003]. The main differences between the definition produced in this study and previously used definitions were the inclusion of aseptic technique issues and deviations from policies or procedures as errors. Previously, there has been uncertainty as to whether aseptic issues should be included within an error definition. Most researchers have overcome this by collecting and reporting such data separately from the error rate. [Mansfield, 2001; Wirtz *et al.*, 2003; Cousins *et al.*, 2005]. In contrast, two studies evaluating prescribing error scenarios found that most scenarios not considered to be errors were deviations from policies and guidelines [Dean *et al.*, 2000; Ghaleb *et al.*, 2005]. A possible explanation could be that there is limited guidance available on IV preparation, so that where it does exist it should be adherence to this. The NPSA commenced wide stakeholder consultation in January 2006 on a draft patient safety alert 'safer use of injectable medicines in near-patient areas' [2006]. The outcome of this consultation will be very interesting as it requires up to date written protocols and procedures on the prescribing, preparation and administration of injectable medicines and essential information for this to be available at the point of use. Therefore, this describes minimum

national standards for organisations which can be evaluated by audit. It also provides safer practice standards, which are standard operating procedures. These could be adopted as minimum national practice standards and could be used to identify sub-optimal practice. Many of the equivocal statements are likely to be included in this alert, and it would benefit from review after this alert has been published.

All the error categories related solely to preparation and used in previous studies (table 2.2) were considered to be errors by this panel. Most of the scenarios that respondents felt should not be classed as error related to poor practice.

Previous Delphi studies evaluating prescribing error scenarios have finished with groups of scenarios that are errors, those that are not and included 'situations that may be considered prescribing error, depending on the individual clinical situation' [Dean *et al.*, 2000; Ghaleb *et al.*, 2005]. This strategy was not adopted to minimise variability when the definition was used. Instead scenarios that remained in the equivocal category at the end of the study were left as equivocal issues. Data on these issues could be collected as the researcher's discretion, but should be reported separately from the error rate.

3.9 Overall conclusions

Agreement on what constitutes an IV medication assembly or preparation error in hospital clinical practice and a framework of error scenarios was obtained. This framework consisted of three categories of scenario: those that were considered an error, those that should be excluded and those where no consensus was reached. This definition and framework can now be used for observational audit for the quantification of IVMPE. Adoption of the IVMPE definition and framework would reduce variability in what is considered to be an IVMPE. Observation studies devoted to the preparation stage would collect data on potential IVMPE. Actual IVMPE can only detectable by observing both preparation and administration. The definition developed now requires practical evaluation.

Chapter 4

A pilot audit of a consensus-derived framework for intravenous medication assembly and preparation errors in hospital clinical areas

4.1 Background to study

Audit has been used to assess compliance with medicines management standards for aseptic dispensing in unlicensed facilities as a quality assurance and control measure [Farwell, 1995; NHSE, 1999b]. Therefore, it is logical also to use audit to assess compliance with unlicensed dispensing in clinical areas. This has not previously been possible because there have been no standards against which to audit.

A practical, explicit definition and framework for hospital intravenous medicines assembly and preparation errors in clinical areas was agreed by international experts from medicine, nursing and pharmacy, [see chapter 3] where an error was defined as:

"The preparation of an IV medication that deviates from the prescription, manufacturer's guidance, national or locally agreed policy, procedure or guidance, or generic standards for clean or aseptic preparation."

This pilot study will use this definition and framework as audit standards to develop an observational audit tool to evaluate when IV medicine preparation errors occur. The adoption of such an audit tool in practice would allow meaningful comparison of findings between and across study settings [Crowley *et al.*, 2004a,b].

4.2 Aims

The aim of this pilot study was to determine whether the data collection tool developed could feasibly be used to record the number and type of IV medication assembly and preparation errors in hospital clinical settings.

Objectives.

- To establish the training required to ensure observers have the necessary skills and experience for data collection.
- To assess the feasibility of using an observer recorded data collection form in clinical areas.
- To determine if the data collected shows whether an error has occurred.
- To suggest how error categories can be amalgamated for compatibility with the NPSA medication data set of the NLRS.

- To highlight areas that would benefit from refinement before a large-scale study could be undertaken, or a generic training package developed.
- To determine what is required to develop a full training pack to allow the Trust and other centres to use the audit tool.

4.3 Study methodology

4.3.1 Research strategy

Direct observation is the 'gold standard' for detecting administration errors, and was employed in this study [Allan & Barker, 1990; Flynn *et al.*, 2002]. The framework established in chapter 2 was intended to guide data collection of directly observed practitioners preparing IV medicines. Observational research is a valuable tool that enables researchers to document actual events, rather than relying on reports that may not accurately represent what happened [Smith, 2002]. The audit tool was designed to enable quantification of IVMPE and poor practice. Quantitative observational study has been defined as

"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.161].

The IVMPE framework was developed as an audit tool, where it was envisaged that the data collector would not participate in IV preparation or administration. This has been defined as

"Non participant observation studies are those in which the researcher records activities and behaviours of those under study in the capacity of an outside observer" [Smith, 2002;p.162].

Observational research studies have previously been used in a variety of health care settings, including critical care, theatres and medication administration [Carthey, 2003].

Advantages

The advantages of using quantitative non participant observation are summarised below:

- Enables capture of events as they happen.
- More reliable and valid than self reports.
- Greater precision on timing and duration of events.
- Greater accuracy in time ordering of variables.

- Some healthcare settings and tasks are better suited to this method e.g. theatres, dispensing, medicines administration.
- Not reliant on written reports that may be biased from intentional misinterpretation or misconceptions.
- Independent of willingness to report incidents.
- Does not depend on existence of complete and accurate documents.
- Not reliant on memory.
- Enables detection of errors, where staff may be unaware.
- High response rate with single observer (above 80%).
- Researcher has control over completeness and quality of data captured.
- Useful as a sole research method, and also in combination with another data collection method as this improves reliability and validity e.g. video recording [Barker *et al.*, 2002b; Bowling, 2002; Pope *et al.*, 2002; Smith, 2002; Carthey, 2003; Bryman, 2004]

Disadvantages

There are a number of disadvantages to observational techniques that can affect the validity of the study. These require careful consideration to minimise bias, and are summarised below:

- Labour intensive technique.
- Expensive as often requires trained healthcare professionals.
- Fatigue, need to maintain attention for long periods. In long data collection periods or studies more than one observer is needed.
- Observers need careful training, rehearsal and competency assessment both in observation and the study topic.
- Transferring skills and knowledge from the expert to novice observer can be difficult.
- Must remain unobtrusive when data collecting.
- Quality of the data collected is highly dependant on the observer.
- Need to adapt readily to different settings and conditions.
- Need accuracy of perception of detail.
- Observer must be situated where they can observe all necessary data.
- Participants may be less inclined to participate, or may modify their behaviour if the research topic is sensitive.

- Lower response rates are achieved where the observer's presence is unsettling or disrupts activities.
- Observer's personal and interpersonal attributes are also important e.g. maintaining a fair-blame culture.
- If more than one observer is used, inter-rater reliability should be undertaken to check for consistency.
- Bias introduced by the research process or observer's presence [Allen & Barker, 1990; Dean & Barber, 2001; Bowling, 2002; Smith, 2002; Carthey, 2003; Bryman, 2004].

The main issues with observation are effects created by the observer's presence and by the research process and are known as reactive effects or the 'Hawthorne effect' [Bowling, 2002; Smith, 2002].

The Hawthorne effect describes the situation where

"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 may affect the validity of the study. Measures to minimise this include:

- Spending time with staff in the study area before data collection starts.
- Providing assurances regarding:
    - Confidentiality of results,
    - Anonymity of data (where relevant),
    - Importance of continuing with usual behaviour.
- Emphasising the breadth of data collection to minimise where behaviour could be modified.
- Discarding initial observations, as the observer's effect reduces with time [Bowling, 2002; Smith, 2002].

Except for the last recommendation, all of the above measures were employed in this study.

Observer bias has been defined as

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

This is minimised by careful observer training, with attention to recording what actually happened, not what was perceived and inferred [Bowling, 2002].

As discussed previously IVMPE are readily detected by direct observation, so other less intrusive research methods were unsuitable. The observers were trained both in non-participant observation and no-touch aseptic techniques. This provided them with a clear understanding of what they needed to observe, the data they needed to collect and how to minimise the impact of their presence on the study participant. It was envisaged that any inconvenience created through observation would be minimal, but could not be excluded.

In observational research a delicate balance is required between providing potential participants with sufficient study information to allow an informed decision to participate, yet avoiding introducing bias by a change in behaviour [Smith, 2002]. In previous observational studies of medication administration errors, the study's aims have been withheld to minimise bias and alternative rationale for observation provided [Dean *et al.*, 1995; Hartley & Dhillon, 1998; Taxis & Barber, 2003a]. However, Armitage [2005] argues against this approach, suggesting that to comply with the Government's strategies on research governance and an open, fair culture the methods should be transparent with participants fully consenting [Department of Health, 2001b, 2005]. In this pilot study an undisguised approach was chosen as the study was on a sensitive topic, and aimed to test the audit tool not the participant. In addition the study could not easily and credibly be explained in any other way. A potential limitation of disguised observational methods is that knowledge of the intended prescription places the observer in a difficult ethical position; if an error occurs they have an ethical duty to intervene [Dean & Barber, 2001]. Pre-registration pharmacy graduates were used as observers as they would have sufficient knowledge and skills to enable them to be trained in observation and aseptic techniques. To further minimise bias; prescription details were recorded from the patients medication chart after the dose had been prepared.

Research participants might feel uncomfortable being watched whilst undertaking routine duties. However, the study's objectives were undisguised, and research participants who felt uncomfortable were unlikely to consent to participate in this study.

The benefits of adopting consistent terminology have already been highlighted [chapter 2]. Therefore to allow data sharing and comparison the IVMPE framework derived [chapter 3] was mapped to the NPSA NLRS dataset [NPSA, 2003b], this is summarised in table 4.1.

Table 4.1 Summary of IV medication preparation error codes and comparison with the NPSA NLRS in-process error descriptions dataset release 1.2.1.

Error category	**Explanation and framework agreed**	**NLRS code**
Wrong route	Preparing a medication dose for administration intravenously when it is prescribed by another route (i.e. wrong route).	Wrong route-P
Wrong medicine	Where it is imperative a named brand is used, use of any other brand (e.g. conventional amphotericin B vs. lipid based amphotericin) 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 drug / medicine-K
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).	Wrong / unclear dose or strength-J
Wrong medicine formulation	Preparing an IV dose using the incorrect medicine formulation is an error, e.g. a depot formulation is given IV. (Where the product is unlicensed for IV use but is a documented accepted practice, this is acceptable).	Wrong formulation-L
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.	Wrong method of preparation-N
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 minibag plus infusion device that has a vial of powder attached, or vigorously shaking a medication that foams e.g. 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).	Wrong method of preparation-N
Un-prescribed error	Preparing for an individual patient, an IV medication that is not prescribed (excludes flushes).	Other-Z
Calculation error	Any calculation mistake that produces a preparation (± 10% dose instructed) is an error.	Wrong/ unclear dose or strength-J
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.	Wrong method of preparation-N (Care: overlaps with equipment codes)
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).	Wrong / transposed / omitted medicine label-I
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.	Patient allergic to treatment-E

Table 4.1 continued... Summary of IV medication preparation error codes and comparison with the NPSA NLRS in-process error descriptions dataset release 1.2.1

Error category	Explanation and framework agreed	NLRS code
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 multidose 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 / omitted / passed expiry date-F
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).	Wrong storage-Q
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. epoprostenol). 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.	Wrong method of preparation-N

4.3.2 Study setting

Clinical areas were recruited from an acute teaching hospital NHS Trust located on four sites, providing a wide range of secondary and tertiary specialities with more than 1500 inpatient beds [Anon., 2006b]. The pharmacy department was well integrated into patient

care and worked closely as an integral part of the care team. This Trust supported a no-blame culture, with learning from incidents and hazardous practices.

The study Trust had comprehensive written guidance on prescribing and drug administration procedures [ORH, 1998] and guidance was provided in the 'Intravenous Drug Administration Guidelines' [ORH, 2002]. This A4 lever-arch file, available in all patient areas, contained an IV administration procedure, with individual monographs for each IV medicine used within the Trust. The information contained within the monograph was designed for use in conjunction with the medicine manufacturers' package insert, British National Formulary and Summary of Product Characteristics.

A comprehensive training programme was established for those registered nurses, midwives, operating department assistants/practitioners new to IV medicines administration. Separate training was provided in-house to radiography staff. Staff transferring from another healthcare setting into this Trust had to demonstrate competency in practice, before being permitted to administer IV medicines unsupervised. Doctors were not included in the in-house training programme, as this was considered to form part of their undergraduate curriculum [ORH.NOC, 2000].

Study design

Prior to the study, support was gained from the Pharmacy Department; Nursing Directorate; Trust Management and research approval was sought and granted. An application was made to the local research ethics committee [REC: 05/Q1606/22] but the committee decided this study was service development and therefore did not require ethical approval.

4.3.3 Data collection tool

A list of the variables required to assess whether an error had occurred according to the IVMPE definition and framework agreed in Chapter Three was prepared. This minimum data set was used to develop a data collection tool for the structured observation and recording of IV medicines preparation. The design of the data collection form was based on one used in similar research [Hoppe-Tichy *et al.*, 2002]. As this was to assess the suitability of the data collection form and not to assess the staff, personal information was not required; details of the staff observed and patient details were not recorded. A draft of the data collection tool [appendix 18] was pre-piloted by the researcher on a general

medical and surgical ward with the staff and manager's permission. Minor adjustments were made to the form to improve data recording before use on the study wards. The amended version is shown in figure 4.1. From the nurses interviewed [see chapter 5], it was estimated that on general wards each nurse did not prepare more than five doses during a 'typical' day shift. Based on previously reported error rates, it was envisaged that observing 20 IV medicines doses in area would be sufficient. A 13% hospital IVMPE had previously been reported [Taxis & Barber 2003a]. Therefore a sample of 20 doses from five clinical areas (100 doses) was considered a large enough pilot sample.

4.3.4 Sample recruitment

Practising Pharmacists based within clinical areas were asked to identify potential study areas and anaesthetists suitable for inclusion in this study. These pharmacists were aware of the numbers and types of IV medicines prescribed in their clinical area, the proportion of those requiring preparation in the clinical area, staffing levels and the physical environment used for IV preparation. It was important that study areas recruited had good working relationships between nursing and pharmacy, as this allowed support for the observers and appropriate follow up of any concerns raised during the audit.

Purposive sampling is defined as

> *"The identification and selection of particular individuals who share characteristics relevant to the study, and whom the researcher believes will be most informative in achieving their objectives"* [Smith, 2002;p.119].

This method was selected for the study to ensure that piloting was undertaken in a diverse range of clinical areas that frequently prepare IV doses. Random sampling was not necessary as generalisation or a representative sample was not required. Five clinical areas were selected for this study across a wide range of clinical settings. These included operating theatres, paediatrics, general medicine, surgery and critical care. For each clinical area, the clinical pharmacist who suggested the anaesthetist or area made an informal approach to the ward manager or nurse in charge to establish whether they wished to be involved with the study. This included consideration of local issues such as ward relocations, staffing etc. To prevent bias, the selection excluded those areas where staff that have come forward for inclusion in the lead investigators' other research.

Figure 4.1 Data collection form

CONFIDENTIAL
Product number (for coding):

Pilot audit data collection form for intravenous medicines prepared in clinical areas

Use ONE form per observed practitioner and product

Date: /04/2005 Observers initials:

Ward /department name: Site: Ch /JR / RI

Job title of practitioner observed:
Staff nurse
Team leader (nurse)
Sister/Charge nurse
Practice development nurse
ODP
Consultant
Other .....

Were hands visibly soiled before starting iv **assembly**?	Yes	No
Were hands **washed** before iv **preparation**?	Yes	No
Were hands cleaned with **alcohol/alcohol gel** before preparation?	Yes	No
Were gloves worn for preparation?	Yes	No

PTO to record observations....

Prescription details from drug chart, document exactly what is written/printed (record details AFTER observation)

Item prescribed (name and brand where stated)	
Dose and duration for infusions	
Route	
Time dose due (24 hour clock or state am/pm)	
Which section of the drug chart is it prescribed on	Once only As required (prn) Regular medicine section Infusion therapy PCA Other.....

Figure 4.1 Data collection form *continued...*

Observe dose prepared and record ALL of the following details

Start time (24 hour)	:		
Medicine (generic name)			
Brand name, or generic manufacturer			
Quantity & strength dose units selected			
Where had medicines been stored?	CD cupboard / fridge / drug cupboard/ other.....		
Within manufacturers expiry date?	Yes	No	
Tamper evident seals intact on **everything** assembled?	Yes	No, *explain...* Date opened? not stated /.....	
Visual appearance of all ingredients chosen acceptable?	Yes	No	

Diluent/solvent name	na / WFI / NS / G5 / manufacturer supplied / other.....	
Diluent/solvent volume	ml	
Addition & mixing appropriate?	Yes	No
Volume of mixed product withdrawn	ml	

Infusion/diluent name	na / NS / G5 / DS / H / other.....	
Infusion/diluent volume	ml	
Volume of mixed/ready diluted product added	ml	
Addition & mixing appropriate?	Yes	No

Filter device used?	Yes No	type.....
Additions made using na / needle-free system / orange, blue, green needle		other..... ...
Make of syringe used?	B-D / other type.....	

Product labelled with?	Patient name	Yes	No
	Medicine	Yes	No
	Dose	Yes	No
	Route	Yes	No
	Diluent/infusion	Yes	No
	Total volume	Yes	No
	Concentration	Yes	No
	Time made	Yes	No
	Date made	Yes	No
	Signed	Yes	No
	Check signature	Yes	No

Visual appearance of final product acceptable?	Yes	No
Any special precautions used (e.g. light protection)?	Yes *what?*.....	No
Clean technique acceptable?	Yes	No/unsure *explain why...*

Now record prescription details for this product overleaf...

In the selected areas, the lead manager/nurse was asked to consent to their staff participating in the study. They were given standard information on: the study aims, study dates, number of IV doses to be observed, invitation letter and participant study information leaflet. All ward managers agreed to be included. Practitioners involved in IV medication assembly and preparation in the selected clinical areas were approached to participate in the study. For convenience, eligible staff that might be working during the data collection period were invited to participate.

A wide variety of staff worked in theatres without a ward-based pharmacist. Therefore anaesthetists with established links to pharmacy were approached for inclusion in this study.

Staff needed to be familiar in their working environment to enable robust testing of the audit tool and so temporary staff were excluded. For convenience student nurses were excluded as permission from the School of Nursing would be required.

Exclusion criteria:

- Co-workers for the project.
- Student practitioners.
- Staff authorised to administer injectables that require no manipulation at ward level e.g. infusion fluids.
- Agency staff.
- Bank staff that are unfamiliar with the clinical area.

Inclusion criteria:

- Registered doctors, nurses, midwives, qualified operating department assistants/practitioners that prepare and administer IV medicines including regular bank staff.
- Clinical areas were sampled from the John Radcliffe, Churchill or Radcliffe Infirmary sites (this was due to the geographical location of the observers).

The researcher approached the anaesthetist directly with the study aims, study dates, number of IV doses to be observed, invitation to participate letter and study information leaflet. Potential ward participants were given an outline of the study through an oral presentation by the researcher at a convenient time and place e.g. at ward hand-over. An

invitation letter, consent form and written information pack were supplied to those eligible for inclusion [appendix 19-21]. Those interested in participating were asked to either place their reply slip into a sealed clearly labelled envelope placed on each study ward one to three weeks prior to data collection, or to contact the researcher by email or pager.

Observer selection

Healthcare staff, such as nurses and pharmacy technicians, that understand asepsis issues and undertake IV medicines preparation as a regular part of their job would be suitable as observers. Four Pre-Registration Pharmacists were recruited opportunistically as observers. These were familiar with ward-based working, the Trust prescription chart, local injectable information sources available in clinical areas, microbiology and asepsis issues.

Observer training

In order to ensure consistency the observers received standardised training in two main areas: 'best-practice' for IV preparation in clinical settings and observational data collection. The researcher trained them in observation which included the study aims and remit, ethical issues, data collection, and being objective, non-judgemental, perceptive, alert, unobtrusive. A skilled pharmacy technician with a background in aseptics and prior experience in similar data collection assisted with this training. A commercial manufacturer had undertaken observational research on IV preparation errors in Europe and produced a booklet on 'Good practices of I.V. preparation' [appendix 22] and CD training package 'Training module on Good Practices in IV Drugs Preparation' [Baxter, 2002, 2003]. Permission was obtained to use this material to train the observers. Finally, a range of IV preparations were demonstrated and data collection practised in a 'class-room' environment on 20th and 21st April 2005.

The pre-registration pharmacists were familiar with ward-based working and that errors cannot be entirely eliminated within healthcare, as this formed part of their routine work and training. As these observers may have had some concerns about the observation and data collection for example, uncertainty of whether they had spotted an error, this was addressed by training in the research method. In addition a daily debriefing of each observer was undertaken by the researcher.

4.3.5 Data collection

Written consent was obtained from those who agreed to participate in the study. Each observer introduced themselves to the clinical area, and negotiated convenient weekday times for data collection. Initial observations were used to familiarise the observer with practice and the clinical area when no data were collected. Once familiarisation was achieved data collection for the study commenced. Data were collected from April to May 2005, with continued observation in each clinical area until 20 prepared IV medicines doses had been observed. Where possible, doses were observed from more than one participant in each area. The observer watched IV medicines preparation and recorded data on the data collection form. They positioned themselves where they could see the preparation, but attempted to be as unobtrusive as possible. If the observer was unsure of how to interpret any of the details they has observed, they made details notes on the data collection form and discussed this with the researcher.

If the observer noticed what they believed to be a medication error of which the participant was unaware, they suggested to the preparer that they believed a possible error may have occurred. The observer then asked them to get the preparation checked by another qualified member of staff. If they believed this had the potential to harm the patient if administered, they informed the ward pharmacist. This would allow the pharmacist to investigate the event, and where appropriate follow the Trust incident reporting procedure. If the participant admitted deliberately harming a patient, the observer confirmed what they had heard. If this were correct, they would terminate the observation and immediately report this to the ward pharmacist.

At the end of data collection the observers independently recorded data on a variety of demonstration IV preparations, which included intentional errors. This was undertaken to establish whether recording was consistent and accurate. A group debriefing session was held on 2nd June 2005 with the observers and researcher to discuss any issues which arose with the methodology as well as suggestions for improvement. This allowed information on the suitability, practicability and appropriateness of the data collection tool to be gathered. This information was recorded by the researcher as hand written notes. Discussion between the researcher, demonstrator and observers of the differences between their recorded observations, along with issues arising during the analysis were used to

refine the data collection tool, see figure 4.2. This was piloted on demonstration IV preparations on 12th July 2005 to test for consistency.

4.3.6 Data storage

Data collection forms were stored in a locked filing cabinet within the pharmacy department and will be kept for ten years. A copy of the data entered onto the spreadsheet will be retained. This data will not contain any personal information and will be stored on the pharmacy server accessed only by a password.

4.3.7 Data analysis

During the analysis stage some of the categories required more explicit criteria in order to determine whether an error had occurred. These issues were: faulty labelling, where the minimum label requirements had not been set. Therefore these were analysed, as the medicine name and a dose or concentration were imperative. The error category that advocated that large bore needles used to withdraw solution from glass ampoules constituted an error fell into the equivocal category and was excluded from the error framework. During the development of the framework it had not been conceived that a solution would be withdrawn from glass ampoules directly into the syringe without a needle, so this issue was not addressed. However this was included as poor practice during the analysis. Other issues not previously identified as errors were reported as poor practice issues.

The data from each observation was entered on an Excel spread sheet. Twenty records were independently selected by a lay person and data entered checked to ensure the quality of data entry. The data were analysed to detect where potential errors occurred and categorised according to the IVMPE definition framework [Crowley *et al.*, 2004b]. These errors were then coded according to the NPSA NLRS data set for patient safety incidents shown in table 4.1 [NPSA, 2003b]. Descriptive statistics were used.

Field notes were taken by the researcher whilst training the observers, and during debriefing and feedback sessions. Content analysis was used to identify common themes.

Figure 4.2 Revised data collection form

CONFIDENTIAL IV Product number (for coding): ☐

Data collection form for intravenous medicines prepared in clinical areas

Use ONE form per observed practitioner and product, circle or tick appropriate response.

Date: day-month-year **Observer identifier:**

Ward/department name: ..... ***Hospital Site: Ch / JR / RI**

Patient identifier: ..... **Date of birth** ..... **Patient weight**.....**kg**

***Job title of practitioner observed:** (as name badge)
- ☐ sister/charge nurse
- ☐ nurse team leader
- ☐ staff nurse
- ☐ other.....

Were hands visibly soiled before starting iv **assembly** session?	Yes	No
Were hands **washed** before starting?	Yes	No
Were hands cleaned with **alcohol/alcohol gel** before starting?	Yes	No
Were gloves worn for preparation?	Yes	No

Comments.....

Now record observations overleaf...

(Include details of any errors that the preparer identifies and corrects below)

Prescription details from medicine chart *(Record only AFTER observing product preparation)*

Is the medicine you observed prepared for this patient prescribed? **Yes** **No**

If yes record exactly what is written/printed, do not interpret or alter details.

Name (generic name and/or brand)	
Dose	
Route	
Time dose due (24 hour clock, or state am/pm)	
***Other information** documented for this item e.g. infusion duration (include all information e.g. pharmacist annotation)	
*Which section of the drug chart is it recorded on?	☐ Once only ☐ As required (prn) ☐ Regular medicine section ☐ Infusion therapy ☐ PCA ☐ Other.....

Figure 4.2 Revised data collection form *continued...*

Observe intravenous dose prepared and record ALL of the following details

Start time (24 hour)	:	
Medicine (generic drug name)		
Brand name, or generic manufacturer		
Quantity & strength dose units selected		
Where had medicines been stored?	□ CD cupboard, □ fridge, □ drug cupboard, □ other.....	
Within manufacturer's expiry date?	Yes	No
Tamper evident seals intact on **everything** assembled?	Yes	No, *explain...* Date opened? □ Not stated / *(date)*
Visual appearance of all ingredients chosen acceptable?	Yes	No, *explain ...*

Volume of medicine withdrawn from original container?	□ None (dry powder), or .....ml	
Diluent type?	None / WFI / NS / G5 / DS / H / manufacturer supplied / other.....	
Diluent volume	ml	
Diluent added & mixed appropriately?	Yes	No
Volume of mixed product withdrawn/total volume?	ml	

Volume of mixed product used in next step?	.....ml	
Further diluent type?	None/ NS / G5 / DS / H / other.....	
Further diluent volume	ml	
Medicine added & mixed appropriately?	Yes	No
Final volume of mixed product?	ml	

*Filter device used?	Yes, type.....	No
*Additions made using (tick all that apply): □ direct into syringe, □ needle-free system, □ orange, blue, green needle, □ other	*Make of syringe used (tick all that apply): □ B-D standard syringe □ B-D insulin syringe □ other.....	

Product labelled (acceptable if product details are visible)?		Yes No
If yes, what information was recorded (tick all that apply)		□ Patient name
□ Medicine name	□ Diluent name	□ Time made
□ Dose	□ Diluent volume	□ Date made
□ Route	□ Total final volume	□ Check signature
□ Concentration	□ Signed	□ Other.....

Visual appearance of final product acceptable?	Yes	No / Unsure *explain why...*	
Any special precautions used (e.g. light protection)?	Yes *what?*.....		No
Clean technique acceptable?	Yes	No / Unsure *explain why...*	

Now check you have completed EACH box above, then record prescription details overleaf..

WFI=water for injections; NS=sodium chloride 0.9%; G5=glucose 5%; DS=glucose 4% & sodium chloride 0.18%; H=Hartman's solution * Details may require site specific adjustment. Data collection sheet, revised July 2005.

4.4 Results

A total of 68 IV medicines doses were observed by four observers, details of which are shown in table 4.2 below. On the general medical, surgical and paediatric wards, the majority of doses were intermittent antibiotics. Within theatres and critical care, more specialist medicines were seen which included bolus doses and intermittent and continuous infusions. Nursing staff undertook the IV preparation in all areas except the operating theatre.

***Table 4.2** Details of medicine dose observed by area and medicine.*

Clinical area	Observer Initials	Number of medicine doses observed	Type of healthcare staff observed	Medicine name	Number of doses
General Surgery	C, A, B	10	Staff nurses (all)	Cefuroxime & metronidazole Cefuroxime† Meropenem	7 1 2
Acute general medicine	C	18	Staff nurses x17, Sister x1	Cefuroxime & metronidazole Pabrinex™ Cefuroxime Omeprazole Benzylpenicillin Meropenem Flucloxacillin	5 2 7 1 1 1 1
Paediatrics	A, D	17	Staff nurses (all)	Co-amoxiclav Metronidazole Meropenem Gentamicin	5 1 6 5
Critical Care	A	12	Staff nurses x11, Sister x1	Cefuroxime Ranitidine Noradrenaline Metoclopramide Actrapid™ Insulin syringe	4 4 1 2 1
Theatres	A	11	Consultant (all)	Propofol & lidocaine Clonidine Magnesium sulphate Fentanyl Lidocaine Atracurium	2 2 2 1 3 1

† One dose recorded as cefuroxime only prescribed, but cefuroxime and metronidazole was prepared [S4].

4.4.1 Training the observers

After initial training, feedback from the observers suggested that they felt competent and ready to commence piloting. Comparison of their observations from the classroom simulation observations showed proficiency with observing and recording data correctly on the audit form. Some, but not all of the intentional errors were detected by each observer. The observers found the group discussion held after these observations very helpful. They

suggested that there was much for them to observe, with many intentional errors and this had limited their recording. They also found the 'unreal' classroom environment a hindrance. They advocated retesting after some real observation, and this simulation was repeated after the piloting.

The post-pilot simulation demonstrations showed an improvement in the number of errors observed and recorded. The observers felt more confident in their observation, particularly as they were now familiar with the data collection form. There remained some inconsistency between what the observers had recorded because in some cases an error had not been noticed.

4.4.2 Observations of IV preparation

Errors were observed in 27 (39.7%) of the 68 doses prepared. For six doses more than one error was noted. Most errors were due to wrong mixing and addition or faulty labelling. Details of the errors observed and their coding within the IVMPE framework, and NLRS are shown in table 4.3.

A few observations had some inaccuracies and these are described in the table footnote. However, as each of these observations was associated with another observed error. Therefore, this does not alter the number of doses with errors observed.

The intentional addition of lidocaine to the propofol was classified under wrong drug/medicine as anaesthetic practice is to record that the patient has just received propofol, where in fact propofol and lidocaine was administered. The lidocaine is used to reduce the pain associated with propofol administration at induction, prepared aseptically immediately before administration [Astra Zeneca Ltd, 2006].

In addition to errors, the observers also documented two areas of poor practice. These were extrapolating between the marked volumes on syringes. For example, doses of 5.25ml were measured from a 10ml syringe marked in 0.5ml increments [P45, P38, P42] and 9.56ml measured using syringe with accuracy to 0.5ml [P37, P34, P43, P44]. The other issue identified was withdrawing solutions from a glass ampoule directly into a syringe, without using a needle.

Table 4.3 Details of IVMPE observed (n= 68 doses)

NLRS category	**IVMPE category**	**Examples of error observed**	**Total number of errors with observation codes**
Wrong method of preparation	Wrong addition / mixing	Undissolved powder left in vial; air bubble not expelled before volume checked; not shaken; no mixing after addition.	16 errors: [S4[1], S5, S8, M13, M15, M18, M20, M23, M27, P35, P39, P42, P45, CC48, CC50, CC52, T66]
Wrong method of preparation	Wrong preparation technique	Unacceptable clean technique; re-use of single dose container.	2 errors: [S6, T58]
Wrong / omitted / passed expiry date	Expired / degraded or unknown expiry	Unsuitable appearance; glucose 5% tamperproof seal open	2 errors: [M24, CC50]
Wrong / transposed / omitted medicine label	Faulty labelling	Missing medicine name; missing dose.	9 errors: [S1,S2,S3,S7, M12,M15,M21,M27,T66]
Wrong drug / medicine	Wrong medicine	Cefuroxime & metronidazole prepared but cefuroxime prescribed; lidocaine added to propofol prepared but not prescribed.	2 errors: [S4[2], T65]
Wrong method of preparation	Diluent error	Prescribed 5ml final volume but made to 50ml.	2 errors: [S4[3], CC 50[4]]

S4[1]- recorded as acceptable mixing, but observer annotated that a clump of undissolved medicine was noted in the vial, recoded as an error; S4[2] - recorded as cefuroxime prescribed, however cefuroxime and metronidazole was prepared; S4[3]- data transposition error between 2nd diluent volume and volume of solution added; CC 50[4]- final volume of noradrenaline syringe prescribed documented as 5ml, possible 'slip' as usually 50ml.

Information on hand cleanliness before staff began an IV preparation session showed that no-one began preparation with soiled hands. However, hand-washing, using an alcoholic gel or wearing gloves was inconsistent. There are some commonalities with wearing gloves in adult medicine and surgery, whereas in theatres hands were always washed. This is shown in table 4.4. Where the observer was unable to determine what had happened, these were recorded as 'unsure'.

Table 4.4 Observed hand cleanliness before IV medicines dose prepared (n=68 doses)

Clinical area	**Were hands visible soiled before starting IV assembly?**	**Were hands washed before starting?**	**Were hands cleaned with alcohol / alcohol gel before starting?**	**Were gloves worn for preparation?**
General Surgery (n=10)	No = 10	No = 3 Yes = 5 Unsure = 2	No = 4 Yes = 4 Unsure = 2	No = 0 Yes = 10
Acute general medicine (n=18)	No = 18	No = 15 Yes = 3	No = 18	No = 0 Yes = 18
Paediatrics (n=17)	No = 17	No = 4 Yes = 11 Unsure = 2	No = 5 Yes = 12	No = 13 Yes = 3 Unsure = 1
Critical Care (n=12)	No = 12	No = 7 Yes = 3 Unsure = 2	No = 6 Yes = 5 Unsure = 1	No = 1 Yes = 9 Missing data =2
Theatres (n=11)	No = 11	Yes = 11	No = 7 Yes = 3 Unsure = 1	No = 9 Yes = 0 Missing data =2
Totals	No = 68	No = 29 Yes = 33 Unsure = 6	No = 40 Yes = 24 Unsure = 4	No = 23 Yes = 40 Unsure = 1 Missing data =4

4.4.3 Feedback from the observers

Analysis of the observers' comments identified four common themes, which were:

- Observation and aseptic training.
- Access to observe staff.
- Culture/blame issues.
- Data collection form issues.

Observation and aseptics training

The observers reporting feeling inexperienced in both observation and practical aseptic issues. They suggested that qualified pharmacist and technicians were ideally suited to undertake this audit because they had been taught aseptic theory. However, the observers found that this was not always easy to translate into interpreting practice. For example, was forcefully squirting a solution into an infusion bag adequate mixing? The pre-registration pharmacists had not yet visited an aseptic unit and they suggested that orientation or prior experience in an aseptic unit would be beneficial. In addition the opportunity for a 'practical hands-on play' with the same equipment that staff in clinical areas used would have been helpful.

The observers also suggested additional ward orientation, and time observing and familiarising themselves with the clinical area in advance of data collection. They advised that training should include the common drugs likely to be seen and common combinations used, so they would be able to anticipate staff actions.

Access to observe staff

In ward areas the ward sister was pivotal to the success of data collection as the nurses trusted and respected them. They acted as the 'gatekeeper' to negotiating access to observe staff. Observers reported a variety of ward attitudes, ranging from "very nice" to "brusque." In addition they identified the need for persistence to ensure they were able to maximise opportunities for observation. In some situations they felt they were intruding.

Although most of the medicines were scheduled for administration between midday to 2pm, this coincided with other ward commitments such as hand-over. Therefore it could be difficult for the observer to establish when IV preparation would occur. They suggested that ideally the data collector would be ward-based to avoid missing doses prepared and ensure they were present from the start of preparation. Some observers reported that when they arrived on the ward at the mutually agreed time to find assembly had already taken place.

Culture/blame issues

Some of the nurses appeared to be very nervous about being observed. One observer suggested they considered this a cultural issue. Despite awareness that the data collection tool was being tested, not the individual, some nurses asked the observer how they had performed.

Data collection form issues

The observers found data collection time consuming. They reported that it was easy to miss details during the observation since the procedures happened very quickly. In particular it was difficult to see the volume drawn into a syringe without being obtrusive. They commented that it was easier to collect data when the medication was checked by a second member of staff.

A number of suggestions to improve data collection were made. These were:

- Request that all the medicines and diluents are left out, rather than discarded to allow recording of expiry date details etc.
- Add an introductory paragraph to instruct the observer to record details of all errors noted and corrected by the preparer.
- Revise the drug labelled section to that if the details were already evident from bag they do not need to be written on label e.g. metronidazole.
- Consider revising the drug labelled section to allow recording of "not labelled but given straight away".
- Add a column for either washed hands or alcohol gel used.

Once the observers were familiar with the data collection form, they found it easy to complete. When conducting the audit they suggested the first five observations undertaken should be discarded as the observer may have missed events. As there were so many details to watch in such a short time frame they recommended observing the preparation first and then completing the form retrospectively. This would reduce the instances of missing data on the data collection form. Difficulties were reported with observation in theatres environment. These arose because the medicines were often administered without a prescription, which it was presumed was completed retrospectively. In addition where medication administration was recorded, it was on a separate document, the 'anaesthetic record' instead of the patients drug chart. This practical limitation has previously been identified [Wheeler & Wheeler, 2005]. At induction of anaesthesia many medicines were given in rapid succession and it was impossible to observe and record the detail using a separate data collection sheet for each medicine. It was recommended that the data collection sheet would need modification before it was suitable for use in theatre environment.

4.4.4 Analysis and coding of observations

During analysis it was apparent that weight should be included on the data collection form to enable clarification of correct doses in clinical areas such as paediatrics.

4.5 Discussion

4.5.1 Training of the observers

The observers were trained in two areas, aseptic technique for IV preparation and observational data collection. This posed several study limitations. Observational research methods were new to all observers who had little exposure to qualitative or social research methods. Therefore, they had difficulties understanding some of the intricacies of this method. Additional in-depth training and practice with observational techniques would have been beneficial.

Although the pre-registration pharmacists had received theoretical instruction in aseptic preparation, they had limited or no experience of this area in practice. It became apparent that theoretical training did not cover much of the knowledge and skills required to determine if minimum accepted IV preparation standards had been met. Therefore, additional training in aseptic techniques was required. This was provided by pharmacy technicians with experience in aseptic preparation. This was an important obstacle, as the observers needed to gain an understanding of the rational behind the practice to apply to the observation. It was important to demonstrate a variety of different methods, to familiarise the observer with aspects they might observe on the wards. The feedback from the observers highlighted that additional in-depth training was required. Therefore, it is recommended observers should either have recent training and experience within a pharmacy aseptic unit, or an orientation and assessment of competence in aseptics would be required in order to conduct the audit.

Ideally multiple observers would be used in the audit to minimise fatigue and attention loss during the long data collection periods. Inter-rater reliability could then be assessed before data collection [Dean & Barber, 2001]. This would highlight any inconsistencies which could be remedied to ensure the reliability of the data collected. Inter-rater reliability could also be checked during the data collection period as a quality assurance measure.

Previous work has shown that researcher and observer bias does not alter the overall medication administration error rate [Dean & Barber, 2001]. Comments from the observers highlight that at times they felt intrusive and inexperienced within the clinical environment. Therefore the presence of the observer and the research process may have altered the nurses' behaviour, introducing bias.

In addition the observers would have benefited from additional ward orientation and time spent observing IV preparation. Staff in the clinical area would then become used to the presence of an observer. At the same time the observer would become familiar with the environment, processes, common medications used and their appearance.

4.5.2 Feasibility of data collection

Recruitment into the study was slower than anticipated. This was in part due to the limited time when the pre-registration pharmacists could be released to undertake the observation. In general they were only available from 9am to 2pm. This meant they were able to observe doses due at 12 o'clock. However, they rarely observed any 'as required' doses or continuous infusions. In this study it appeared that doses were more commonly due on the morning or evening medicine round.

Despite reassurances that the study trust advocated a fair-blame culture, and that the study aimed to test the audit tool not the staff, it appeared that nurses were concerned about being observed. This identified the need for sensitivity and careful explanation before undertaking patient safety audits. This could be overcome using disguised observation. However, as audit findings would be shared within an organisation, it is important that participants were fully informed of the study aims. In addition, this supports the philosophy of an open and learning culture, central to patient safety [NPSA, 2003a].

The data collected contained the occasional missing value. Comments from the observers suggested that this arose from the volume of data recorded, particularly during early stages of data collection. Therefore, their suggestion of excluding some of the initial data collection forms so ensuring comprehensive data capture is recommended. To prevent missing data on the data collection form, the researcher could check the data collection forms at the end of each collection period and clarify any omission with the observer. In cases where the observer was unsure, detailed notes on the form enabled the researcher to interpret the observations.

The study identified the difficulty of data collection in the operating theatres using the audit tool. This was because practice differed from other settings in a number of ways. These were:

- At induction of anaesthesia a large number of medicines are given in rapid succession posing difficulties for observation [Fraind *et al.*, 2002].
- The anaesthetist is often the prescriber, preparer and administrator, in such cases a prescription is not required before the medicine dose is prepared, as The Medicines Act [1968] allows this to be documented retrospectively.
- Medication details are recorded on the anaesthetic chart, and not always written out in full, with abbreviations in routine use.
- The addition of lidocaine to the IV preparation immediately before use to minimise pain on injection.

These issues confounded data collection in this area. The differences in clinical setting should be incorporated into the error framework, as this could also apply in other settings e.g. resuscitation on a general ward. In this study the prescription details had not been recorded before the patient was transferred into the operating theatre, hence multiple missing data entries for this clinical area. Further work evaluating the best approach to gather data on IV medicines doses prepared is required. Consideration should be given to using multiple observers or using observation in conjunction with video recording. Such combined methods have been used during simulated paediatric resuscitation [Kozer *et al.*, 2004]. If multiple observers were used each observer could focus on a single medication. To ensure data were accurately observed and recorded it is unlikely that every IV medicine prepared could be included in the study, instead a sample of IV doses prepared could be captured within an observation period. An alternative strategy would be to collect information on the prescription once the patient had returned to the ward area and the anaesthetic record completed.

4.5.3 Pilot study findings

Errors were detected in 39.7% of doses prepared. This is higher than the 13% previously reported in a UK hospital [Taxis & Barber, 2003a]. The majority of errors were reported in the labelling or faulty addition and mixing categories. The data was mapped onto the NPSA NLRS medication categories, with the majority of errors assigned to wrong method of preparation (18 of 68 doses prepared). Previous work has also reported faulty reconstitution, addition and mixing to be a common problem [Hoppe-Tichy *et al.*, 2002; Wirtz *et al.*, 2003]. Inadequate labelling has often not been looked for in previous similar studies. One study reported 43% of IV doses prepared in UK hospitals contained some

type of labelling error, and that in 20% of cases where the label was missing or incomplete the dose was not administered to the patient immediately after preparation [Cousins *et al.*, 2005]. The findings from this pilot study support previous observational findings.

No attempt was made to assess the clinical significance of the errors observed, as this study was to assess the suitability of observational audit methods. However, most were likely to be of none or minor significance to the patient. The tool is suitable for use in conjunction with a previously validated scale to assess the clinical importance of observed errors where all errors are submitted to a panel of four practitioners to rate the severity outcome for the patient [Dean & Barber, 1999]. The panel would contain at least one of the following pharmacist, nurse and physician. Those selected would also has an understanding of the patient safety agenda and able to put potential incidents in clinical context.

Analysis of the data collected identified four values that appeared incorrect. In one, the observer had recorded acceptable reconstitution of a powder, but noted a clump of undissolved powder in the medicine vial [$S4^1$]. This was recoded as an error by the researcher, but without the annotation would have been missed. In another case the prescription details recorded were only for cefuroxime, but cefuroxime and metronidazole was prepared. It is unclear whether the wrong medication was prepared, or this was a data recording error [$S4^2$] as other problems were identified with this observation [$S4^3$] and data recoding [$S4^1$]. On another occasion the total volume of a noradrenaline syringe prescribed was recorded as 5ml. As this would usually be 50ml, it could either be a prescribing error or a data recording error. Patient identifiers were not required for the audit, so it was impossible to retrospectively verify this information. However, this information would be collected in a formal audit. Data appeared to be have transposed between two adjacent boxes, where one required the volume of second diluent added and the other the total volume of solution. This appeared to be a data entry error. In the last three cases, an error had been noted in another part of the preparation of the dose, so would not alter the number erroneous doses. However, it would have added three false errors to the total.

The extrapolations between syringe markings noted in paediatrics were small and would not have been significant enough to be greater than 10% of the required dose. Therefore, it was appropriate for these to be recorded by the observer as practice issues rather than error.

No-one started IV preparation with visibly soiled hands. Approximately half of those observed washed their hands before preparation, and about one third used alcohol gel to cleanse their hands. This contrasts with data previously collected in the UK in 2001-2002, where hands were never washed before preparation [Cousins *et al.*, 2005]. One explanation for this could be the national high profile *"Clean Your Hands"* campaign [NPSA, 2004].

4.5.4 Revisions to the data collection tool

A number of useful amendments to the data collection form were recommended by the observers, and implemented. During data analysis it was discovered that patient's weight had not been requested; this was needed to confirm weight based doses. This should be added to the data collection form. The data collection form was revised to include these details, and successfully retested by the observers on simulation IV preparations, shown in figure 4. 2

Piloting identified three issues that were not considered in the IVMPE framework. These were the preparation and administration of doses where the prescriber is also the preparer and administrator as in theatres. In such cases, preparing a dose without a prescription would not be considered an error. Another scenario that was not envisaged was withdrawing medication directly from a glass ampoule into a syringe. The scenario 'withdrawal from glass vials must be via a filter needle, or 19-gauge or narrower needle' was not considered the basis for an error by respondents in the previous study [see chapter 2]. From the observation in the audit it would have been relevant to ask whether withdrawal from a glass ampoule without using a needle, or similar device, would have considered an error. Lastly, the addition of lidocaine to the active medicine to minimise pain on injection had not been considered, so no agreement had been reached on how this should be documented. It is appropriate that all medication a patient receives should be recorded, including local anaesthetics.

4.5.5 Further work

To enable this audit tool to be used in other settings, further guidance would be needed to allow consistent use. This should include preparation of the following:

- Instructions to describe the information available to staff preparing IV medicines.
- Instruction to familiarise the audit team with organisational and local policies, procedures or guidance that cover IV preparation.

- Preparing a list of medicines where filtration would adversely affect the stability.
- Preparing a list of medicines with special requirements together with the requirement, such as light protection or plastic incompatibility.
- Modification of the final data collection form to include local information to minimise repetitive data entry, such as hospital site.

Standardised training material for the observers on IV preparation would ensure greater consistency. This could be in a variety of audiovisual formats, and could include guidance on good practice for IV preparation in clinical areas as well as error containing scenarios. Specialist advice could be sought to develop a database for data entry and analysis. All observed incidents should then be rated for the likely clinical outcome to the patient.

4.6 Conclusions

The audit tool has been validated for use in both adult and paediatric general and specialist ward areas. Refinement of the data collection form or method is required before use in a theatres environment. Observers undertaking this audit need training and assessment in observational techniques and aseptic preparation prior to use.

Chapter 5

Nurses' perceptions of intravenous medicines assembly and preparation in clinical areas - a medicines safety perspective

5.1 Background to study

The proposed research will focus on the preparation of those medicines that require manipulation in the clinical environment. This preparation stage is located between medication supply and medication administration. Intravenous medicines that require no manipulation in the clinical setting fall outside the scope of this study. Gandy and colleagues [2002] proposed that these stages should be termed assembly and preparation. The multi-professional derived definitions for both are detailed below:

Assembly is,

"*Gathering together on a cleaned tray, trolley or appropriate work surface, all of the items of equipment and pharmaceutical agents required for the aseptic preparation and administration of a medicines to a patient, whatever the form, route, and method/technique of administration*" [Gandy *et al.*, 2002;p.244].

Preparation is,

"*Preparation follows assembly. It is the procedure of using all of the assembled items in drawing up, mixing, combining or reconstituting the pharmaceutical agents, diluents and/or infusion fluids into the right form, combination and strength according to the patient's prescription sheet, and via the correct delivery vehicle/administration device. Preparation includes following clinical guidelines for the correct use of equipment*" [Gandy *et al.*, 2002;p.244].

However, an alternative definition of preparation has also been proposed

"*The manipulation of ingredients and components to make the final product*" [Clinical Resource and Audit Group/NHS Scotland, 2002; p.6].

Little is known of the steps involved with IV medicines preparation, concerns, difficulties encountered, and the sources of guidance or advice used by staff in resolving problems. A study to investigate the views, problems and solutions encountered by clinical staff in IV medication assembly and preparation on a practical level would be both timely and shed light on this poorly researched area.

5.2 Aims

The study aims were to explore nurses' views and opinions on the practical problems they have experienced during IV medication assembly and preparation in clinical areas, and to describe the solutions they used to resolve these issues.

Objectives

- To describe the steps in assembling IV medicines in clinical areas.
- To describe the steps in preparing IV medicines bolus and infusions in clinical areas.
- To elucidate nurses' perceptions regarding problems encountered during IV medicines assembly.
- To elucidate nurses' perceptions regarding problems encountered during IV medicines preparation.
- To establish nurses' perceptions of why these problems arise.
- To identify how nurses resolve these problems in practice.
- To establish whether there are links between intravenous training, competency and experience with regards to problem identification and resolution.
- To suggest how and where Pharmacy should prioritise its resources to improve IV medicines safety.

5.3 Study methodology

5.3.1 Research strategy

To elucidate nurses' views and opinions required a qualitative research method that allowed subjects to express their views freely and in detail. Face-to-face unstructured interviews were used as these allowed complex, sensitive and open-ended questioning, with the ability to probe and clarify issues [Frey & Oishi, 1995]. As an exploratory study, in-depth and extended responses were required. An ethnographic approach was used to enable understanding of the professional's views in their own clinical setting, and to allow the identification of previously unknown issues [Fetterman, 1998].

5.3.2 Study setting

Subjects were recruited from the two main sites of the Oxford Radcliffe NHS Hospitals Trust which provide a wide range of secondary and tertiary specialities for approximately 1,100 inpatients. Pharmacy is well integrated into patient care and works closely as an integral part of the care team. This Trust supported a no-blame culture, with learning from incidents and hazardous practices.

The arrangements for guidance on IV prescribing, drug administration and training were as described in section 4.3.2.

Study design

Prior to the study, support was gained from the Pharmacy Department and Nursing Directorate. Trust research management and local ethical approval was applied for and granted [REC 04.OXA.023].

5.3.3 Data collection tool

The researcher was trained in ethnographic and in-depth interview research methods following published methods [Spradley, 1979; Gillham, 2000]. Data were collected by unstructured in-depth ethnographic interviews between the researcher and a single subject. This type of method required skill, with particular attention to avoid leading the participant. It is important that the participant's meaning was clearly understood, without misinterpretation. Wherever there was potential confusion, clarification was sought. Probes and prompts, especially non-verbal and those communicating active listening were widely used. The researcher adopted the terminology used by the interviewee, and adopted a neutral mindset, so as to prevent introducing bias through verbal or nonverbal techniques [Spradley, 1979; Burgess, 1984; Gillham, 2000; Fetterman, 1998].

Designing the interview schedule

The interview schedule was designed to gather demographics and ask about key details about IV medication assembly and preparation identified from published literature, and then discuss issues raised by the participant. Its format was based on Spradley's [1979;pp.85-91] 'Grand Tour' descriptive questions which,

> *"Aim to elicit a large sample of utterances in the informant's native language. They are intended to encourage an informant to talk about a particular cultural scene"* [p.85].

This technique allows freedom within the interview, where the aims of the interview and the topics limits are agreed at the outset. The participant is allowed to direct the shape and format of their responses. The interview schedule acts as prompts on a checklist; this flexible approach permitted questions to be asked when appropriate, including varying the question order [Burgess, 1984].

Pilot interview

The proposed interview schedule was piloted on two nurses who worked outside the study Trust [appendix 23]. The schedule was amended in light of comments and feedback from

the interviewees, particularly to clarify the wording for the target audience, shown in figure 5.1.

(To be read by the interviewer before beginning the interview)
Hello, my name is Clare Crowley. I am the lead researcher on the project entitled: healthcare practitioners' perceptions of intravenous medicines assembly and preparation in clinical areas - a medicines safety perspective. This project is part of my PhD studies at Cardiff University. I am interested in your thoughts and opinions on these issues and would like to spend up to an hour to discuss them.

Thank you for your willingness to participate in this research project, it is very much appreciated. I plan to tape record the session, but will destroy the recording after I have completed my PhD research. I need a recording of your agreement to this so will start the recorder now.....

Just before we start the interview I want to reassure you have very definite rights.
First, your participation in this interview is entirely voluntary.
You are free to refuse to answer any question at any time.
You are free to withdraw from the interview at any time.
The interview will be kept strictly confidential and will only be available to members of the research team.
Excerpts of this interview may be part of the final report, but under no circumstances will your name or identifying characteristics be included in this report or any publication.

Please confirm that you understand that should you disclose that you have caused deliberate harm, or are aware of some one who has, but have done nothing about this I will terminate the interview? I am then required to start a trust incident report, which includes the serious incident policy?

I would be grateful if you could sign the consent form.
(Completed forms -interviewer keep one copy, leave other copy with participant.
Where consent not obtained, destroy form and audio recording and thank participant)

Then, shall we begin.....
If you have any questions or would like anything clarified, please ask me as we go along.
(Unlimited non-verbal and verbal probing and prompting at interviewers discretion)

First I would like some background information on where you work.
Which wards or departments do you work in?
What type of patients do you care for in your clinical area(s)?
In a typical shift how many intravenous doses would you administer to a patient?
Of these, how many would require some form of manipulation at ward level before you could administer them to the patient.
In a typical shift, how many staff would be eligible to do this?

Grand tour questions
This card contains definitions of intravenous medicines assembly and preparation.
(Give 'show card' with definitions on.)
Please take your time to read this, I am going to leave you to do that. (***Check*** – Have you had an chance to think about that? ***before proceeding***)
How would you refer to these processes?
Is that what most people would say?
Are there any other terms or names you would normally use?

Figure 5.1 Interview schedule

It is these areas that I am interested in, so I would like to restrict the focus of the interview to these issues.

What are the common stages in iv medicines assembly ***(substitute their terminology)***
How would you usually make an iv bolus dose in a syringe?
How would you usually make an iv infusion dose?
Can you recall the last five or so iv doses that you made on the ward?

Now I would like you to imagine that you are making an iv bolus drug in a syringe of your choice. Can you talk me through each of the steps that you would take, from reading the prescription through until you are ready to start administration? ***(if can't think of example suggest iv furosemide)***

Now I would like you to imagine that you are making an iv infusion drug of your choice. Can you talk me through each of the steps that you would take, from reading the prescription through until you are ready to start administration? ***(if can't think of example suggest iv antibiotic infusion)***

Mini tour questions:
What difficulties do you come across when doing these tasks?
Can you think of some specific examples you could tell me about?

How do you overcome these difficulties?
Can you talk me through two different examples you have been involved with, and show me how they were solved?

Typically, what sources of advice or information do you use?
Can you give me the names of the books, websites etc ***(use prompt from above question)*** that you refer to?

How long have you been preparing iv medicines for?
How did you learn your skills for assembly and preparation ***(use their words)?***
Can you describe in detail any training that you have undertaken about iv medicines?
Do you have any suggestions about how this could be improved?

What do you feel are the most important areas that should be looked into, to make preparing iv medicines easier?

What do you feel are the most important areas that should be looked into, to make preparing iv medicines safer?

Can you suggest some examples of how this might be improved?

Which drugs cause you a problem when making up?
Can you explain why this is?
Can you recall a specific example?

Can you recall the circumstances where you were most concerned about making up iv doses?
Could you explain why this is?

Do you ever ask for a colleague to check your preparation?
If yes, could you expand on when?
Can you give me some specific examples?

Figure 5.1 Interview schedule *continued...*

Are there any safe practices that have been put in place where you work?

Now I am coming near the end, are there any issues you would like to raise?

Within this Trust, please state your current title and grade for your main job.
What length shifts do you work?
Do you also work elsewhere?
If yes, please tell me about this...

Finally then, if it were up to you, what do you feel is the most important issue to tackle first?

Is there anything else you would like to add?

Thank you, you've given me a lot of useful material. I'm really grateful.
(Issue leaflet)

Probe reminders
What makes you say that?
You've lost me there, could you explain....
What exactly do you mean when you say "....."
How did you cope with that?
Let me see if I've got things in the right order...
What happened after that?
Tell me a bit about...
What were your expectations?

Prompt reminders (use bold ones first)
Interruptions
Ward staffing/nursing establishment
Nursing shortage/lack of registered nurses
Obtaining drug supplies
Priority amongst other nursing duties
Maths skills/drug calculations
Culture
Appropriate work surfaces
Induction process
Medical training

Figure 5.1 Interview schedule *continued...*

5.3.4 Sample recruitment

It was anticipated that the sample size would be small, ideally 20 subjects; a maximum of 50 subjects was set for feasibility purposes.

Subjects were recruited by an opportunistic sampling strategy. Consent was gained from the managers/nursing leads for each clinical division for their staff to participate in this study, with the potential service benefits to the Trust used as a motivating factor for their involvement. All divisions granted approval, and were asked to display poster advertisements in staff areas.

Inclusion criteria

Nurses involved in IV medication assembly and preparation in hospital clinical areas including bank and agency staff.

Exclusion criteria

- Bank staff that also work weekdays (8am-6pm) at the Radcliffe Infirmary.
- Expert advisors on the project e.g. IV therapy practice development nurse, and any colleagues aware of the lead investigator's professional role.
- Student practitioners.
- Those that practiced exclusively outside the hospital setting e.g. community midwives.
- Staff authorised to administer IVs that required no manipulation at ward level e.g. fluids.

As the researcher had worked as a clinical pharmacist at the Radcliffe Infirmary since January 2004, subjects that may have come into contact with the researcher in her professional role were excluded from the study. The researcher had attempted to preserve her research anonymity through avoiding visible working on the recruiting sites, including weekend and on-call duties. Recruitment to the study was slow; therefore a substantive study amendment was applied for to extend those areas eligible for inclusion to the care of the elderly wards at The Radcliffe Infirmary. Although this was granted, no one from this site was interviewed.

Posters were hand delivered to all clinical areas to be displayed in prominent staff areas e.g. tea room, requesting those involved in preparing IVs to contact the researcher for further information [appendix 24]. The poster was also displayed on the intranet. Potential participants who contacted the researcher were screened for study inclusion [appendix 25], and those eligible were sent a letter at their work address with details of the study, information; consent forms and a confidentiality form [appendix 26]. They were asked to indicate their willingness to participate on a reply slip. This was returned through the internal mail to the researcher care of the Pharmacy and Therapy Director's Personal Assistant to prevent coercion or bias. The researcher could also be contacted by a radio pager dedicated for this study. Each responding participant was then contacted at work to arrange a suitable date and time for interview. This was verified by telephone 24-48 hours before the agreed meeting in a manner convenient to the respondent.

5.3.5 Data collection

All interviews were carried out in a neutral, private area remote from both the participant's working environment and the pharmacy department. This minimised bias, background noise, and interruptions during the interview. On the John Radcliffe site the Patient Advice Liaison Managers office, located near the main entrance was used. At the Churchill site, a consulting room within the Hugh Ellis Paediatric Assessment Centre was made available. However, some participants were interviewed at an alternative location because of participant preference e.g. ward seminar room.

Information disclosed during the interview was anonymised. The only exception was to be if participants disclosed awareness of they, or another, causing deliberate harm. If this arose, the ethics submission indicated that interview would be terminated and the process outlined in figure 5.2 followed. Participants were made aware of this in the written information previously issued, and it was also reiterated before the interview started.

As the research area was a sensitive issue it was possible the participants might become upset or distressed whilst discussing issues. This was more likely if they realised during the interview that they had been involved or had witnessed a preparation error. Therefore, if the participant became obviously distressed the researcher would terminate the interview. It was intended that the interview guide would be modified in light of key themes identified from the interviews. No modification was required. Sampling was continued until no new themes emerged in subsequent interviews. Once this stage was reached two further interviews were performed to confirm theme saturation.

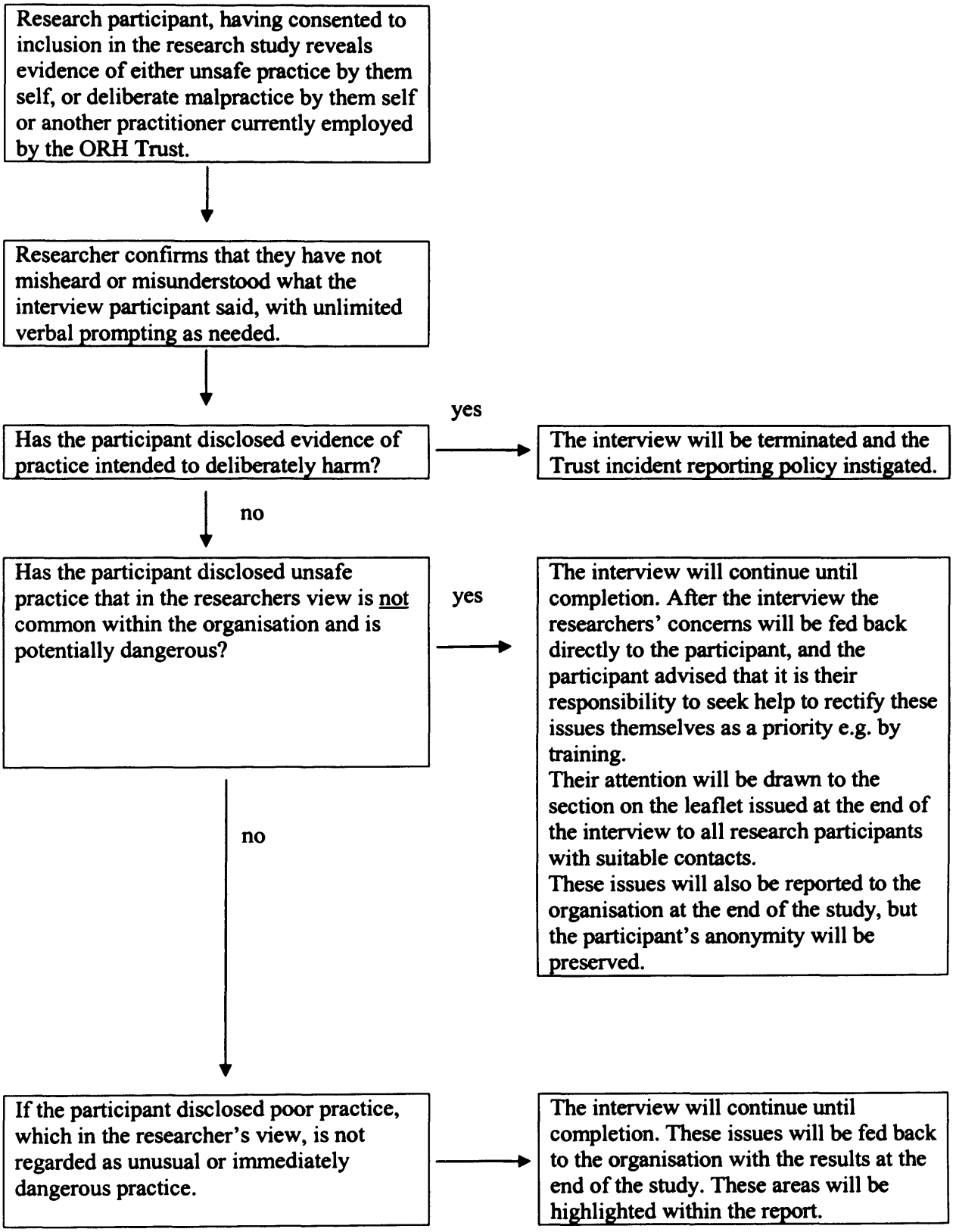

Figure 5.2 Procedure to be followed in the event of actual or potential disclosure of unsafe or deliberate malpractice by an interview participant during the research interview.

The interview

The interviewer confirmed that written consent had been obtained before the interview started, and verbally checked that the participant understood. They were reminded to ask any questions, or to ask for clarification at any stage. The researcher was able to make notes for use as prompts during the interview, and explained to the participant that this was to avoid interrupting them. To enable active listening and a verbatim record, the interview was audio recorded onto a memory card using a digital voice recorder (Sanyo ICR-B150). A leaflet containing general information on IV medicines assembly and preparation with practical tips was issued to each participant at the end of the interview [appendix 27].

5.3.6 Data analysis

Each interview transcript was downloaded to an ORH computer, with additional password security. The interviews were transcribed verbatim with respondents' details and clinical areas coded to preserve confidentiality. The coding data were kept separate from the transcripts. The audio recordings, transcripts and back up computer files were stored in a locked filing cabinet within the pharmacy department, only accessible to the researcher. Once the thesis has been completed and the degree awarded, these recordings will be destroyed.

The transcripts were imported into a computer assisted coding package [QSR N6], and qualitatively analysed using the 'framework' analytic approach [Ritchie & Spencer, 2002]. The key features of framework analysis are:

- Grounded or generative – developed from original accounts and observations of the participants.
- Dynamic – open to change, addition and amendment throughout analysis.
- Systematic – permits methodical treatment of all similar units of analysis.
- Comprehensive – enables full review of the data collected.
- Easily retrievable – allows between- and within-case analysis.

It is undertaken in five stages, with both concurrent and sequential working between stages. These are summarised in table 5.1. To ensure quality, the researcher's PhD supervisor independently validated the themes identified.

Table 5.1 Summary of the process of framework analysis [Ritchie & Spencer, 2002]

Sequence	Analytical stage	Description
1	Familiarisation	The researcher immerses themselves in the data collected.
2	Identification of thematic framework	Recurrent themes that emerge as important to those interviewed are recorded. A list of key issues, concepts and themes is compiled, with consideration of the research aims and emergent issues. This is iteratively applied to the transcripts and refined until the emergent and analytical themes are clear. An index framework with categories and themes produced.
3	Indexing	The index is systematically applied to the transcripts.
4	Charting	The indexed data is collated under its coded theme. For each theme a summary of each respondent's view is made.
5	Mapping and interpretation	Key themes arising from the data, charting from section 4 and the research aims are noted. The characteristics of each category's range, limits, commonality and divergence are recorded. Check for association, explanations and within and between respondent's attitudes and opinions. Suggest strategies for change.

5.4 Results

5.4.1 Recruitment results

A total of 19 nurses replied to the recruitment invitation, of which 16 consented to and completed the interview. Three nurses were lost to follow-up, one due to the unreliability of the internal post, one did not reply and the third went on long-term sick leave after agreeing to participate.

The nurses ranged from D to I grade with previous and current experience in a variety of clinical settings including general and specialist surgery, medicine, emergency and critical care environments caring for both adults and children. All respondents were female and had been preparing IV doses for between six months to over 30 years. Further demographic elaboration has not been undertaken as it could enable respondents to be identified.

5.4.2 Interview results

Thematic analysis of the transcripts identified three broad categories. These are described below:

- Description of the preparation process.
- Physical constraints on the preparation process.
- Issues that arise during the preparation process.

An overview of the thematic framework is given in figure 5.3

Category	The preparation process	Physical constraints on the preparation process.	Issues that arise during the preparation process.	Information and training
- Theme.	- Definitions. - Terminology. - Process described.	- Workspace. - Interruptions. - Time pressures and competing commitments. - Staff availability. - Unavailability of equipment. - Unavailability of medication. - Culture.	- Medicines specific issues (problems and solutions): *- Mathematics and measurement.* *- Reconstitution and mixing.* *- Operator caution.* *- Overarching issues* - Global solutions: *- Labelling.* *- Checking.* *- Presentation of the medicine.*	- Evidence of a training or competency deficit. - Skills and knowledge base. - Initial training. - Ongoing training. - Competency.

Figure 5.3 An overview of the categories and themes identified.

5.4.3 THE PREPARATION PROCESS

The nurses were asked a variety of questions to establish their views on the scope and components in the IV preparation process.

5.4.3.1 Definitions and terminology

During the interview definitions of IV medicines assembly and preparation were shown, and comments requested. The responses showed that assembly was not a concept used in their practice. Typical comments received are shown below.

I wouldn't quite call it assembly, its IV preparation, gathering your equipment the whole thing is a preparation of going on [N07:64-66].

...I don't think anyone would say assembly [N08:159-160].

It's not such a conscious action that ... it seems to come across as when it's written down as IV medication assembly [N16:112-114].

The nurses included assembly under the umbrella of preparation, as illustrated by the following comments:

...it just all comes under the one thing, preparation. You can't really split it down [N07:66-67].
I probably would call the whole lot preparation and not distinguish between one and the other. From start to finish I prepare it by getting it together and putting it together [N09:49-51].

The preparation of the flush solution(s) was described as an integral part of the preparation stage. The comments highlight that the boundaries of where preparation starts and finishes varied between respondents. A pre-preparation process was described which included evaluating the patient's suitability for medication, or establishing the patient's vascular access. The limits of where preparation finished and administration began were also discussed. Some typical examples are described below.

...depends if they've got IV fluids running or not. If they've IV fluids running the I'll get a 5ml flush if they haven't then I'll get a 10ml flush...[N10:135-137].

But it also takes on the patient condition as well, because sometimes before you even get to go and think of preparing a medication, you're already assessing whether the patient has allergies ..., whether they're suitable for medication. So why go and start preparing it if they can't have it? [N08:146-150].

I think preparation is quite a descriptive word. It describes the whole process really up to the point of actually administering, to me. I mean that includes the preparation of just immediately prior to infusing it at the bedside, or administering it at the bedside. So that would include the extra hand washing or hand rub, or clearing the bed space... [N03:77-82].

Respondents reported using a range of every day terms to describe assembly and preparation, summarised in figure 5.4. They did not appear to clearly distinguish the composite stages involved, but gathered them all under the umbrella of IV administration. The term the nurses repeatedly cited was 'drawing up'.

Draw up, drawing up, draw up the IVs	Mix, mixing, mix up
Get ready, get an IV, get together	Prepare, preparing
Give an IV	Put it up
Make up, making up	Reconstitution

Figure 5.4 Everyday terms that nurses used to describe IV assembly and preparation

5.4.3.2 Process described.

An overview of the stages the interviewees undertook when preparing an IV medication dose, starting from when it is clear a dose was required, until preparation was completed are shown in figure 5.5

When describing the steps involved in preparing a medicine dose it was apparent that there were common actions predominantly undertaken by most of the nurses interviewed.

However, in other areas there were inconsistencies in practice, as the nurses reported approaching similar tasks in different ways. One nurse eloquently described this as:

I think for the most part, I would say probably 90 to 95% of what we do is the same [N14:897-898].

Those interviewed identified a number of areas of controversy with respect to preparation practice. A typical example is described.

And there's always a bit [of a] *debate, you know, over whether you should clean things or you shouldn't clean them and what size needle you should use and things like that you know, but the Trust doesn't have a stance on any of that, ... its all about your own professional practice* [N04:532-536].

The nurses were asked to recount the steps involved in preparing an IV bolus dose of their choice. A summary of these, identifying areas of commonality and divergence is shown in table 5.2.

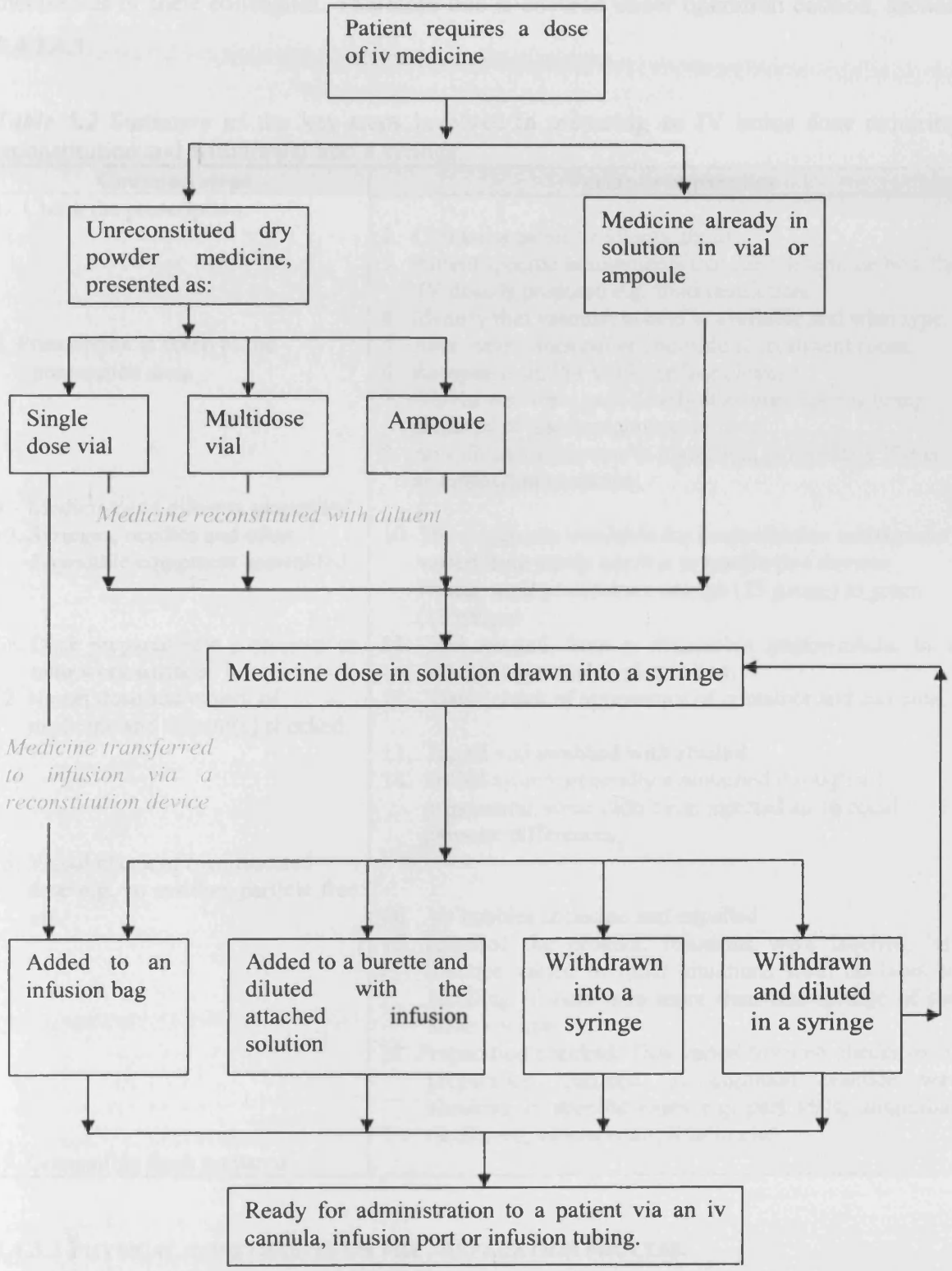

Figure 5.5 Schematic representations of different paths that may be taken in preparing on IV medication, depending upon the initial medicine presentation and intended method of administration.

The nurses interviewed revealed particular anxiety and concern about using needles during IV preparation. Most of this concern arose from a fear of needle stick injuries to

themselves or their colleagues. Therefore this is covered under operation caution, section 5.4.3.4.3.

Table 5.2 Summary of the key steps involved in preparing an IV bolus dose requiring reconstitution and withdrawal into a syringe.

Common steps	Variance in practice
1. Check the prescription.	
	2. Check the patient's allergy status.
	3. Patient specific assessments that may determine how the IV dose is prepared e.g. fluid restriction.
	4. Identify that vascular access is available and what type.
5. Prescription is taken to the preparation area.	5. Area varies from patient bedside to treatment room.
	6. Receptacle and/or work surface cleaned.
	7. Gloves are worn, particularly if an antibiotic is being prepared or glass ampoules are used.
	8. An information source is consulted, particularly if it is an unfamiliar medicine.
9. Medicine and diluents assembled.	
10. Syringes, needles and other disposable equipment assembled.	10. The equipment available for reconstitution and transfer varied from solely needles to needle free devices. Needle used varied from orange (23 gauge) to green (19 gauge)
11. Dose prepared into a receiver or onto work surface.	11. This ranged from a disposable papier-mâché to a designated reusable plastic tray.
12. Name, dose and expiry of medicine and diluent(s) checked.	12. Visual check of appearance of container and contents.
	13. Top of vial swabbed with alcohol
	14. Sealed system generally maintained throughout preparation, some didn't e.g. injected air to equal pressure differences.
15. Visual check of reconstituted dose e.g. no residue, particle free etc.	
	16. Air bubbles collected and expelled.
	17. Labelled the product. Infusions were labelled, but practice varied in other situations from no label to labelling if there was more than one syringe of the same volume.
	18. Preparation checked. This varied from no checks to all preparation checked. A common practice was checking in specific cases e.g. part vials, unfamiliar medicines, vancomycin, insulin etc.
19. Compatible flush prepared.	

5.4.3.3 PHYSICAL CONSTRAINTS ON THE PREPARATION PROCESS.

5.4.3.3.1 Workspace

During the interviews the nurses expressed numerous issues relating to the environment in which IV medicines preparation occurred in their clinical area. The nurses identified difficult situations and predicaments which they had encountered. Typical examples are given below.

Problems

... at the moment the area we prepare our IV drugs, is the same area we use to check controlled drugs, and the same we use to unpack pharmacy when it comes. So its one big work station, but we only got one work area that is flat and clean enough to use for preparing IV drugs, so its currently got lots of uses [N09:663-667].

...I don't like two lots of drugs on one table.... I think it's a recipe for disaster, we draw up so many drugs, any drug, that if I was drawing up metoclopramide and someone else put cyclizine on the side, I don't want to accidentally pick up their cyclizine while I'm drawing up my metoclopramide. I want to make sure my drug stays separate from their drug, to make sure I don't accidentally pick up their syringe... [N09:195, 199-203].

In an ideal world you would have a designated area for preparation of intravenous drugs [N01:567-568].

Summary: The respondents advocated a designated area for IV preparation. However, in reality some found that they prepared IV doses in conditions they considered less than ideal.

Solutions

Some examples of the ways in which the respondents had overcome the difficulty associated with no dedicated workspace for preparing IVs are shown below.

The main thing is space and if you've got more than one person making up drugs it's easier to come back and wait until later on, but that's not always practical [N09:188-200].

...some will come along while I'm in the middle of drawing something up and [someone] *come along and start something next to it. And what I tend to do then, is the tray I already got to one side, I put everything in the tray and then work from the tray then, rather than work from the work surface* [N09:212-216].

... the only solutions that you come up with was like to have another little trolley, that you like, like the patients bedside trolley which you say push over and then say draw up on there [N08:684-686].

So, sometimes you might take it all, what you require to the patient's bedside if there were too many people around... [N08:729-730].

...redesigned our treatment room and we just had basically kitchen units and kitchen surfaces put in. But it meant that we had long bench areas where someone could work one bench and you could work on another bench [N13:389-392].

Summary: The nurses acknowledged that a dedicated space for IV preparation was the ideal. However, in practice they had developed local solutions which partially addressed this limitation.

5.4.3.3.2 Interruptions

A common issue identified by the nurses as problematic were avoidable interruptions and distractions during the preparation process. These they identified as creating opportunities for error.

Problems

The nurses interviewed identified a range of problems created by interruptions, examples are described below.

Distractions I think are a problem because I think that's possibly when errors happen [N03:715-716].

I think they [interruptions] *are potential areas where errors could come in, 'cause if you can't concentrate properly ...* [N05:546-548].

I think a lot of it is being disturbed with either phone calls or other members of staff coming in. Sometimes there can be a lot of staff in any one area at any one time, and you're kind of; you know battling a bit for space. That's very dangerous because then you've got a lot of drug charts laid out in front of you, and that is an issue [N13:347-351].

... if you leave a tray unattended somebody could have put something else on that tray or taken something off that tray so, it's time consuming because you just have to go through the process of checking the bottles and the vial etc and everything again, so that you can be sure that what you are drawing up is what you intended to draw up [N03:360-374].

So when you draw up or prepare a drug for somebody that is number one priority and you've got to concentrate on that and not try and do six other things at once. But if you have to stop what you're doing, well you have to start again from scratch... You have to discard all that and go to the cupboard again and start absolutely from scratch... [N12:461-464, 466-467].

Summary: The nurses interviewed revealed that avoidable interruptions interfered with their concentration, and increased the likelihood of not completing the preparation task as intended.

Solutions

Several suggestions for minimising interruptions were given. Typical examples are described below.

I think the main bonus of it is having this admin person there who can just field things a bit for us, just for 5 minutes whilst you finish what you're doing, because it doesn't actually take you very long but it's not a good idea to be interrupted [N05:577-581].

... if you had a room that was solely designated to drawing up drugs and only had the equipment for drawing up drugs in there. People could assume that if the door was shut and you were in there drawing up drugs, that that was your job for that moment and not to disturb you [N03:380-384].

...maybe some sort of notice on the door saying please don't interrupt unless you have to... [N05:781-783].

If for instance I was drawing up a morphine infusion there's no way I would go to the telephone for that. I would just ask someone to phone back. So you just have to weigh up what you're doing with the need for being distracted or taken away from it [N03:391-395].

So there's always interruptions all the time and you have to be able to say "well no I'm doing this", but then you know it's going to take 10, 15 minutes to sort of draw it up, give it. It's just trying to stay focused and concentrate [N15:368-372].

I normally try and get a quite time to do things, or if it gets really pushed I'll say to someone else I've got all this to do, do you mind doing that for me or something [N10:356-360].

But then very often I won't start doing it, if I think I'm going to get called away. If I'm waiting for a phone call I wont go in treatment room and start drawing up antibiotics because there's no point if I'm going to get called away half way through [N09:466-469].

Summary: From the interviews, the nurses were aware that distractions could give rise to errors, and advocated several practical measures to minimise these including challenging non urgent requests for their attention, instigating 'no interruption' during drug administration and using clerical staff as an initial point of contact for queries in clinical areas.

5.4.3.3.3 Time pressures and competing commitments

Preparing IV medicines was just one of a wide range of duties that nurses were required to perform. The nurses interviewed recounted the need to prioritise their workload and manage IV preparation along with competing commitments.

Problems

Some typical examples of the issues the nurses confronted everyday are described below.

...one of the bigger problems is that sometimes the ward is just so busy that you are trying to juggle several different jobs at the same time [N03:360-362].

Time, is usually quite a constraint because there lots of other things going on at the same time, so the sort of the time that the IV drugs are due often corresponds with when you're trying to do other drugs as well [N15:238-240].

... you worry that one of these days you know there could be a mistake made because you are rushing and you shouldn't. It's not something that should be rushed but you feel that you do sometimes just to get everything done for somebody [N02:267-268].

... sometimes you know things have to be done at speed because they want the patient to have a, the drug now and they want to get them down to some department. There's a lot of pressure to do things very quickly sometimes. Um, sometimes, you know, if you are sort of fingers and thumbs because you're trying to do things in a hurry you can drop something, in which case you rather have to go back to the drawing board to wash your hands, to get another sterile syringe, needle, drug, whatever you know it breaks up the proceedings a bit and I suppose also the more of a hurry you're in and so on mistakes are more likely to happen [N12:438-446]

... the last few nights have just been overwhelmingly busy and therefore I've been quite late with my IVs. I'm very aware that it's quite late and therefore I am sort of, I feel myself under stress to get them out and in there, you know, as close as possible on time bearing in mind that you've got to give them again at 6am in the morning, so that makes me quite anxious. Being tired is a big thing, especially on night duty [N13:354-360].

Summary: The nurses reported that clinical areas are busy with a heavy workload, and that preparing IV medicines was a competing pressure.

Solutions

The nurses interviewed suggested a number of solutions to resolve the problems they experience with time pressures and competing commitments affecting IV medicines preparation. Typical examples are given below.

The main way round it, is you've got two members of staff on night shift who both do intravenous antibiotics then you can split it up between you, then you only do one or two each [N09:756-758].

What we do say to them is to delegate their intravenous things if they're busy [N09:830-831].

I think it's just time management on the nurses side to look at their charts and see what they've got to give and what time its got to be given and actually manage their time appropriately to fit it in [N15:454-456].

Lunchtime isn't as bad even though antibiotics are all due at the same time, one person will do them at half 12 and the other will do them at half one [N09: 225-227].

... our intravenous antibiotics are given at 6 o'clock in the morning, so is frusemide [furosemide] *given at 6 o'clock in the morning... ... any IV drug that's written up for 8 o'clock is given prior to the arrival of the day staff, so it gets actually given earlier than 8 o'clock* [N01:550-551,554-556].

So that's the oral drug round that shifted to the morning staff... And we're not doing both oral drug round and IV drug round as it were so that I think probably weighing up the pros and cons is probably slightly safer [N13: 760, 764-766].

... whether you had a cor.., pool team of IV administrators that came round to the ward and gave IV drugs? [N13:654-656].

... the only other thing that would maybe improve practice is if you had one person on that shift whose responsible for giving all the IV drugs... [N13:641-643].

Summary: The nurses provided a variety of suggestions to overcome the time required and pressures involved with IV preparation. These included delegating IV preparation and administration to another nurse on duty, reconsidering the scheduling of medicines administration rounds and reassigning this responsibility.

5.4.3.3.4 Staff availability

The nurses interviewed reported there was a shortage of suitably trained nursing staff, and this was a constraint on preparing patients' IV medicines.

Problems

Typical examples of staffing problems described during in the interview are provided below.

...wards are quite short [of nurses] *and we're forever lending to other wards* [N10:616-618].

Yeah tiredness is quite difficult actually. It's all right at 10 o'clock at night because that's your normal sort of waking sort of working pattern, but when you've been awake all night and often have worked during the day, which you will find with bank nurses happens all the time [N13:462-465].

... the girl I was working with on Thursday night had worked an early shift and was working the night shift, so that happens therefore, you know it will happen. It will get worse and worse as NHSP [National Health Service Professionals i.e. NHS bank staff] *are becoming increasingly unable to fill our shifts and therefore the ward will be relying on substantive staff to do it* [N13:468-472].

Summary: Those consulted reported a shortage of qualified nursing staff, and difficulties recruiting temporary staff to fulfil the nursing establishment. This shortage was considered to impact on the nurse's ability to prepare IV therapy.

Solutions

The only solution given was to increase staffing.

...lots more time, more nurses... [N10:616].

Summary: No solutions were given, with the exception of needing qualified nurses if IV preparation practice were to continue in its present format.

5.4.3.3.5 Unavailability of equipment

The interviewees highlighted problems with the availability and accessibility of the disposables e.g. needles, syringes. This posed a problem when they were required for medicines preparation and were not available, particularly during times of high usage.

Problems

Typical examples of the problems that the nurses recounted with missing equipment are shown below.

They [general hospital stores] *know what our routine stock would be but if our demands have been greater than our routine stock then they don't know that. ... We pre-empt that and say look we need extra this week or whatever. But then you run into problems with storage space, you know we don't have the space to store vast amounts of extra equipment, and because it then becomes a hazard you trip, you know you're going to trip over it, or store it in places that aren't particularly appropriate* [N03:414-416, 418-423].

When you've run out of needles or syringes and you have to go down to the store cupboard and to get them and bring them back up because somebody hasn't bothered? ... normally our night staff are very good and they fill it all up for us, but sometimes if it hasn't been done and you've run out or somebody's used the last one and not gone and got another box [N10:671-673, 675-678].

... you go to get something and you find that you've run out and somebody hasn't reordered it, that's always a pain in the neck. Umm it's often very practical things ... [N14:673-674].

And of course if you're waiting, then the patients waiting as well and that can be problematic at times too [N14:686-697].

Summary: The nurses suggested that to prepare patients' IV medicines in a timely manner, the disposable equipment needs to be readily accessible in the preparation area. In addition they need such supplies to be provided in a manner that could accommodate variable demand.

Solutions

The only solution one interviewee provided was to source it from another clinical area.

... waiting for it to come up from stores takes time, so we often go to the wards from either side and beg, steal and borrow it. [N03:403-405].

Summary: A nurse reported difficulties in obtaining equipment in a timely manner. Consideration needs to be given to managing peaks in demand for disposable equipment.

5.4.3.3.6 Unavailability of medication

The nurses interviewed in this study recounted problems when medicines were unavailable. They suggested that it often arose due to a lack or planning and foresight.

Problem

The nurses described the situation where they had become reliant on the availability of stock medicines. Typical examples are given below.

... the biggest difficulty is that you get there and somebody's used the last dose and hasn't said so, ... especially with the antibiotics is you have to give them every 6 hours to keep the levels up. So you're then having to chase pharmacy to get some more, you know which just takes time... [N04:238-242].

Certainly that happens a lot on the [Clinical area 22], *just because they're so many people that are on so many intravenous drugs and erm.... particularly at the weekends, there always seems to be such bad planning for the weekends. You would think by now everybody would have the weekends sussed and try and look at things on Thursday evenings and Friday during the day and say you know, have we got enough to see us through the weekend or not? But certainly I've had situations where you've gone to get something and its not there and err and then you have to spend time calling round to other wards and saying, you know have you got any of this? You know and can you spare us some, can you spare two because I'm going to give one now and one a 6 o'clock in the morning?* [N14:701-711].

... you quickly need to draw up an adrenaline infusion and you go to the cupboard and somebody hasn't restocked it. Umm it's been a particularly busy shift or something and they just haven't got there yet and then you have to run off and the pharmacy box hasn't been emptied for example..., you're rummaging though the pharmacy box [N16:566-570].

Summary: The nurses interviewed identified a lack of forward planning to prevent running out of IV medication prescribed, or routinely used in their clinical areas.

Solutions

The nurses explained that to resolve this issue, advance planning was needed, to prevent shortages. It was important that such issues were communicated from one nursing staff team to the next and to pharmacy colleagues.

...that's the last dose that I'm going to give for example and we need some ordering ... [N06:337-339].

It's [an] *individual's responsibility to think ahead. Not everyone does that, but it has to be almost ingrained to become part of a culture and thinking, right it's the weekend and we need to get, you know, Fridays the only day we get some antibiotics or some ranitidine. So let's order some more, and so it's just sort of thinking really* [N13:456-461].

We do have a daily, a pharmacist who comes round every day so if we run into problems with stock items then we generally report it to her and she'll try and speed things up to get us some up, or we can just take a patient prescription down to the pharmacy... [N03:434-438].

Summary: The nurses identified that an integral part of patients IV therapy is taking responsibility to ensure that medication for subsequent doses is available in the clinical area.

5.4.3.3.7 Culture

The nurses interviewed raised concerns about several cultural issues which they considered affected patient safety.

Problems

A number of difficulties were shared during the interview. These included the nurse's ability to ask questions, even if these were directed to a senior or more experienced colleague. They disclosed that they did not feel this aspect of a no- or fair-blame culture had been adopted, and that incidents were not universally accepted as opportunities for learning. Two examples of safety culture issues raised during the interviews are shown below.

...we're all too accepting of we come to work, and this is what we've been told to do. It doesn't mean that it's all right, it's like if somebody comes out and says that's OK you give it, and they're a very senior person. It takes a very long time to be able to learn that skill to be able to say no [N08:728-730].

...we say we're blame free but I think a lot of people, when they write their incident reports especially if you know, you're an adaptation nurse and you've come from another country

and you know they're terrified if they make a mistake they might be deregistered or you know have to go home, so you know, them writing an incident form is something they really have grave fears about the consequences, whether they're going to get into serious trouble, what's going to happen from this. ...for them to recognise that incident reports are there to help us [N08:1062-1069, 1075-1076].

Summary: The nurses had reservations about how embedded the safety culture was within the Trust.

Solutions

Those interviewed advised that incident reporting, and its potential value should be included in IV training.

I think it would be nice if we could get into a situation where we all realise that its better to tell everybody what you've done [N08:1054-1056].

One nurse reflected positively on their efforts to minimise interruptions, and demonstrated learning from those colleagues creating the distractions.

We've actually now started saying to the doctors "I'm sorry I can't talk to you at the moment you'll just have to wait a minute" [N05:555-556].

...and they're more used to it now and they will actually if they see that were busy doing something like that, they will actually just stand and wait [N05:559-561].

Summary: Those interviewed advocated further work to embed a fair-blame culture within the organisation, to enable staff working with patients to share any incidents and concerns.

5.4.3.4 ISSUES ARISING DURING THE PREPARATION PROCESS.

The nurses discussed numerous problems and potential issues that they had encountered during IV medicines preparation which related to a medicine or the physical task of preparation. These are summarised in table 5.3.

The problems identified were categorised into four major areas:

1. Mathematics and measurement – these centered on calculation tasks, many of which needed to be completed before preparation of the dose could begin.
2. Reconstitution and mixing – numerous issues associated with practical aspects of reconstitution, dose withdrawal, additions and pharmaceutics were incorporated into this category.

3. Operator caution – this encompasses issues where the operator had heightened awareness primarily due to health and safety issues or error prone packaging and labelling.
4. Overarching issues – issues encountered throughout the preparation process.

Table 5.3 Problems reported when preparing intravenous medicines†

Problem type	Details of problem	Example
MATHEMATICS AND MEASUREMENT	Calculation issues	Unfractionated heparin infusions, adrenaline, paediatric doses, weight-based dose regimens, iron infusions
	Weight based regimens	Vancomycin, gentamicin, aminophylline, infliximab, acetylcysteine
	Small doses	Insulin, octreotide, paediatric doses
RECONSTITUTION AND MIXING	Highly effervescent	Tazocin™
	Foams	Vancomycin, infliximab, streptokinase, ciclosporin, teicoplanin
	Heavy, so settles as a concentrated layer in the infusion	Potassium chloride, ciclosporin
	Difficult to accommodate the stated reconstitution volume in vial	Vancomycin, flucloxacillin, Tazocin™
	Time consuming to reconstitute	Teicoplanin, immunoglobulin, Tazocin™, dantrolene, clarithromycin, amphotericin, vancomycin.
	Vacuum packed	Aprotonin, glyceryl trinitrate, fluconazole, propofol.
	Require filtering	Abciximab
	Multiple vials needed to prepare dose	Gentamicin, acetylcysteine
	Light protection	Sodium nitroprusside
	Physical strength required	Withdrawing 50ml fluid from a 500ml infusion
OPERATOR CAUTION	Objectionable smell	Paraldehyde, acetylcysteine
	Stains	Multibionta™
	Toxic metabolite	Cyanide from sodium nitroprusside
	Similar names	Medicines starting cef... e.g. cefradrine, cefuroxime
	Needle use	Widespread but particularly used when adding to infusion bags.
	Similar packaging	Potassium chloride and miniplasco™ diluents, lidocaine and sodium chloride miniplasco™, different strengths of vancomycin.
OVERARCHING	Time consuming	Cefuroxime and metronidazole co-infusion, controlled drugs
	Unfamiliar	Infliximab, adrenaline
	Expensive	Infliximab

† To protect interviewee confidentiality the following examples have been taken from interviews N01-N16.

The nurses reported a variety of difficulties that arose with particular medicines. In some cases, they revealed that if they knew of potential difficulties in preparing the medication then they would approach the preparation task in a different way.

Some medicines appeared in multiple categories, such as vancomycin, gentamicin, infliximab.

5.4.3.4.1 MATHEMATICS AND MEASUREMENT

The nurses were concerned when preparing medicines that required one or more calculations in the preparation process.

Problems

The nurses highlighted the types of calculation that they found most troublesome. Examples are:

... I have to be honest and say that [in] *paediatrics all doses are based on weight and that terrifies me, absolutely terrified me* [N02:722-723].

I can work out drug calculation its not that I can't, but I don't feel confident in complex calculations for things like drugs specifically for children. When you go mmol per kg, mls per kg ... [N02:726-731].

...gentamicin I found a real problem because the prescriptions write up some astronomical amount like seven hundred and eighty or something like that and the vial that it comes in are actually mg, 80mg in 2mls and erm you know I'll be the first one to admit that maths has not always been my strong point and I find the calculation for that quite difficult ... [N14:1105-1110].

... if you're feeling rushed or under pressure, sometimes it can be difficult to calculate and your brain will just go, oh no! [N15:269-271].

Summary: Dose preparations requiring complex calculations, particularly weight based regimens, were a source of worry and anxiety for the nursing staff interviewed

Solutions

During the interviews the nurses shared different ways of overcoming this problem. Examples of these are given below.

I always check things like that with my colleagues; you know just to make sure that I've got the math [sic] *correct* [N14:1110-1112].

... we've got round the weight issues because we've all got little cards that tell us how much we need for what weight, which is fantastic, as you know you've got to draw up that many mls... [N02:633-636].

... an adrenaline infusion for a patient that was really, really sick and I really just could not get my head around the 1000 and the 10,000 and one in, and phoned up CCU [Coronary Care Unit] *and their senior nurse kindly came round and helped me with it* [N02:769-772].

Summary: The nurses interviewed were aware of the potential mistakes involved in calculation and described the additional safety measures employed to support their practice.

5.4.3.4.2 RECONSTITUTION AND MIXING

5.4.3.4.2.1 Foaming

The nurses described a phenomenon called 'foaming', which occurs when a medicine if shaken forms a froth which prevents accurate dose measurement. Sometimes this foam was produced reconstituting a freeze-dried powder. Many of those interviewed reported that teicoplanin was prone to this particular problem.

Problem

During the interview the nurses were asked to elaborate on the problems associated with foam production, some examples are given below.

And does the frothing cause a problem? [discussing teicoplanin]
Can do in that I think sometimes the dose isn't drawn up right, well not the total dose, if you draw up froth and you look at the vial and it looks like you've got your 2mls in there which is what you require, once it all completely settles you may actually have only about a ml in there. So [if] *people don't wait for that defrothing to happen then potentially you've got the wrong dose* [N03:631-637].

...you have your little vial of teicoplanin and you have your little vial of, I think its 3mls of water for injection and you don't think its going to be enough and your automatic reaction is push it in, put it in and push it in straight away and then shake it all, but you have to put in it a tiny wee bit and a time and roll it and then keep pushing it in and rolling it, pushing it in a rolling and it, and it just takes for ever and even rolling it and pushing it in if you roll it too quick or you push it in too quick it will just froth and you cant give it because you have to wait until it, you either have to throw it out or leave it for 20 minutes to get the froth down [N07:460-470].

... we give two thrombolysis drugs here streptokinase and tPA and the tPA comes with the vacuum things, and the transfer device and then you just whack one in and its mixing itself up as your getting the pump ready. Whereas this other stuff, streptokinase you're having to

mixing it up and you have to be really careful; cause it just bubbles and bubbles and bubbles if you're not really gentle with it. That's horrendous drug to mix, absolutely horrendous [N02:559-605]

Summary: Nurses reported that medicines known to foam are time consuming to prepare. Rushing such preparation in these situations only created other difficulties and took longer than cautious preparation in the first place.

Solution

The only solution that the nurses provided was to reconstitute the medicine slowly, an example of which is given below.

You just have to do it really, really, really slowly but it takes longer and the thing is you, another one of clinical area 2 pressures is the 20 minute, door to needle time so you have to get it out as fast as you can. So you're trying to mix it slowly but you want to do it quick at the same time. So it's a bit of nightmare drug to mix really [N02:599–605, 609-613].

Summary: For medications known to foam, the interviewees advised that the only option was to allocate time to reconstituting them slowly.

5.4.3.4.2.2 Difficult to withdraw dose

Injectable medicines are usually supplied as vials or ampoules in which is a liquid or dry powder. In the preparation process the medicine has to be withdrawn from its original container. The nurses interviewed identified that this task could pose difficulties.

Problem

One nurse described a particular problem encountered with ciclosporin. This is described below.

... with some of the solutions its very difficult to get all of the solution from the top of the vial, the ampoule, glass ampoule from the small hour glass bit down into the bigger bit at the bottom. It's quite tricky to get it go down there before you then snap it off. So sometimes you have to do it as a two part process draw it up from the bot...., from the bottom part of the ampoule and then draw it up from the top part [N03:343-349].

Summary: It was reported by the nurses that some injections were supplied to clinical areas in packaging that makes it difficult to prepare the IV dose.

5.4.3.4.2.3 Reconstitution issues

Many of the IV medicines issued to clinical areas were provided as dry powders, requiring reconstitution with a diluent before use. Nurses reported a variety of problems associated with this task.

Problem

Two typical comments were made about reconstitution, a characteristic example of each is provided below.

... as you dissolve it says put in 20ml. If you put in 20mls it creates such a large volume it won't fit back into the syringe again. So you either have to use a 30ml syringe, which most places, and we don't stock, or put 19mls in and draw it back [N09:697-700]

... sometimes depending on the antibiotics it can take a while to reconstitute. Umm when you've injected your sterile water it can take a while so you can be there agitating it for a while... [N16:602-605].

Summary: Nurses found that some IV medicines posed unforeseen problems during reconstitution.

5.4.3.4.2.4 Glass ampoules

The nurses interviewed had concerns about medicines supplied in glass ampoules.

Problem

The nurses reported difficulties with glass ampoules, they were particularly anxious because of the risk of self injury.

I've got bit of a thing about snapping off the glass vials ...because I've cut my hand a couple of times [N11:396-397, 399].

Glass ampoules are difficult to break sometimes not always but sometimes. Sometimes they're so easy to break that you're almost putting too force on a, too much force on them they shatter. They shatter in your fingers, which is why I wear gloves for doing that particularly. Some of them are very, very difficult to break [N03:312-316].

Summary: The nurses expressed concerns about medication supplied in glass ampoules for health and safety reasons.

5.4.3.4.2.5 Vacuum packed medicines

During the interviews, an issue that most of the nurses raised was difficulty manipulating certain medicines. In particular those that needed more than 10-20ml of diluent to be added to reconstitute a medicine caused difficulties during preparation.

Problem

The nurses interviewed found difficulties when attempting to withdraw some solutions from a vial, whilst at the same time maintaining a sealed system. This is illustrated below.

Some of the bigger bottles with bungs in, are actually very hard to draw the solution out of because of the vacuum [N03:641-642].

Summary: The nurses reported difficulties when withdrawing solutions from vacuum packed drugs.

Solution

Several nurses reported how they had overcome this problem by balancing the pressure differences inside the vial with the environment. Representative examples of this are shown below.

... in those instances I put a little air inlet in, so a tiny orange needle, just stick an orange needle in and it acts as an air vent and you can draw the drug up easier so they are quite tricky [N03:644-647].

... the interlink system is very, very good, in that you do have a fairly wide bore that makes it easier to draw up things, drugs that are in that kind of vacuum [N01:299-301].

Summary: Nurses overcame the problems associated with dose withdrawal from pressurised container can be overcome through balancing the pressure with the external environment.

5.4.3.4.3 OPERATOR CAUTION

Those interviewed shared concerns about using needles and the potential for needle stick injuries and advocated the need to change the way in which drug solutions are withdrawn into syringes from the manufacturer's container.

Problem

Nurses raised inconsistencies in practice with regard to the availability of vial access devices. This is illustrated by the example provided.

I can't quite understand how the same hospital, you know different sites in the same Trust is [sic] *using a different system I would have thought it would be standardised amongst the Trust, but its clearly not* [N11:1046-1049].

When questioned about why the nurses preferred needle free systems, they cited safety concerns. Typical examples were:

Just because you weren't handling needles so the safety aspect... [N10:608-611].

I'm thinking purely from a health and safety point of view [N16:872-873].

...the whole issue that I've talked about access to the containers and reducing the risk to the nurse as she's preparing those particular medicines. I don't like the system here on the ward I don't like using needles and would prefer that to change [N12:1230-1233].

...one of the concerns that I have is that if I'm working with antibiotics I don't to be splashed with them and I don't want...any contact with them, because the antibiotics not for me. ...if you use needles to do that process [reconstitution]*... You might end up with a bit of splash back using a needle to go into the vial or when you're pulling out* [N14:248-255].

Summary: The nurses highlighted safety concerns with respect to needle use and antibiotic aerosolisation, particularly when alternatives were available in some areas within the Trust.

Solution

The nurses revealed that some clinical areas used a needle free system called Interlink™, whilst others had encountered this on other wards or during prior employment. This was the solution advocated by some nurses to reduce needle use.

I would like a system where you don't have to use needles. [N10:571]

We had the needle less system which was better basically than having to use needles..., because you were less likely to stab yourself and any patient [N11:538-541].

If it's a glass vial, I think that's about the only time when you'd would use a needle then replace it with this plastic thing [needle free system], *or you'd need to use a needle say putting it into an infusion* [N11:568-571].

I'm not sure if they can really eradicate the sharps thing.... ...but as much as possible, if its being just lessened the use of needles and things it would be great [N06:673-677].

Summary: Those nurses interviewed advocated changing to needle free systems wherever possible.

5.4.3.4.4 OVERARCHING ISSUES

5.4.3.4.4.1 Unfamiliar medicines

The interviewees commented that when they were asked to prepare a new or rarely used medication this required concentration and additional attention to detail.

Problem

Some examples of their feelings when presented with an unfamiliar medicine to prepare are shown below.

... it's like anything I think, if you're unfamiliar with it and you haven't come across it before, it tends to be very, it tends to slow you up, quite a bit. But once you are familiar with it that obstacle is taken away [N01:329-332].

...if its something I've not come across before, if its something that I'm not familiar with, if its something new, then I would be concerned [N15:629-631].

Summary: Preparing unfamiliar medicines takes additional nursing time and resources.

Solution

Those nurses interviewed typically referred to the Trust IV guide when faced with an unfamiliar medicine requiring preparation in the clinical area. In specialist areas, they described how proactive training can circumvent this problem. Examples of experiences given by the nurses interviewed are described below.

...have an IV drug book, with sort of policies of how to draw them up etc on the ward. So anything that I'm not familiar with or use on a regular basis, always refer to that [N15: 629 - 642].

...the first time I started on [Clinical area 23], *the infliximab, that is quite specialist to* [Clinical area 23], *not many other place give it. So the first time I came across that somebody actually stood by me and went through it and taught me exactly how to draw them up, what to do, how to do it, how to give it, sort of step by step so now I'm confident with it. It's not a problem. But I do the same now for anybody else who's coming across it for the first time and teach them step by step because it's an unfamiliar drug* [N15:633-641].

Summary: When nurses have to prepare unfamiliar medicines, problems are minimised through local guidance being available in clinical areas and training for unfamiliar items.

5.4.3.4.4.2 Global solutions

Some of the suggestions given by the interviewees to overcome the practical difficulties they described could be applied to the whole preparation process, rather than solely to a specific medicine. Such global solutions were labelling, checking and review of the medicine presentation.

5.4.3.4.4.2.1 Labelling

The nurses interviewed all reported that they would label an IV infusion. However there was wide variation in practice with respect to IV bolus preparation. Some nurses described other ways in which they identified the boluses or flushes. Typical examples are provided below.

I label infusions; I don't label bolus doses unless I am in a position where I have two syringes of the same size with the two different drugs in them and I don't want to run the risk of not knowing which one I am giving. So I label those. Most common one for us is when you're giving morphine and you've drawn up saline as well... [N01:171-175].

...use the needle less thing for drawing up, and probably just leave the needle-less one in the saline, so I know which one, because their both 10mls effectively [N04:144-146].

... I think it's quite important that every-body's drugs, intravenous drugs like that are labelled with their name on. I just think it's a safer practice [N05:482-484].

I tend to put the patient's name on the bottom of the label, though our labels up here don't actually prompt you to, but I tend to. They don't have.., it seems very strange [N09:164-166].

[I label] *only infusions, because boluses you'd draw it up, check it with your colleague and administer it straight away...*
... if we were giving boluses of midazolam ... make it 1mg a ml so its easy to see what were giving, and then we would label the syringe and we'd have it there to give say 1ml or 1mg bolus at a time [N16:543-544,548-552].

... if you have to draw up a lot of drugs for the one patient. You draw it up, you label it, you draw the next one up, you label it. You don't leave it so you have a few syringes and think oh what did I put in that? [N01:534-537].

Summary: The nurses routinely labelled IV infusions and were aware of the potential for confusion when bolus doses were prepared with a flush. In these cases they used a variety of different strategies to enable identification of the IV medicine.

5.4.3.4.4.2.2 Checking

The nurses interviewed identified that although the local hospital policy did not require checking, there were a variety of situations where they would ask a colleague to check their preparation. Others used the local IV guide as a reference to check against, particularly in situations where they felt more vulnerable. Typical examples are shown below.

Potassium has to be double-checked. Obviously CDs, anything that is slightly out of the ordinary, anything that isn't, isn't one of our familiar, familiar drugs really... [N03:825-827].

...get insulin and heparin checked as well

Because it's such a concentrated small amount... [N03:833-836].

...heparin because it's a calculation and it's so you know again it's a very powerful drug, you get it wrong it can be life threatening ... [N03:839-841].

... if it was a cardiac drug I would definitely [have it checked] [N04:776-777].

... or if it's a calculation I would ask them to work it out. I wouldn't tell them what I worked I've out. I'd ask them to work it out just to make sure, so like as a double check that we'd come out with the same sort of numbers [N04:777-780].

.... if I'm feeling particularly tired like on night duty in the morning, I know I'm tired so I might actually check something [in the Trust IV guide] *whereas I wouldn't maybe if I was feeling not tired. Or if I was feeling very busy I tend to maybe check the literature more even though I think I know it* [N13:289-294].

...because I'm not very experienced, I always check the guidelines written up by the Trust to make sure that you know, I'm doing it correctly... [N14: 213 - 215].

Some of those interviewed identified concerns about the robustness of the checking process and what a second check actually entailed. Several nurses had reservations about the benefit of routinely checking all IV preparations. These ranges of opinions are illustrated in the example given below.

You don't have to double-check anything in this Trust... [N04:782-783].

... I think people just presume that you have, that you have got the right stuff you know and they just quickly look at it, you know so its not as robust as sort of sitting there and you both going through it together and you know, but I think research has shown that anyhow, that second checking doesn't really make a lot of difference. I think it's just a prudent thing to do... [N04:794-799].

... my opinion that a proper check would be literally that you hand over what you've prepared with like all the empty bottles and bits and bobs that you've used with the prescription and say can you check that for me please and then you go and stand back and don't have anything to do with it ... [N05:857-861].

I think the problem is that the persons that checking it has to have enough self-confidence that if they're not sure they will risk saying I'm not sure because they lay themselves open to being wrong [N05:875-878].

It's a culture thing as well because when you ask someone to check what you're doing you actually want them to confirm that your right, don't you really? [N05:898-900].

I'm not 100% convinced in my own mind that getting another qualified nurse to check a drug before you give it is necessarily another safety step, I'm not convinced [N05:836-838].

... if I'm drawing it up I've already double checked it myself, I don't feel the need to have someone else checking it. And it always concerns me that if I've got someone else checking it I'll not check it as well myself [N09:301-304].

I worry more about double checking someone else's things just in case they haven't checked it right beforehand. I sometimes think if they think someone else is checking it they do it quite blaze as they think oh somebody else will check that [N09:317-321].

Summary: The nurses interviewed were uncertain or questioned the benefits of routinely checking another nurses IV preparation. However, many did advocate a second check with specific medicines or scenarios where they believed errors were more likely.

5.4.3.4.4.2.3 Presentation of the medicine

From the nurse interviews it was apparent that medicines were provided to their clinical areas in a variety of different forms or presentations. Some preparations, such as parenteral nutrition and chemotherapy were supplied ready to administer to the patient. Others require several manipulations and/or calculations before the medicine was transformed into a ready to administer form. They found this process time consuming and it also created opportunities for error. Typical examples of the comments regarding the medicine presentation are shown below.

... the main risk would be people mixing the wrong fluid with the wrong drugs, or the wrong doses in the wrong volume. But I can't see a way that it can be got around, unless everything was premixed... [N16:935-938].

...like the gentamicin that's ready in solution ...the ready prepared ones are good. In that you haven't got that extra stage [reconstitution] *which is all very time consuming. ... It all*

takes time so you're down to the time element and the user-friendly... [N03:588, 579-580, 583-594].

... it would be lovely if it was premixed and just draw it back and you haven't got all the worry of mixing it in [reconstitution] [N07:871-873].

If they [antibiotics] *came in a vial already mixed and you just had to draw it up and give it to the patient, or it was in a syringe and you just gave it to the patient. That would be lovely...* [N16:899-901].

Ready dilute, that would, I think it would be much easier to check it would be ready reconstituted you'd maybe reduce the risk of error through the process and it would save time [N16:1028-1030].

... those little packs were they come with the water, you know like for tPA when you have a vacuum and you have the right amount of water and literally you just put the water in on one end and the powder and the other and they just mix up together like that. That's brilliant, ... its right dose, right amount and ... it just mixes so much better [N02:585-590].

... pamidronate which now comes with its own diluent in it. Its very clear pamidronate gets dissolved in 3mls of water because it comes with 3mls of water, so that's very clearly how it gets dissolved and that prompts people to know it must be dissolved because it comes with its own diluent. ...I think it takes away, takes away the margin for error [N09:591-597].

... we have emergency drugs that can be found in a crash trolley that are pre-drawn and they are very easy, 'cause you just grab it and check it and give it... [N01:235-237].

It would be easier if somebody else drew them up for use and that they came, arrived made. Or that they were made on the ward in a separate area but made by a designated person who was making them up and labelling them up so that they were there ready... [N03:671-674].

...if they were all pre-prepared and just arrived as something you could just click together and deliver, that would be nice [N08:864-865].

The thing that would be useful, would be to have the drug ready made in a way that you would have gone in and made it yourself, but if you provided it ready to go but in the wrong way that may not help at all [N10:664-666].

They [the hospital] *do pre-filled epidural syringes and also pre-filled PCA* [patient controlled analgesia] *syringes and they are more expensive, but if it stopped... drug errors and sort of maximised the nurse's efficiency ... there's a lot to be said about that* [N13:671-674].

... anything that can come ready-mixed, should be ready mixed. I think the less number of steps that you have to do; the less chance there is for a mistake. If it comes ready mixed then you can't mix it wrong, can you? [N05:731-734].

Summary: Those interviewed advocated that whilst nurses continued to routinely prepare IVs in the clinical setting, they would prefer presentations that required minimal manipulation before administration as it saved time and prevented errors. Alternatively some suggested that this task could be delegated to specific staff, so that nurses were issued with ready to administer doses.

5.4.3.5 TRAINING AND INFORMATION

Training, competency and information issues were raised within both the preparation process and problem medicines sections. These are discussed together below.

5.4.3.5.1. Lack of information or guidance on preparation

Within the study Trust the nurses interviewed revealed that the main sources of information they used to prepare IV doses were the manufacturer's package insert and the locally developed Trust IV guide.

Problems

The nurses interviewed explained that information provided by the manufacturers for those preparing medication was valuable, but needed to be in a convenient format for healthcare staff. Some commented that the information leaflet was not always supplied with medicines when dispensed from pharmacy. Illustrative examples of the problems this posed are described below.

... a couple of years ago you could go along and take out that insert if you weren't familiar with the drug and you could read it, it would tell you the indications, the contraindications. It would tell you how to draw the drug up, with solutions it could be mixed in etc., and how quickly to administer it; now it's a patient information leaflet. And it's an intravenous drug that a patient can't give themselves and I'm sure the idea is you hand them the leaflet if they are interested in having a read about the drug you're just about to give them. But they're absolutely no use to the person who needs to give the drug, and I don't understand the sense of it in that if you did give it to a person there is usually 10 doses in most of the boxes that we give, so you would have to take it back off of them again to give it to the next patient. But this..., it means you are wholly reliant upon, I know that Pharmacy in this Trust supply a book with the most commonly use intravenous drugs in it and they go through indications, contraindications, side effects and how to prepare the drug and how quickly to administer it. But there is no way it can cover every drug that is given [N01:351-368].

... if it's a drug that isn't individually boxed that comes up, in a white box from pharmacy [a repackaged dispensed item] *sometimes people take the* [manufacturer's] *information*

sheet out and they don't replace the sheet in the box, so its not always there...[N03:493-496].

...they're [information leaflet] *quite hard to understand, which is why I always go to our book* [iv guide] *that we have* [N15:596-597].

Summary: The nurses required information in a convenient, readily accessible manner to enable them to appropriately prepare medicines in clinical areas.

Solutions

The nurses interviewed routinely used the local hospital IV guide for information about preparing IV medicines. Where this information was not available, they relied upon a variety of other resources, ranging from more experienced nursing colleagues, to colleagues in other areas where the medicine was used more often. They also accessed the pharmacist during the working day as well as out of hours. Typical examples of the ways nurses sought information are provided below.

... it's easy in this Trust because this Trust has actually got a great big folder with every drug you're likely to give so it does make it a lot easier for us [N09:618-620].

... when I first started giving IV drugs there wasn't a book [Trust IV guide] *so that's been a major help because you used to have to read all the leaflets, we used to keep leaflets in a folder, for each of the drugs. But since the books come out that's been fab* [N10: 474 - 477].

...Pharmacy in this Trust supply a book with the most commonly use intravenous drugs in it and they go through indications, contraindications, side effects and how to prepare the drug and how quickly to administer it. But there is no way it can cover every drug that is given.... we have another two folders with protocols that we have put together for all the drugs that we use within [clinical area 3]... [N01:364-371].

...other members of staff that have been doing it, because you may not know, but other people might have used it... [N07:617-619].

... ring the senior nurse on [N10:426].

... sometimes certain drugs are used a lot more in certain areas. So maybe ITU use it a lot so I'd probably ring them and see what they say. ... Just speak to the senior nurse on, usually [N10:429-430, 432].

Tend to ask the pharmacist, ... there's the pharmacy information [Medicines Information] *if there any problems that no one else can answer* [N15:459-460].

... if its 2 o'clock in the morning and then you end up bleeping an on-call pharmacist... [N01: 377 – 378].

The nurses found other information sources were less useful when it came to advice on IV preparation. Examples of which are given below.

... the thing about the BNF [British National Formulary] *is its good but it's limited* [N01:379-380].

...it [the BNF] *doesn't tell you how to mix it up, how much water to put it in or anything like that, you have to go and source that from other places...* [N04:404-406].

I know that you can get information via the clinical intranet that would take me a bit of time to work our way around that, so I would use other resources first... and I would probably go to the pharmacist before I would go to the clinical intranet [N01:414-418].

...in my experience, don't trust a doctor when it comes to looking for whether it should be given neat or whether it should be mixed and stuff like that, I wouldn't, I would rather find out for myself via an alternative route [N01:401-404].

Summary: Routine guidance on preparing IV medicines was available in the hospital IV guide. Where additional information was required this was not readily accessible and was sought from other nursing colleagues or pharmacists.

5.4.3.5.2 Evidence of a training or competency deficit

During the interviews areas of inadequate training, or failure to apply these skills in practice were described. These portray the issues the nurses encountered in practice. Below are two scenarios, with the nurses' suggestions for how each dilemma was addressed.

Example problem and solution A

... it's quite common to see people pushing it [morphine] *in and you see, you know, a percentage of the drug dribbling out, and you know that that's not exactly the right amount...*
... sometimes if they just sort of put it [morphine] *in and the syringe is completely full* [with diluent] *they will loose some of their morphine and so the patients not getting as much.* [N08:382-384, 376-378].

... if you've got your 9mls of solution and you've 'drawn it down' and then add your drug, so you sort of make sure that it comes down a little bit, then inject it in and then bring it to the top [N08:374-375, 378-379].

Example problem and solution B

I think [what] *is desperately important is aseptic technique and cleanliness, keeping things sterile, clean hands, clean hands, clean hands ...sometimes when my patients are on wards here and I see nurses come up to, and you know, they don't wash their hands, and I find it frightening* [N05:711-715].

I would hope very much that any [training on] *IV drug mixing, reconstituting, whatever even just giving it involves a huge, you know, a really heavy session about aseptic technique and clean hands* [N05:718-720].

5.4.3.5.3 Skills and knowledge base

The nurses interviewed reported a great variability in the training provided to qualified nurses on IV preparation. It was suggested some of this could be explained by the time elapsed since registration, inconsistencies between training sites and also no nationally agreed curriculum. In general, the nurses explained there appeared to be little focus upon the preparation stage during formal IV training. Those interviewed had acquired their preparation skills from watching other colleagues and during subsequent practical supervision.

Problems

The nurses identified that preparation is rarely covered in the formal IV training process, as shown below.

...any focus on IV administration has always been on the drug you're giving, the side effects and how you give it. It's never been on sort of the whole process of checking that really, and how you draw that up... [N13:591-594].

Interestingly enough, [I learnt] *purely by watching other people and having a mentor, which are pros and cons aren't there? But nobody ever taught me how the, no one ever taught me the procedure of IV administration full-stop. It was not included in my training...*[N13:570-573].

...the Trust I trained in, they did go into quite a lot of details about mixing, about the preparation you know about the importance of, you know, keeping things clean and all that...[N04:505-507].

...I remember my lecturer saying to us "you know about how you could mix certain drugs with certain amounts of fluid" she said "but you all work in different areas it's too much to go into, it's in your book" [N16:836-838].

...having completed the [IV] *study day, then* [I] *had to be formally assessed with the mentoring watching you draw it up, going to the patient and watch me administer it, and assess me as safe and signed off* [N09:709-711].

And there's always a big debate, you know, over whether you should clean things or you should clean them and what size needle you should use and things like that, you know. But the Trust doesn't have a stance on any of that, ... it's all about your own professional practice [N04:532-536].

... as a student [nurse] *you watch and depending on where you are you can practice* [N07:660-661].

...I'm sometimes concerned that because people aren't taught the practicalities of it, that they're just, one scenario fits all, which it doesn't [N04:600-602].

Summary: Training for IV medicines preparation was either rarely covered or not included either at undergraduate level or during hospital IV training.

Solutions

Typical examples of the suggestions given by the interviewees to resolve these training issues are provided below.

I would say the IV study day should include actually being shown how to draw it up and how to, things like keeping the syringe attached to the vial so your not breaking the system twice... [N09:559-569].

I think more emphasis on the actual preparation would be good ... ...having more of a policy on how to draw up and much more clearer, rather than just saying add saline to this [N02:498-500].

...be useful just to as part of your training, spend about an hour. Even if it is just with syringes and needles drawing up saline, mixing it with antibiotics, drawing out of glass vials, getting used to the feel of it, because when just qualified you're quite nervous about it anyway because, you know you've been bombarded with you know I could give drugs to patients, they could have an anaphylactic reaction, they might arrest. So your nervous about doing that anyway and then you've got to get used to umm the feel of drawing drugs up. It's just a whole new way of manipulating a syringe [N16:852-860].

...having more of a policy on how to draw up and much more clearer rather than just saying add saline to this [N02:499-500].

Summary: The interviewees considered that practical, hands-on training should be provided for nurses undertaking IV preparation. Such training would provide nurses with the skills and knowledge that could be readily transferred into practice, and would be realistic and achievable in the clinical setting.

5.4.3.5.4 Initial training

The nurses also described concerns they had with the undergraduate nursing curriculum.

Problems

The issue of when and how the training was delivered arose. There was concern that the impetus to increase the number of IV trained staff might lead to student nurses qualifying and being expected to prepare and administer IV medication from the outset, i.e. as soon as

they become registered. Those interviewed considered this unrealistic, and suggested that it should be addressed as a post registration nursing competency.

... they wanted student nurses to come on to the ward from their training fully trained up in IV drugs and administering them. And I have personally grave concerns about that... [N13:777-779].

I think that the newly qualified nurses should be busy running their patient workload not trying to do intravenous antibiotics and extending the role at the same time [N09:793-795].

At the moment we're kind of squeezing IV therapy in amongst everything else. ...I think [N13:827-828].

From their responses, the nurses interviewed described different experiences and exposure to IV preparation during their pre-registration training, depending on their mentor and clinical setting.

... as a student [nurse] *you watch and depending on where you are you can practice* [N07:660-661].

Concern was expressed by the interviewee's about ensuring that training was practically focused, and reflected the work-based needs.

...I'm sometimes concerned that because people aren't taught the practicalities of it, that they're just, one scenario fits all, which it doesn't [N04:600-602].

...it's just the thing of; if you're faced with a drug you know how do you practically? How do you go from the drug in the vial to giving it to the patient? You know what are the various options? How do you find out? That, that part of the training, so then when people take that into the practice they're automatically thinking right this is the drug, how do I find out how to, you know what are my areas, sources of knowledge you know, and what is good practice and what isn't...? [N04:840-847].

Summary: Some of the interviewees recommended that training needed to provide nurses with the skills and underpinning knowledge which could be readily transferred in practice. Training also needed to be realistic and achievable in the clinical setting.

Solutions

The general sentiment, shared by respondents, was that nurses needed some time post qualification before undertaking IV duties. A typical quote is shown below.

I do think that people should be qualified at least 6 months before going ahead to do intravenous administration post-registration [N09:813-815].

Summary: The interviewees recommended that nurse IV training should be provided several months post registration.

5.4.3.5.5 Ongoing training

Problem

The nurses identified that once trained; there was no follow up training or a re-certification process. An example of their views is supplied below.

There's no update, there's no sort of going back through and just reminding... just going back through the basics really... [N02:677-678].

Summary: The nurses reported that no formal ongoing training on IV therapy was provided.

Solutions

The nurses interviewed made several suggestions about ongoing training and also how this could be delivered.

... maybe something like that [an IV update] *would be quite nice to keep things fresh in people's minds...And maybe that's a way of picking up... ... if they're not that competent, or there is a problem... Its one way of picking it up and it's a safeguard for the Trust...* [N02:678-679,683, 684-685,687].

...if there was a link person on the ward that went on regular updates and then fed back to the staff. I mean we tend to have link people for most things... [N15:498-500].

... educational board that would sort of sit on a ward for a month or two and you would bring that up with kind of a couple of on the ward workshops to sort of improve that [N13:610-612].

...whether there should be more emphasis from ... each divisional professional development nurse? [N13:627- 629].

Summary: A variety of suggestions by the interviewees for updating and educating staff on IV issues were given.

5.4.3.5.6 Competency

Some of those nurses interviewed drew on previous experiences and advocated that competency needed to be demonstrable. Some clinical areas had introduced local competency assessments, to standardise practice.

Problems

Typical examples of the comments received are described below.

... part of that training involved doing a practical assessment on drug administration, which is something I think is severely lacking from project 2000 onwards... I would be an advocate of going back to the old style training and have it as a practical assessment that if you fail that, you cannot pass your training and register [N01:276-278, 819-822].

I think they're right in this Trust with saying, just having done the study day doesn't mean that your competent, and so its good to have these competencies signed off [N11:484-486].

Something which we do which encourages safe practice is that any-one to work on here, regardless of which Trust they've come from gets assessed when they work on the ward [N09:769-771].

Summary: The interviewees identified that competency assessment in the workplace is beneficial as it allows identification of problems. Further investment in competency assessment could make significant improvements.

Solution

A few suggestions were provided by the nurses to resolve competency issues. They are illustrated by:

[Where competency was not demonstrated] *... I would much rather they went through our own Trust training, that clearly their training; their previous training wasn't the same as ours. ... they repeated our Trust training, but up until then they get supervised* [N09:779-782].

...to have an annual drug assessment... I feel as though that that would be a very good idea [N08:761,763-764].

Summary: The nurses interviewed provided limited suggestions to address competency issues. However, revalidation or supervised practice prior to undertaking the Trust IV training was suggested.

5.5 Discussion

This study examined nurses' views and opinions on the difficulties they experience whilst preparing IV medicine doses in the clinical area. It then sought an understanding of why they thought these issues arose and how they could be resolved.

The findings show that these problems can be broadly divided into two categories: environmental issues that constrain the nurse's ability to prepare IVs and the problems that arose with the medicine or associated with the specific preparation.

5.5.1 Study limitations

Participants were opportunistically recruited to the study, and may represent those with an interest in IV therapy or patient safety. Sampling continued until theme saturation; however staff who did not volunteer for this study may have held different views and opinions. Ideally staff would have been randomly selected by grade and then by speciality. The data from qualitative studies are never generalisable, but this method of recruitment would have maximised the chances of scoping each category identified in the framework analysis, and might yield additional categories. It was apparent that the full characteristics of each category: range, limits, commonality and divergence may not have been fully elucidated where there was only one solution identified e.g. staff availability. The study was restricted to nurses since it was exploratory and they perform the majority of ward based IV preparation. Other staff that prepare IV medicines such as midwives, anaesthetists, doctors could have been recruited, and it would be interesting to compare issues other staff groups raise with the nurses' views.

One limitation of the interview approach is the participants can only raise issues which they are aware of and their discussions may not truly reflect how they behave in practice [Savage, 2000]. Some of the nurses interviewed struggled to visualise a preparation, to enable its step-by-step description. One solution would have been to use simulation, but participants' behaviour still might differ from practice. In addition, respondent fatigue would have become a problem if this lengthened the interview. These limitations could be overcome by field observation in the clinical environment. Other researchers employing informal discussion whilst undertaking disguised or direct observation of IV preparation and administration cite similar limitations with this study methodology However, in those studies direct observation did not allow in depth exploration of issues and was restricted to those preparations observed [Taxis & Barber, 2003a]. It is increasingly difficult to justify disguised observation methods; similar research has been performed with an undisguised approach [Tissot *et al.,* 2003]. It would appear that by combining the findings from each study method the limitations of each may be addressed. This is known as 'triangulation'

and is widely used in health services research to gain different perspectives on phenomena and to assess the validity of data [Smith, 2002].

Recruitment was slower than anticipated; this appeared to be due to problems with releasing staff from their clinical duties, low organisational morale and fear of discussing this sensitive area. If staff had been personally reimbursed for attending the interview this might have improved recruitment. Although midwives were approached for inclusion in the study, none volunteered. Their inclusion may have altered the findings of this study. It is important that participants' reservations about openly discussing hazards and incidents are not underestimated. The requirements for the participant information sheet may have raised concerns that participants had not even considered e.g. 'your employment will not be affected in anyway'.

5.5.2 The preparation process

It is interesting to learn, from the nursing perspective, that IV preparation is a continuous task and includes assembly and preparing the dose and any flush solutions required. This differs from the work undertaken by Gandy and colleagues [2002] to ascertain common nomenclature for parenteral aseptic medicine preparation within pharmacy and on wards. Their findings clearly differentiate between assembly and preparation, and no reference is made to preparing flush solutions. They do acknowledge that assembly meant very different things to nurses compared with pharmacists, but found nurses did use the term when gathering various components for administering drugs to the patient. An explanation for this could be the attempt to establish a commonality between pharmacy and ward terminology. With pharmacy aseptic dispensing, the assembly and preparation tasks are clearly differentiated and may even be undertaken by different staff. In addition medication provided from pharmacy in a ready to administer form is not supplied with a flush solution. This may be because the pharmacy service is not provided at the point of patient care. The type of flush solution, if one is needed, is governed by the vascular access device that the medicine will be administered through and concurrent IV fluids, clinical context etc. Therefore this information is patient specific and will vary within the patient's hospital stay. These issues highlight differences between aseptic preparation in pharmacy and clinical areas, and suggest that it is not possible to adopt uniform nomenclature for both settings. This is problematical as different healthcare staff use different terminology and understood different things by the same term. This raises important issues, as in order to

establish inter-professional dialogue to address preparation concerns, it is vital that everyone understands the terminology and uses it in a consistent manner.

It has been suggested that the preparation process ends with a ready to administer dose with parenteral giving set attached and infusion device available [Gandy *et al.*, 2002]. This is broadly congruent with the interviewees' replies. However results from the interviews suggest there is an additional step, before assembly, which has not previously been identified. In this step the nurse considers the clinical context of the patient, what vascular access the patient has and makes decisions which influence how they prepare the dose e.g. bolus for administration via a central route or peripheral intermittent infusion. This 'pre-preparation' stage needs to be included within the IV medicines use process. However, nurses in the study did not readily identify with the term 'assembly'; it would seem pragmatic to combine the assembly and preparation tasks under the broader preparation term. Preparation should also include the drawing up of appropriate flush solution(s). This differentiation into preparation and administration already breaks down a process that nurses tend to group under the overarching heading of administration [Dougherty & Lister, 2005]. Gandy and colleagues [2002] used different terminology which was the start of the 'aseptic process' where for nurses this begun with hand washing before preparation. It would appear that a profession understands itself, but this is not shared across professional boundaries.

When the interviewees' description of the preparation process is compared with professional nursing standards there are deviations from those standards. These included employing good hand washing and drying techniques, maintaining a closed preparation system wherever possible, inverting the container a number of times to ensure mixing, adequate cleaning of additive ports of infusion bags and the tops of medicine vials and ampoules [Dougherty & Lister, 2005; Royal College of Nursing, 2005]. It is of concern, that those interviewed did not adhere to their professional standards for IV preparation and administration; further investigation of this is warranted. One possible explanation is that the nurses do undertake these tasks but failed to describe them at interview. This could be validated by direct observation of the nurses. However, this would not explain all deviations, as upon direct prompting about some of these issues the nurses shared and justified their routine practice e.g. not shaking a minibag after adding a reconstituted antibiotic powder.

5.5.3 Physical constraints on the preparation process.

The nurses interviewed identified the following environmental issues that hindered their ability to prepare IV medicines: inappropriate workspace, interruptions, time pressures, competing commitments, inadequate staff, the unavailability of medicines or equipment and cultural issues.

In the largest published study of its kind, from Japan in 1989, 2,800 IV medication incidents and near misses without resultant patient injury were analysed to determine the causal factors [Kawamura, 2001]. Eight major causes of IV injection errors were identified, of which three are similar to this study's findings. These were:

1) Interruptions in the middle of tasks. Staff caring for multiple patients requiring simultaneous yet different interventions combined with frequent distractions.
2) Crowded workspaces and inaccurate mixing processes. Where workspaces were being used for tasks other than IV preparation and were poorly designed. Deficiencies in the preparation procedures were identified e.g. multiple doses being prepared simultaneously.
3) Time pressures arising from an imbalance between the available staff and resources and the work required.

There were great similarities between the studies in their findings with respect to physical constraints, despite the work being undertaken in Japan some years ago, and not restricted to the preparation stage. Suggestions were given for each of the causes identified. These were:

1) Re-organising work processes so that clinical staff were not required for administrative duties e.g. employing clerks.
2) Re-considering the layout of workspaces to prevent errors. Standardise preparation processes to eliminate error-prone activities e.g. preparing more than one medicine at a time, no checking system.
3) Improve work systems to reduce time pressures; they acknowledged this needed addressing at organisational level including middle management input [Kawamura, 2001].

Elements of each of these suggestions were proposed by some of the nurses interviewed. However, less emphasis was given to involving management in potential solutions.

In 2001, 88 of 90 nurses working on four ward at a Japanese hospital replied to a survey to determine those working conditions that were associated with 'near-miss' IV medication errors. They found more errors reported with lack of experience on the particular ward and higher workload. The suggested that experienced nurses and a 'lack of fatigue' may improve medication error detection before administration to the patient [Seki & Yamazaki, 2006].

The only issue not previously identified as a separate category were the safety culture influences. In contrast, Taxis and Barber [2003b] identified cultural context as a contributor to IV drug errors. An editorial argued there is a complex interplay of factors associated with decreased performance and patient safety. The authors suggested that multimodal strategies that address team relationships, leadership and job design need to be addressed alongside issues of long work hours and inadequate sleep [Firth-Cozens & Cording, 2004].

Tissot and colleagues [2003] investigated medication errors in 523 doses to identify associated risk factors. Injection administration was not found to be a risk factor, but nurse workload and prescription issues were identified.

Other research on general medication errors within the USA, Europe and the UK lends additional support to these findings, sometimes using slightly different descriptors for the causal factors. Those identified included: distractions, tiredness, exhaustion, stress, heavy workloads, poor skill mix, long hours, staff shortages, job overload, long drug rounds, lack of confidence to challenge, inadequate support from senior staff, stressful atmosphere, busy wards, working overtime, unsafe working practices and lack of concentration, care or attention to detail [Gladstone, 1995; Meurier & Vincent, 1997; Osborne *et al.,* 1999; Tissot *et al.,* 1999, 2003; Hand & Barber, 2000; Pape, 2003; Taxis & Barber, 2003b; Mayo & Duncan, 2004; Abeysekera *et al.,* 2005; Zavery *et al.,* 2005].

Interruptions on drug rounds have been studied, with nurses disturbed on average seven times per round, and a maximum 29 interruptions recorded [O'Dowd, 2004]. Similarly the nurses in that study felt there should be no interruptions, as being diverted from the task at hand was potentially dangerous. The Trust concerned was investigating ways to reduce interruptions and were trying protected meal times. Publications of their findings are

awaited. Another suggestion was to allocate and clearly identify one nurse to be the 'medication nurse' enabling them to focus on medication without interruption or distraction [Capriotti, 2004; Pape *et al.*, 2005; Wrench & Allen, 2006]. This mirrors suggestions made by the interviewees.

Greengold and co-workers [2003] evaluated the impact of a dedicated nurse assigned to prepare and administer medicines to 16 - 18 patients, compared with a general nurse responsible for six patients. They found no impact on error rate, and postulated this could be due to an incomplete knowledge of each patient's clinical condition or else the ratio of patients per administration nurse required to reduce errors was exceeded.

Previous IV errors studies in the UK and Germany have highlighted the lack of a dedicated workspace to prepare IVs as error contributing, forcing nurses to prepare doses in less than ideal conditions. In general, wards had no dedicated preparation area; therefore they used a store room, patients' bedside or nursing station for this task. [Taxis *et al.*, 2003; Tissot *et al.*, 2003]. The nurses interviewed described similar scenarios. The findings from a survey of preparation facilities on 71 wards in two UK hospitals revealed that 78% wards had cultured medicines preparation areas [Zavery *et al.*, 2005]. This highlights the lack of recognition of the importance of design to patient safety within the NHS [Department of Health and the Design Council, 2006]. There are already plans to rectify this within the revised draft hospital HBN. This requires a dedicated easily-cleanable area for IV medicines preparation, with good lighting that is removed from thoroughfares and common sources of environmental contamination [Architects for Health, 2006].

The findings from this study, supported by the literature, highlight the importance of holistically evaluating the IV medicines preparation process, as environment, management and the organisation's culture can affect patients' safety. Consideration and suitable priority should be given to overcoming these problems. It is paramount that such factors are included in the planning and design of new clinical areas.

5.5.4 Issues arising during the preparation process.

There were a variety of factors that posed problems with the preparation process, these included the following issues: mathematics and measurement, mixing and reconstitution, operation caution and overarching issues.

The mathematics and measurement category mainly encompassed problems with calculations. The literature shows that nurses' mathematical proficiency is inadequate [Bindler & Bayne, 1991; Blais & Bath, 1992; Hutton, 1998; Wilson, 2003; Oldridge *et al.*, 2004; Wright, 2004]. Gladstone [1995] gathered information on the mathematics qualification of 81 trained nurses at a district general hospital and discovered that 60.5% had 'O' or CSE level mathematics, yet 18.5% did not have any formal qualification. The majority (81.2%) had subsequently had their calculation skills evaluated during their training. Other work suggested that as there is no minimum mathematics qualification needed to enter nursing, mathematics should be taught in the nursing degree and potential students should not be excluded solely on the basis of inadequate mathematics qualifications [Hutton, 1998; Wilson, 2003]. This is contrasted with Wright's [2004] finding that basic mathematic theory required for medicines calculations was not taught at the local nursing school.

Trim [2004] questioned the robustness of relying on drug calculation tests to assess nurses mathematical skills as this has not proved reliable in identifying those likely to make errors, nor does having the test affect error rate [Conti & Beare, 1988; Ludwig-Beymer *et al.*, 1990]. Blais and Bath [1992] identified three domains of medication calculation deficiencies: mathematical, conceptual and management, where conceptual errors were most common. Conceptual errors were those associated with difficulty 'setting up' the problem. This finding has been confirmed by other workers [Segatore *et al.*, 1993; Arnold, 1998, Weeks *et al.*, 2000]. Nurses found calculations easier in clinical practice where the ability to visualise the scenario helped them to resolve it. It is recommended that mathematical proficiency needs practical evaluation and that conceptual issues should also be addressed [Wilson, 2003].

Poor mathematical skills are also prevalent amongst other healthcare staff, and is of concern if staff are unable to convert between units and concentration as this is fundamental to effective prescribing, preparation and administration [Perlstein *et al.*, 1979; ISMP, 2003a; Oldridge *et al.*, 2004; Wheeler *et al.*, 2004]. Solutions proposed to overcome this include the use of a dose conversion chart for medicines with concentrations expressed as a percentage or dilution ratio e.g. adrenaline, lidocaine and standardisation to a single concentration or applying warning labels where standardisation is not possible [ISMP, 2003a].

Numerous studies have shown that miscalculations contribute to errors [Gladstone, 1995; Flynn *et al.*, 1997; Hand & Barber, 2000; Ross *et al.*, 2000; Mayo & Duncan, 2004; Preston, 2004]. Complex calculations are recognised to increase the potential for IV medicines preparation error [Clinical Resource and Audit Group. NHS Scotland, 2002]. Several tools have been developed to risk assess IV medicines preparation, amongst the risk factors included are use of part of a medicine ampoule or vial, complex calculations and multiple dilutions [Beaney *et al.*, 2005; Tunstell, 2004]. The NMC [2004a] advises that two practitioners should be involved in complex calculations. Trim [2004] suggests a pocket sized formulae card should be available for use in clinical areas. The nurses interviewed cited similar concern regarding calculations and also identified similar solutions.

Paediatric patients are more susceptible to errors as medicines are provided in adult dose units, yet these patients' doses vary according to age, weight and organ function [Schneider *et al.*, 1998]. Neonates are especially vulnerable to tenfold and 100-fold errors, further confounded by the frequent need to use adult strength dose forms [Chappell & Newman, 2004]. The results from this study reveal that of 1,348 IV doses from 336 neonatal prescriptions, 25% used less than one tenth of a vial and 2.4% doses administered were for less than one hundredth of a vial [Chappell & Newman, 2004]. This poses particular difficulties in emergency situations where IV medicines are needed rapidly. Parshuram and colleagues [2003] studied IV morphine infusions prepared on paediatric and neonatal ICUs. Analysis of the morphine concentration in those syringes where the label and prescription were identical revealed that the concentration deviated from the prescription by more than 10% in 65% of syringes (n=232). No tenfold errors were found, 6% of errors were double or greater concentration.

Several ways of minimising errors in paediatrics have been proposed. These include standard tables with guidance on dose, calculation, preparation and monitoring of IV medicines, limited prescribing to predefined standardised IV concentrations, individualised emergency medication sheets, standardisation to a single strength of high risk drugs e.g. morphine, and pharmacy supplying ready to administer syringes [Santeiro *et al.*, 1992; Ross *et al.*, 2000; Lucas, 2004; Mitchell *et al.*, 2004]. In the present study there were a few comments regarding the difficulties associated with paediatric calculation and dose

measurement. However as many of the participants worked primarily with adults this may explain the limited comments received.

The mixing and reconstitution category consisted of practical problems encountered during dose preparation. The RCN IV therapy forum [2005] has published national practice criteria which require organisations to have a protocol for reconstituting, which should be developed with pharmacy input. This was not present in the Trust when the study was undertaken, but knowledge of those medicines that cause particular problems would be invaluable in producing such a document. Mixing and reconstitution errors were one of the main types of IV error identified from IV studies and general studies within intensive care where the IV route is commonly used [Schneider *et al.*,1998; Taxis & Barber 2003b; Tissot *et al.*,2003; Wirtz *et al.*, 2003; Cousins *et al.*, 2005].

One particular hospital IV guide contains information on the different ways in which medicines are provided to clinical areas and provides generic information on the associated disadvantages [Schulman *et al.*, 1998]. For example reconstitution is time consuming, especially if the powder is difficult to dissolve and care is needed with drugs susceptible to foaming as there is a risk of withdrawing an incomplete dose. The disadvantages given where similar to those described by the nurses in this study [Schulman *et al.*, 1998]. This is consistent with the RCN infusion therapy standards [2005] which require a protocol for reconstitution, produced with pharmacy input. They also require the Trust to list those medicines which the nurse may not reconstitute. From the information gained in the interviews, the study trust complied with these criteria, through information provided in the IV monographs.

In this study the nurses identified problems with manipulating some medicines. Where multiple manipulations were required, such as in preparing a once daily gentamicin infusion, this posed a risk of microbial contamination of the product, because of the numerous manipulative steps [Beaney *et al.*, 2005]

The operator caution category primarily included health and safety issues or areas where the operator needed to exercise particular care due to error prone packaging and labelling. Error prone packaging and labelling caused problems when the names looked or sounded similar e.g. cefradine, cefuroxime, ceftriaxone, cefotaxime etc. or where similar strengths

of the same medicine were not clearly distinguished. This problem is widely acknowledged to contribute to errors, with the pharmaceutical industry identified as key to resolving these issues [Kawamura, 2001; Taxis & Barber, 2003b; Mayo & Duncan, 2004]. A systematic review of the literature was undertaken to evaluate recommendations to prevent IV bolus administration errors in theatres [Jensen *et al.*, 2004]. Much of the material available for review was opinion rather than experimental data. However, the authors were able to make four 'strong' recommendations (a-d below) and three recommendations (e-g below). These were:

a. Read and carefully check the medicines label.
b. Optimise the legibility and contents of labels and syringes, according to agreed standards with respect of some or all of the font, size, colour and information included.
c. Syringes of prepared medicines should be labelled.
d. Medicines, their storage and workspace should be formally organised with attention to tidiness and the positioning of ampoules and syringes. Similar drugs should be separated and dangerous drugs removed from theatres where possible, or separated.
e. Labels should be checked specifically with a second person or device (such as a bar code reader linked to a computer) before they are drawn up and administered.
f. Stock holdings should focus on minimising the risk of drug error and any changes in packaging should be notified in advance.
g. Similar packaging and presentations of medicines contributes to error and should be avoided wherever possible.

They concluded that

"The present disregard for patient safety in the presentation of drugs by many manufacturers is unacceptable" [Jensen *et al.*, 2004; p.501].

Within the UK, improvements in medicines packaging and labelling have been made with the medicines regulatory authority's best practice guide [MHRA, 2003]. Some pharmaceutical companies, mainly generic manufacturers, have redesigned their packaging and labelling, however healthcare professionals believe that further improvement can be made [Gross, 2005a]. The recent publication of 'Information design for patient safety' provides further guidance for packaging designers and pharmaceutical companies about oral dose forms and dispensing labels [Helen Hamlyn Research Centre, NPSA, 2006]. However many of the key messages are more widely applicable. This document described best practice, user testing and a concise 24-item checklist of problems, with associated recommendations to resolve them e.g. small type size is difficult to read therefore use body

text in a minimum of 12 point font size. It has been recommended that prior to formulary inclusion hospital organisations should proactively review the risks posed by the packaging and labelling of a medicine throughout the medicines use process [Jones, 2003; Murri & Somani, 2004]. Pharmaceutical companies also need to consider the way in which their medicine are used and consider all safety aspects as part of the development process [Jones, 2003; Gross, 2005a].

Within the NHS a national risk management initiative, the 'purchasing for safety' strategy has been developed to aid decision making in the purchasing process for licensed medicines for secondary care [Alldred, 2006]. The aim is to highlight features that may increase the risk of errors, verify the product as fit for purpose, and determine that the manufacturer's prior performance has been acceptable. Where there is no option but to purchase items with medium to high risks, this information will be shared to enable hospitals to manage these risks locally. Therefore, the onus for risk assessment of unlicensed medicines and 'off-label' medicines remains with the Trust.

In addition, numerous local initiatives have been advocated to reduce selection errors. These include:

- Standardise practice where more than one size or concentration of a similar medicine is available.
- Do not store easily confused medicines with each other e.g. heparin and insulin, both prescribed in units.
- Sound alike medicines should not be stored alphabetically e.g. cefuroxime, ceftazidime.
- Employ 'tall man' lettering, where different parts of the drug name that are prone to confusion are capitalised e.g. DOPAmine, DOBUTamine; vinBLAStine, vinCRIStine.
- Over label unacceptable packaging within pharmacy.
- Read the label three times: when selecting or preparing it, when administering it and when putting it away or discarding it.
- Colour labels/packaging/products should not be relied upon to identify a medicine
- Provide education and training on error prone design issues [Hadaway, 2001; ISMP, 2004; RCN, 2005].

Tools have been designed to assess the risks associated with the preparation of parenteral products in clinical areas and identify as a risk factor, materials hazardous to the operator. This includes teratogenticity, mutagenicity and cytotoxicity [Tunstell, 2004; Beaney *et al.*, 2005]. One tool also identifies the risks associated with opening glass ampoules as well as those medicines that are difficult to prepare [Tunstell, 2004]. These risks mirror those comments received from the nurses in this study.

The concerns that the nurses expressed about antibiotic spray during reconstitution are supported by other work, where overpressure within antibiotic vials caused aerosolisation. In this study the environmental contamination by antibiotics was sufficient to leave an odour, dampen surfaces and inhibit bacterial growth on agar plates in the preparation area [Bradstrup, 2005]. Staff concerns following repeated antibiotic exposure and of needle stick injuries have previously been reported [Mercier, 1994].

Overarching issues related to process problems, with the time consuming or expensive medicines, varied according to the individual's prior experience and exposure. New or unfamiliar medicines featured widely in this category. This is similar to the findings of Taxis and Barber [2003b] where frequent mistakes were reported with new products or uncommon procedures. Other work also supports unfamiliar medicines as a risk factor. Beaney and colleagues [2005] suggested that unfamiliarity with a product or preparation increased the likelihood of error, they quantified this as fewer than six ampoules or vials used within a 12 month period.

The nurses advocated a variety of solutions that could be applied to the preparation process, regardless of which medicine was involved. These included labelling the prepared product and asking a colleague for a check. Marriott and co-workers [2000] surveyed practice across 22 Trusts and reported that independent checks were not routinely performed in any Trust although certain staff groups or clinical areas were using double checks e.g. paediatrics, chemotherapy. Jensen and colleagues [2004] suggested that double checks could have prevented 58% IV bolus administration errors in a theatres environment and was the most effective single error reduction measure. In this study there was considerable debate about the role, limitations and potential benefits of checking by the nurses interviewed. However, nurses' comments in this study showed that in situations where they felt vulnerable e.g. tiredness; or situations where the potential for patient harm

with an error was greater e.g. preparing insulin or heparin; then they employed some form of second check. This check was with a colleague, calculation chart or guideline. Cousins and colleagues [2005] have previously reported inadequate labelling of prepared products and advocated several design solutions which the pharmaceutical industry could adopt to assist with product labelling in practice, such as containers with flag labels that could be transferred to prepared doses.

The way in which the medicine was presented, with those supplied to the clinical area in a ready to administer form, or a solution that solely required withdrawing into a syringe was preferred by nurses in this study. These findings mirror previous work, and the standard set by the RCN [Taxis & Barber 2003a,b; Wirtz *et al.,* 2003; RCN, 2005]. Alternatively it was suggested that IV doses could be supplied to the ward ready to administer, having been prepared either in pharmacy or on the ward by dedicated personnel. These issues were first identified and reported on in 1976, when it was recommended that then need to add IV drugs to sterile IV fluids on wards should be minimised and where necessary this should be undertaken in central aseptic conditions under the control of a hospital pharmacist [Breckenridge, 1976]. These opinions have been re-enforced by other national publications and echo the findings of previous studies [Audit Commission, 2001; Taxis & Barber 2003a,b; RCN, 2005]. It is surprising that despite this volume of support, much progress would be required to comply.

Some medicines can be purchased in a ready to administer form e.g. metronidazole infusion, pre-filled adrenaline syringes. One concern cited by nurses in this study was the increased acquisition costs of using ready to administer products. An economic evaluation in a 'real-life' setting of ready to administer dobutamine infusions compared with those prepared on the ward was undertaken in Belgium [van der Linden *et al.,* 2002]. They reported a 32% saving in nurses' time, lower total costs and raised user satisfaction with the ready made preparation and no difference in safety or efficacy. Economic evaluations that assess the total costs to the organisation need to be undertaken in the UK.

Many hospitals do not have adequate facilities to prepare in pharmacy all injectables that cannot be purchased in a ready to administer form [Turner *et al.,* 2003; Beaney *et al.,* 2005] Therefore, pharmaceutical manufacturers have designed novel reconstitution methods to overcome some of the risks identified with ward based preparation, such as the

Baxter Minibag Plus™ and Macoflex transfer set™. These allow the reconstitution of powders by the infusion fluid through a transfer device or via a special additive port. An evaluation of these systems compared to a conventional needle and syringe technique showed time savings, fewer interruptions, fewer problems, no needle stick injuries and ease of use [Nichols *et al.*, 2001; Turner *et al.*, 2003]. User satisfaction and cost savings were greatest with the vial transfer device [Turner *et al.*, 2003]. When the Minibag Plus system was compared with needle and syringe technique, significantly fewer doses were microbially contaminated (0 vs. 21%). However, no change in clinical outcome was observed [Nichols *et al.*, 2001]. There are a variety of needle free transfer devices commercially available, which include some of the devices described by the nurses interviewed e.g. Interlink™ system. In contrast, the nurses interviewed perceived the main benefits to be fewer needle stick injuries, minimising contamination of themselves and the product. Time and financial savings with fewer in use complications were not discussed by the nurses. These needle-free devices are only suitable where the dose required is a multiple of a whole vial, so they are unsuitable when only part of a vial is required such as in paediatrics.

Additional safeguards have been advocated for 'high-alert medications'. These are those where the risk of patient harm as a result of error are increased [Cohen & Milo, 2000]. Hadaway [2001] advised that such products should be purchased premixed or prepared in the pharmacy department and supplied to the clinical areas in a form ready to administer. It is also recommended that multi-step products, multiple dilution products and products requiring mixing created opportunities for error, so they should be avoided [Jones, 2003; Gross, 2005a]. Previous research has identified multi-step preparation, where drugs need measuring and diluting or reconstituting, as an error prone stage in the IV MUP [Taxis & Barber, 2003a]. It is recognised that ready to administer preparation are more costly; however it has been suggested that the additional expenditure provides higher product quality and lower risk to the patient [Jones, 2003].

5.5.5 Information and training

The nurses needed access to information in order to safely prepare the medicine in their clinical area. The key document they used was the Trust IV drug administration guidelines, which they described as invaluable. A number of suggestions to improve this document were provided. They also relied on the manufacturers package insert, but noted that

recently its format had changed from professional information to a patient information leaflet. This had limited its value to the nurses when preparing the medicine. When the medicine or required information was not contained within the IV guide, information was not easily accessible and nurses relied on colleagues and pharmacists to fill this gap.

It is suggested that current and reliable medicines reference materials should be available for practitioners in their clinical setting, available on the hospital intranet, or in portable format either electronic or paper based [AORN, 2002; ISMP, 2004]. A lack of protocols for the preparation and administration of parenteral medicines has been associated with administration errors within critical care [van den Bemt *et al.*, 2002]. Previous audit across two UK hospitals showed that 48% ward areas (n=71) had no reference sources for IV medicines preparation [Zavery *et al.*, 2005]. Standard guidance for continuous IV infusions within neonatal critical care has been shown to prevent calculation errors [Santeiro *et al.*, 1992]. The nurses interviewed advocated the need for easy access to information in their clinical areas. It would appear that the concerns raised in the Breckenridge Report regarding inadequate training and ready access to information in clinical areas remain [Breckenridge, 1976].

It was apparent from the interviews that there were concerns about the knowledge and skills of some nurses in practice. The interviewees shared examples of poor practice and identified deficits in training provision. Within their professional practice a nurse is governed by the NMC document 'The Code of Professional Conduct' [2004b]. This encouraged nurses to expand their practice, provided they have the necessary knowledge, skills and to accept responsibility for their actions. IV therapy used to be considered as an expanded nurse role, however over the last decade has become a core role [RCN, 2005]. However, from the comments received during the interviews, it would appear that some nurses may not be following their professional code. These findings are supported by previous research examining the nursing causes of errors, where the rationale given for errors made by nurses included a lack of knowledge/information, faulty judgement, and a lack of supervision [Meurier *et al.*, 1997]. In addition, a previous audit confirmed that core standards, such as swabbing the vial's septum were not commonly followed in 99% cases [Cousins *et al.*, 2005]. This is at odds with the RCN practice criteria [2005] requiring aseptic technique be used throughout reconstitution, including adequate cleaning of infusion additive ports, vials and ampoule tops.

Adequate knowledge of a patient's treatment and medicines are key to preventing medication errors. Kawamura [2001] suggested that nurse's knowledge of the new and ever increasing number of specialist medicines was limited. They advocated strengthening of the pharmacists' role and recommended that they should take an active role in nurse training. Their study found that nurses with less than two years experience in practice found the gap between the knowledge they had obtained at qualification and the 'real world' was too vast. Training would need to be adapted to the clinical environment and should also include error prevention [Kawamura, 2001]. Variables reported to affect knowledge include the length of experience, and the level and recency of professional education [Armitage & Knapman, 2003].

The RCN standards for infusion therapy [2005] provide clear guidance on the aspects of practical and theoretical training nurses should have undertaken. This includes legal, professional and ethical issues, mathematical calculations related to medications, risk management, pharmacology and pharmaceutics related to reconstitution. Further elaboration on the knowledge required for reconstitution is also given. It requires nurses undertaking infusion therapy to be clinically competent in all aspects of infusion therapy, and have validated competency in clinical judgement and practice. It clearly places this responsibility jointly with the individual and the trust [RCN, 2005;p.7]

"All staff have a professional obligation to maintain their knowledge and skills [NMC, 2004b]. *It is also the responsibility of the organisation to support and provide staff with training and education."*

The findings of this study showed little attention, if any, was given to the practical training for IV preparation either at undergraduate or post registration level. Most had gained their skills for preparation from observing their colleagues. This reflects a key finding from similar work [Taxis & Barber, 2003b]. Analysis of 85 human errors attributed 41 of these to lack of knowledge, routine and experience in drug preparation. They also found that the practical aspects of IV drug preparation were neither taught nor assessed in their study hospitals [Taxis & Barber, 2003b].

The nurses interviewed in this study advocated that staff should attend update or refresher sessions and that all needed to be able to demonstrate competency with this task. Other workers have also advocated an annual review of IV medicines competencies, in line with other mandatory training [Nicholas & Agius, 2005].

5.5.6 Further work

There was a need for a documented, readily accessible organisational practice standard on IV preparation, information in the clinical area, and a review of IV training and competency. These issues highlight organisational problems with the staffing, equipment and environment in which IV medicines are prepared. It identifies the need for investment in building a safety culture embedded within and throughout the organisation where staff feel valued, able to raise concerns, and learn from incidents and near misses. These specific issues should be addressed by the Trust.

Analysis of this study data using the framework approach identified key categories, but it is unlikely the full extent of each category was explored in this exploratory study. It would be useful for further work to be undertaken to ensure that all categories were identified and also to ensure comprehensive description of their characteristics. Nurses are just one of a range of healthcare practitioners who undertake IV preparation. Therefore views of other healthcare professionals e.g. paramedics, doctors, radiographers, perfusionists could be investigated.

From the comments received from the nurses interviewed, some problems arose from earlier steps in the medicines use process e.g. poor prescribing or pharmacy not supplying manufacturer's leaflets with dispensed items. Therefore the IV preparation process cannot be addressed in isolation. Consideration should also be given to exploring these issues. It would be beneficial to approach some of these research questions in a multiprofessional environment, such as focus groups. This would enable cross boundary issues and solutions to be investigated. Healthcare professionals may not always consider problems or solutions that fall beyond their own professional boundary. However, systematic analysis of the IV MUP to identify where failures occur, using techniques such as failure mode effects analyses, would allow weaknesses to be highlighted. Solutions can then be considered in the wider context, which could include previously unidentified strategies e.g. bar-code confirmation of the medicine's identity.

There are several issues where a further study would provide clarity such as the role of double checking, simulation testing of IV preparation, and annual re-accreditation. The interviewees cited concerns about solutions requiring financial investment. Cost benefit analyses should be undertaken to address this issue, before potential solutions considered.

Future research should clearly distinguish between the IV preparation and administration stages, as much of the current evidence is combined. It would appear that there are additional concerns within the paediatric and neonatal environment, where reliance on adult IV preparation poses unique risks, this would also benefit from further study.

The results from this study could be used to inform future qualitative and quantitative work. The resource implications and practicality of solving some of the issues identified warrant urgent attention.

5.6 Conclusions

It is very important to consider the views and concerns of nursing staff whilst IV preparation continues to occur in clinical areas. The findings from the nurses interviewed in this study suggest that priority should be given to developing solutions to minimise interruptions, to the design and provision of a dedicated work space, to reviewing the availability of needle free devices and to ensuring that all the relevant information required for IV preparation and administration is available to staff in their clinical areas.

There should also be a national review and standardisation of the taxonomy, standards and competency required for IV medicines preparation. In the interim this should be undertaken at a local level.

Healthcare professionals need to work in partnership with medicines manufacturers to enable them to design products that are simpler and easier to use. Preparations requiring little or no manipulation in the clinical area were appealing to nursing staff, although there was concern about the increased costs required to achieve this. Further work should be undertaken to evaluate the cost effectiveness of such changes within the wider healthcare system. Consideration should be given to end user testing before medicines are marketed. Particular attention should be given to using a human factors approach to minimise the potential for error, therefore safeguarding patients.

Chapter 6
Discussion

The introduction to this thesis described the global epidemic of iatrogenic injury in healthcare. The approach adopted in the UK's approach to understanding the scale and nature of this problem was outlined, along with strategies and governmental policies designed to address healthcare deficits. The creation of the NPSA was pivotal in leading patient safety reform in England and Wales [Department of Health, 2001b]. Medication became a patient safety priority, because it is the leading healthcare intervention it was unsurprisingly also a main cause of patient injury [Smith, 2004]. Although there is a vast and rapidly growing body of patient safety literature, a lack of common and consistently applied definitions, terminology and research methods posed difficulties when examining and interpreting study findings [Nebeker *et al.*, 2002; Chang *et al.*, 2005; Woods *et al.*, 2005; Yu *et al.*, 2005]. This was confounded by differences in medication use between study settings and countries [Ghandi *et al.*, 2000; van den Bemt *et al.*, 2000; Cousins, 2005b; Dean-Franklin *et al.*, 2005]. Previous UK medicines safety research had focused extensively on prescribing, dispensing and oral medication administration. More recently, work on hospital IV errors had identified problems with IV administration and highlighted the greater propensity for patient harm [Argo *et al.*, 2000; Bruce & Wong, 2001; Taxis & Barber, 2003a]. IV medicines administration was more complex than oral administration. Some medicines required manipulation in the clinical area into a ready to administer dose. Further investigation of IV medicines preparation in patient areas was warranted [Cousins 2005a].

Therefore, this thesis focused on IV medicines preparation in hospital clinical areas. Specifically, a definition of an IVMPE, with inclusion and exclusion criteria, were agreed. This framework was translated into an observational audit tool and its feasibility assessed. An in-depth understanding of the processes involved with IV medicines preparation was sought and insight into how nurses resolved these issues was gained. Collectively this enabled understanding of how PSIs involving medication arise during IV medicines preparation.

6.1 IV medicines preparation process

The administration stage of the IV MUP encompassed a wide range of practices. This process varied in complexity and the number of component stages, depending upon the

medicine required and its presentation (section 2.2, figure 2.2 and 5.5). At its simplest this was a pre-filled syringe ready to administer to a patient and varied to an individualised multi-ingredient prescription, supplied as constituent ingredients. Only the latter requires a preparation stage, which may take place either in clinical areas or pharmacy controlled aseptic facilities. Initially it was necessary to identify the scope of ward based preparation activities, their limits and terminology. In the Delphi study, previously published definitions of IV medicines assembly and preparation were rejected [Gandy *et al.*, 2002], but agreed after refinement (chapter 2).

Intravenous medication assembly was defined in this study as

"The gathering together on a cleaned tray, trolley or appropriate work surface; the items of equipment and pharmaceutical agents required for the preparation of a medicinal product for a patient."

Respondents did not consider that all equipment and ingredients needed to be gathered from the outset. This may be because of differing practices between clinical areas and pharmacy aseptic facilities.

Intravenous medication preparation was

"The procedure for using the assembled items in drawing up, mixing, combining or reconstituting the pharmaceutical agents, diluents and/or infusion fluids into the right form, combination, and strength according to the patient's prescription sheet. Preparation includes using relevant documentation for preparing the medicinal product, calculations, and labelling."

Respondents rejected the inclusion of any reference to equipment in this definition. This revised form is similar to that proposed by the Clinical Resource and Audit Group of NHS Scotland [2002]. The boundary between the end of preparation and where administration began was not clearly defined. It was suggested that when preparation was remote from the patient, all activities undertaken before the patient was approached should be included in the preparation stage.

These findings contrasted with those from the nurse interviews (chapter 5), where the whole process was commonly gathered together as IV administration. The nurses differentiated between the preparation and administration stages, but not assembly. They suggested that assembly and preparation were a continuous task in clinical areas, rather than the two discreet processes suggested by the definitions. In their opinion, preparing any flush solutions required was an integral part of the preparation stage. In addition they identified a 'pre-preparation' stage that was unique to clinical areas and involved patient

specific assessment, such as the type of vascular access available. This information affected how the IV dose was prepared. The interview findings highlighted differences between preparation undertaken remote from the patient in pharmacy aseptic facilitations and in clinical areas.

It is important that common terminology, understood by all healthcare professionals, is used in medicines research. The findings from this study indicate that terms commonly used by pharmacy in aseptic production cannot be directly transferred to clinical areas and to other professional groups. IV administration should be subdivided into two stages, preparation and administration. Preparation in clinical areas should include patient assessment and preparing any flush solutions, this had not previously been recognised.

6.2 Intravenous medicines preparation error definition and framework

A definition of an intravenous medication assembly or preparation error in the clinical setting was agreed as

"The preparation of IV medication that deviates from the prescription, manufacturer's guidance, national or locally agreed policy, procedure or guidance, or generic standards for clean or aseptic preparation."

The definition incorporates and expands that previously used by other workers [Taxis & Barber, 2003a, Wirtz *et al.,* 2003]. The main differences were including deviations from policies procedures and poor aseptic technique as errors. Inclusion of poor aseptic issues has previously been debated, and details of breaches were collected and reported separately [Wirtz, 2001]. This contrasts with another study where deviation from aseptic technique was firmly embedded within the audit [Cousins *et al.,* 2005]. However it is supported by other studies which demonstrate high levels of contamination when medicines were prepared in intensive care units [Quercia *et al.,* 1986; van Grafhorst *et al.,* 2002].One of the main difficulties encountered when including aseptic preparation within the error framework, was the lack of standards or agreement on what constituted appropriate clean technique in clinical areas. This contrasts with pharmacy controlled aseptic facilities where explicit guidance is available and rigorously enforced [Beaney, 2001].

Delphi respondents' acknowledged that some injectable medicines, such as specials, did not come with manufacturers' guidance and the definition needed to address this issue. Previous definitions have not proposed solutions where medicines have been supplied without manufacturer's guidance. In practice respondents reported that this was often

addressed through local guidance or adopting other published guidance, particularly in paediatrics. Therefore, it was appropriate to include adherence to such guidance within the scope of the definition. However, this raised a potential problem with analysis of this study and meta analysis of published research studies, where different information sources may provide different advice. Agreement was not reached during the Delphi on which information sources should be given priority when assessing compliance with advice. Instead, it was suggested that where conflict arose this should be resolved on a case by case basis. A researcher would need to identify organisational policies and procedures prior to data collection, as they would affect data analysis, and thus error assignment. This highlighted the need for clear explanation of the study setting and working practices in research publications. This would enable readers to compare and extrapolate findings to their organisations' practices.

Prescribing issues were not considered within the error framework. However, there was awareness that prescribing or dispensing errors could become preparation errors, and it was impossible to separate preparation from the earlier MUP stages. Therefore, when agreeing the IVMPE definition it was necessary to assume the prescription was both valid and appropriate. When using the error framework in practice it would be necessary to identify and record prescribing issues separately.

When the IVMPE framework was piloted (chapter 4) a potential problem was highlighted with the definition. Anaesthetists record medication they have administered in operating theatres, instead of writing a prescription giving instructions for administration. This issue is unlikely to arise in other settings in which anaesthetists work such as in critical care, preoperatively and postoperatively, where they do prescribe [Wheeler & Wheeler, 2005]. This had not previously been identified and further work is warranted to explore this.

Audit has been extensively used as a means of providing quality assurance data that minimum standards are achieved and maintained within pharmacy controlled unlicensed aseptic units. It would be a logical to extend this to encompass ward based IV preparation, using appropriate criteria.

6.3 Concurrent IV medicines practice developments

During the preparation of this thesis several developments which affected IV medication preparation in clinical areas occurred. First was the development of several risk-assessment tools which enabled the identification of 'high-risk' items, so these could be transferred for preparation within pharmacy [Tunstell, 2004; Beaney *et al.*, 2005]. Some workers addressed the issue more widely and assessed risks posed by training, facilities, capacity and staffing issues [Lowe & Shaw, 2002; Munro *et al.*, 2003; Zavery *et al.*, 2005] while others have successfully applied prospective risk analysis processes, such as failure mode effects analysis (FMEA) to identify weaknesses and guide improvements [Apkon *et al.*, 2004; Adachi & Lodolce, 2005; Bonnabry *et al.*, 2005].

The NPSA commenced work on a patient safety alert concerning the 'safer use of injectable medicines in near-patient areas', which was released for stakeholder consultation in January 2006 [NPSA, 2006]. This timely document addresses risks throughout the injectable MUP, and is the first to include a comprehensive, yet practical, approach to injectable preparation in all care settings for England and Wales. Although the alert's remit is broader than this thesis, it adopts a similar stance to that agreed within the IVMPE definition and framework, as it incorporates poor aseptic technique and policy and procedure issues.

Appended to the alert are multiprofessional safer practice standards and a standard operating procedure (SOP), both of which include detailed guidance on the preparation stage [NPSA, 2006]. It is interesting that in this study the IVMPE criteria, in asking whether it was acceptable to prepare medicines in advance either generally or in situations where it was paramount that medication delivery was not interrupted, did not achieve consensus (chapter 2). The NPSA standard requires that

> *"Injectable medicine prepared in clinical areas must be used immediately after preparation: they should not be stored before use"* [NPSA, 2006;p.15].

The definition also includes flush preparation within the preparation stage, which mirrors the views of the nurses interviewed in this study (chapter 5).

The SOP section on preparation provides national multiprofessional standards for IV medicines preparation. One of the difficulties encountered during this thesis was the lack of such standards against which practice could be compared. Therefore, issues identified during the pilot study (chapter 4) could be resolved by comparison with this standard,

where non adherence to the SOP would constitute poor practice. An incident which occurred in this study, when a solution was withdrawn directly from a glass ampoule without a needle is such an example. Other criteria where consensus was not gained for inclusion as an IVMPE in the Delphi study, such as hand cleansing before preparation would also be included as poor practice (chapter 3). The SOP facilitates a clear distinction between poor practice and error. Where practice met the inclusion criteria agreed for an IVMPE a potential error would have occurred. If this error was not intercepted and was administered to the patient then it would constitute an IVMPE.

The importance of incorporating design across systems to improve patient safety has already been highlighted [Department of Health and the Design Council, 2003]. This was acknowledged and explored through the report on pharmaceutical packaging and labelling for oral doses, but has yet to be applied to IV medicines. Design has also been incorporated into the revised draft standards of the hospital HBN 'facilities for medicines management'. It is clearly demonstrated by the statement

> *"It is important that adequate provision for medicines storage is made available in wards/clinical areas to ensure safe practice. The National Patient Safety Agency has reported that inadequate and insufficient medicines storage has led to deaths and serious harms due to overcrowding and selection errors"* [Architects for Health, 2006;p.21].

The National Implementation Board for the modernisation of NHS medicines manufacturing and preparation services was established in 2002, with substantial capital investment allocated for modernisation [Gross, 2005b]. NHS manufacturing units produce a wide variety of unlicensed injectable products, in a ready to use format, and it is essential to provide patients with safe injectable therapy. NHS manufacturing and preparation resources are being directed towards those products associated with the greatest clinical risk [Root, 2006]. The implementation board has been working towards standardisation of patient controlled analgesia and epidural preparations for pain control, which will improve medicines safety in this area [Gross, 2005b].

Together, these developments highlight the risks posed by injectable therapy, especially with complex injectable preparation in clinical areas. The findings from this thesis support such approaches yet provide a different perspective for improving medicines safety.

6.4 Capturing data on IV medicines preparation errors

Gathering data on IVMPE poses some unique problems. Document based review and voluntary incident reports are insensitive to these types of error [Barker *et al.*, 2002b]. Observational techniques have traditionally been employed, but are time-consuming, resource intensive and critically dependent upon the competence and skills of the observer and methodological rigour [Allan & Barker, 1990; Dean & Barber, 2001; Flynn *et al.*, 2002]. Therefore, although feasible as a research tool, this may limit the use of direct observation as a quality assurance and governance measure.

Piloting of observational audit of IVMPE highlighted the need for extensive observer training and competency assessment in aseptic technique and observation, supported by orientation in the clinical area (chapter 3). One limitation found was the difficulty of completing the data collection form whilst observing the preparation, due to the speed of the preparation process. This posed additional problems when multiple deviations occurred for a single IV dose. Recent advances using video recording during real and simulated resuscitation, anaesthesia and surgery may overcome these limitations [Mackenzie & Xiao, 2003; Kozer *et al.*, 2004; Weinger *et al.*, 2004]. In the studies audio and video data recording and analysis were used in conjunction with additional data sources, such as the patient's clinical monitoring parameters, direct observation, and document review. The main advantages of video data capture is that it enables every detail to be filmed on the record can be reviewed as needed. Miniaturisation of video equipment with zoom potential allows unobscured views. Disadvantages cited for this technique were consent issues, privacy, confidentiality, practical logistics and litigation concerns [Mackenzie & Xiao, 2003; Kozer *et al.*, 2004; Weinger *et al.*, 2004]. Simulation of IV medicines preparation could be attempted, but this might differ from real-life as the time, patient and environmental factors would be missing. This could introduce bias, and may explain why this has not been attempted.

Another method which has been employed is to assay the IV dose prepared and compare it with the prescription [Allen *et al.*, 1995; Ferner *et al.*, 2001; Parshuram *et al.*, 2003]. This circumvents the many limitations of observational methods, but is only applicable to those medicines that are stable and easily assayed. This valid and reliable method could be used in conjunction with observational techniques to provide a multifaceted insight into how IVMPE arise.

Continuous voluntary incident reporting is likely to remain the main method of capturing information on IVMPE, as it is inexpensive, convenient and can be used continuously within NHS Trusts. However, when hospitals analyse reported incidents it is important they are aware of the limitations and insensitivity of this method. Low reporting rates do not provide organisational reassurances. Currently this is best achieved by direct observational audit.

6.5 Analysing IV medicines preparation

Previous IVMPE studies focused on quantification of the problem [O'Hare *et al.,* 1995; Hartley & Dhillon, 1998; Bruce & Wong, 2001; Hoppe-Tichy *et al.,* 2002; Taxis & Barber, 2003a; Wirtz *et al.,* 2003; Cousins *et al.,* 2005]. In order to appropriately target measures to reduce IVMPE, a clear understanding of how and why errors occur is required [Leape, 1994]. The NPSA has adopted the systems approach to safety; therefore it is appropriate that a human error or human factors approach is employed to understand and analyse incidents [NPSA, 2003a]. Human factors has been described as *"an applied science of system design that evaluates human strength and compensates for human limitations"* [Schneider, 2002b;p.1156].

Leape [1994] advised that true insight into the origins of IVMPE is only achievable through understanding human error and fallibility. Taxis and Barber [2003b] applied human error theory to gain an understanding of how observed IV errors arose. This was achieved by following a standardised protocol for investigating and analysing clinical incidents, rooted in human factors science [Vincent *et al.,* 2000]. Since human decisions and actions are a key component of virtually all incidents, manifesting as active and latent failures [Vincent *et al.,* 1998]. Analysis must extend beyond the active failure that preceded the IVMPE and reach further to explore the local task, team, individual, working environment and organisational factors that were present when the error occurred, and contributed to its genesis.

Human error theory could fruitfully be used to further analyse the nurse interviews (chapter 5). Latent organisation level conditions described by the nurses included: the need to embed a fair blame culture in the hospital, evidence of a training or competency deficit, unavailability of equipment, and safety concerns with needle use. Medication related issues were: ambiguous medicines packaging and labelling, supplying medicines to the clinical

area that required complex calculations and/or manipulations, difficult or time consuming reconstitution, inadequate 'drug additive' labels and inadequate information and guidance on preparation. During the pilot study (chapter 4) the observers also questioned whether the organisation had yet achieved a safety culture. The organisation would benefit from using a tool, such as the Manchester Patient Safety Framework for acute care, to identify what its current safety profile is, and prioritise areas for action [The University of Manchester and Department of Health, 2006].

Error producing conditions were commonly described within the work environment and included; inadequate workspace for IV medicines preparation, interruptions, time pressures, competing commitments, understaffing, inadequate knowledge and skills, and unfamiliarity with rarely used medicines. These conditions were similar to those previously reported from analysis of disguised observation and informal discussion with nurses preparing IV doses on wards [Taxis & Barber, 2003b]. In addition these mirror several of the risks identified in the NPSA injectables medicine alert. These include cluttered workspaces, interruptions and distractions, unfamiliar processes, variable standards of training [NPSA, 2006]. Each of these issues identified needs to be assessed locally, and escalated to higher levels within the organisation when the means to minimise or avoid the risks are beyond their means. During the nurse interviews an example was given where resources were found to redesign the clinical area to produce a designated preparation area. Another nurse in a similar situation was unable to secure resources for such a change; the next level of management needs to take ownership of and rectify this problem. There has been little focus on the managerial and organisational responsibilities for improving patient safety with regard to injectables, even though issues such as inadequate training and information at ward level have previously been identified and made explicit within Controls Assurance [NHSE, 1999b; Taxis & Barber, 2003b; Zavery *et al.*, 2005].

6.6 Potential solutions

There are three ways in which healthcare systems can be designed to be safer by reducing errors and adverse events. These are system redesign to prevent errors, improving the defences within the system so errors become visible and are intercepted, and designing processes to mitigate the effect of errors which reach the patient [Nolan, 2000].

Suggestions for systems change include removing the need for preparation in near patient areas. This could be achieved in a number of different ways. Some medicines can be purchased in ready to administer presentations, such as pre-filled syringes and ready mixed infusions. Wherever possible these should be licensed medicines, supported by unlicensed products from commercial or NHS manufacturing units [Gross, 2005b]. The nurses interviewed advocated providing medication in a ready to administer form. In addition to preventing errors they also suggested that time was saved (chapter 4). The nurses also suggested that it would be useful if complex and time consuming preparations were supplied to the ward 'ready to administer'. Those medicines, assessed as 'high-risk' for preparation in clinical areas, could be prioritised for preparation within pharmacy controlled aseptic facilities [Beaney *et al.*, 2005]. Errors can also occur within the pharmacy, however a robust double checking system is an integral part of the dispensing process, making it more likely that any errors would be detected and intercepted. In addition, staff preparing the aseptic products are concentrating on the single function of preparing the IV dose, with minimal distraction [Summerfield & Lawrence, 2002].

Medicines should be assessed as practical and 'fit for purpose' before they are purchased and supplied to clinical areas. There are several opportunities for error minimisation with this strategy. It would be useful if all licensed medicine were required to undergo user acceptability testing before a product licence were granted. This would ensure that appropriate technical information was included with the product and would identify difficulties that might arise in practice. For example, to administer 10mg vitamin K as an infusion the manufacturer advises this be diluted with 55ml of 5% glucose [Roche Products Ltd, 2006]. However there is no commercially available source of 55ml of 5% glucose. This approach is not available for unlicensed injectable formulations, which may be provided without product information, which may limit user acceptability. This is being addressed in part by the National Implementation Board for the modernisation of NHS medicines manufacturing and preparation services which is developing monographs and stability data for commonly used products [Gross, 2005b].

Other opportunities for intervention of both licensed and unlicensed injectables are at the purchasing stage, where Alldred [2006] provides a purchasing for safety framework. Hospitals also have the opportunity to assess products before they are included on a

hospital formulary. The formulary review committee has knowledge of the intended use against which to evaluate the medicine [Dorey, 2004; Murri & Somani, 2004].

Another option is to change systems focus on reducing complexity, such as the number of steps in the task and the number of choices [Nolan, 2000]. Numerous recommendations in this area have been made which, if adopted, would improve medicines safety. These include ensuring that the correct strength of medicine corresponding to the required dose is available in the clinical area and providing a medicine as a solution rather than an item that requires reconstitution, [Beaney *et al.*, 2005; NPSA, 2006]. Automation offers many opportunities at other stages in the IV MUP, but at the preparation stage, automation is currently limited to bar coding. The impact of its introduction on IV preparation has not yet been evaluated.

Constraints can be used as a defence to restrict erroneous actions and are one of the most reliable strategies in preventing errors. An example of this was the NPSA alert restricting strong potassium containing injectables in clinical areas [NPSA, 2002]. Following the alert, the proportion of NHS Trust with formal controls rose from 25% to 68%, and was associated with a 27% reduction in the quantity of strong potassium chloride concentrate ampoules used [NPSA, 2003c]. The mind functions most efficiently when it is able to focus solely on the IV preparation task without other distractions. This is achieved through increased understanding and avoiding reliance on memory [Nolan, 2000]. One example that was identified by the nurses interviewed was look-alike and sound-alike medicines names. Where possible this should be eliminated, or measures to highlight this used. Pharmaceutical manufacturers are pivotal to resolving this problem. Guidance is available improving the design of oral medicines packaging and labelling, much of which also applies to injectable medicines [Helen Hamyln Research Centre, NPSA, 2006]. For example, the nurses interviewed identified problems when medicines names looked or sounded similar such as cefradine, cefuroxime, ceftriaxone, cefotaxime, or where similar strengths of the same medicine were not clearly distinguished.

Strategies that make errors visible, so they may be detected and intercepted include "double checking" and labelling prepared medicines. The nurses' interviewed (chapter 4) reported that they would always label IV infusions, but their practice differed with regard to IV bolus doses and flushes. In some cases they used alternative strategies for

identification such leaving the plastic flush container on the end of the syringe. They highlighted this as an error prone area, particularly when more than one syringe of the same size was used. Another area for potential error identified by the nurses was that the 'drug additive' label used in the hospital did not require the patients name to be documented. Some nurses added this detail to the label, whilst others applied a patient addressograph to the infusion container. Labelling all preparations would allow staff to readily identify its contents, thus minimising errors. The Trust would benefit from reviewing its guidance on labelling prepared medicines, flush solutions and the 'drug additive' used. This is supported by the findings of the pilot study where labelling errors such as no medicine name or dose were observed (chapter 3). It would also be timely; the NPSA injectables alert SOP provides clarity on appropriate practice

> *"All injections should be labelled immediately after preparation, except for syringes intended for immediate push (bolus) administration by the person who prepared them. Under no circumstances, however, must an operator be in possession of more than one unlabelled syringe at any one time..."* [NPSA, 2006;p.21].

Double-checking was discussed during the nurse interviews; they were equivocal about the benefits of one nurse routinely checking another's preparation. It has been reported a person would detect approximately 95% of all mistakes when checking another person [ISMP, 2003b]. Double checks are most effective when carried out independently, by staff trained to perform these checks. Robust double checking is time consuming, therefore with the current work pressure it is recommended these should be restricted to at error prone steps and high-risk medicines [ISMP, 2003b]. They questioned the robustness of the check and the evidence base to support that it prevented errors. Concerns were raised about its effectiveness, given the hierarchical nature of nursing and the existing hospital safety culture. Despite the potential limitations, most nurses described error-prone scenarios where they advocated a 'double-check' by a colleague. These were situations where their personal performance might not be optimal, such as an unfamiliar medicine, complex calculations and tiredness or 'high-alert' medicines such as insulin and heparin. Another source of checking used was the local IV guide, which for some medicines included a dose check table. There is a potential here for bar-code verification of a product's identity.

Calculations appeared to cause difficulties, and gave rise to concerns amongst the nurses who were aware of inadequate mathematical skills. Numerous studies have shown that miscalculations contribute to errors [Gladstone, 1995; Flynn *et al.*, 1997; Hand & Barber, 2000; Ross *et al.*, 2000; Mayo & Duncan, 2004; Preston, 2004]. Complex calculations are

recognised to increase the potential for IV medicines preparation error [Clinical Resource and Audit Group. NHS Scotland, 2002]. Poor mathematical skills have also been identified amongst other healthcare staff [Perlstein *et al.*, 1979; ISMP, 2003a; Oldridge *et al.*, 2004, Wheeler *et al.*, 2004]. Solutions are required to circumvent the need for calculations and have been discussed previously [section 4.5.4]. This appears to pose particular and unique problems in the paediatric and neonatal setting.

Major issues were highlighted with knowledge, skills and training of the nurses that undertook IV preparation (chapter 5). They described great variability in the training provided both at undergraduate and postgraduate level. Training on IV medicine preparation was provided rarely or not at all. The nurses who were interviewed indicated that formal training focused on theoretical aspects, with preparation skills gained through observing colleagues and during practical supervision after completing theoretical training. The nurses training had varied, depending on where and when it had been delivered, and in some cases occurred 30 years ago. The RCN IV therapy forum [2005] set out the knowledge and skills required for nurses involved in IV therapy, but without a nationally agreed curriculum there does not appear to be robust process for ensuring staff have the requisite skills. An alternative strategy to assure this would be to use a competency framework for IV medicines preparation. This is an appealing suggestion, as training does not guarantee competence in practice. It could be applied to all healthcare staff, would be transferable and provide evidence of pro-active risk management in this complex area. It would also address a further issue, where ongoing training or re-certification in IV therapy was not available. The NPSA in collaboration with Skills for Health have developed a competency template that defines the knowledge and skills needed to prepare injectable medicines and an assessment template [NPSA, 2006]. Organisations should adopt these and use them to identify training needs and plan delivery. Organisations will also be required to have written procedures and protocols for all stages of the injectable MUP. This in addition to setting out practice standards, will also assist training.

There should be national standardisation and agreement of which practical aspects of IV preparation should be formally taught at both undergraduate and postgraduate level. The nurses interviewed expressed concern that training delivered was not always readily transferable into practice. Training also needed to be realistic and achievable in the clinical setting. Hands on experience in skills laboratories would provide familiarity with

the techniques involved and consistency in training. Currently, staff may be learning suboptimal practice from their colleagues. This could then be supplemented with local orientation in their clinical area.

Numerous environmental and facilities issues that constrained the ability to prepare IV medicines were identified (chapter 5). These were the lack of a designated area to prepare IV doses, with cluttered and cramped working spaces. Some nurses had the opportunity to redesign their treatment room to improve these working conditions. These issues should be considered when planning, designing and refurbishing clinical areas within the Trust. Consideration should be given to improving the working environment through fewer interruptions, competing commitments, time pressures and staffing levels. Some solutions, such as minimising avoidable interruptions, could be led at ward level; whilst others require managerial level input.

An interesting issue that had not previously been identified was the level of health and safety concern amongst the nurses interviewed about exposure to antibiotic aerosols, opening glass ampoules and using sharps. Some of these could be addressed through using novel reconstitution and needle-free devices.

Nurses require easy access to information in their clinical area to enable them to prepare IV doses appropriately [NPSA, 2006]. In the study Trust, the main information source the nurses interviewed relied upon was the local IV guide. Other information sources relied upon for other medicines aspects were less helpful for IV preparation. Pharmaceutical manufacturers' leaflets used to be a valuable source of information, but they noted that recently these were sometimes absent or replaced with a patient information leaflet. Where the leaflet was missing, because the medicine had been transferred into a different container by pharmacy during dispensing, the leaflet should also be transferred. Another explanation for the comments received in the study, was that unlicensed medicines do not provide this guidance in any case. This issue is eloquently summarised in the following quotation

"...because they are unlicensed products, they are associated unknowns around patient safety since such products do not bring with them the guarantees of product quality, safety and efficacy that are taken for granted in a licensed medicine" [Gross, 2005b;p.743].

In such cases the local IV guide becomes particularly important. The nurses reported that when they required information that was not in the IV guide, it was difficult and time consuming to obtain. It would be useful if additional insights gained by the nurses through experience could be incorporated into this guide, for example, how to reconstitute teicoplanin without it foaming.

The NPSA alert acknowledged that injectable medicines are often supplied with inadequate or no technical information, and that this is not readily available in other medicines reference sources. The possibility of addressing this deficit by developing a NHS Injectables Medicine Guide is being explored [NPSA, 2006]. Meanwhile, it is important that the local IV guide comprehensively provides information to staff in a convenient, readily accessible manner.

The vital importance of a safety culture has been described [NPSA, 2003a]. Suggestions were received in this study that further work is needed to nurture and embed an open and fair-blame culture. This would facilitate learning and sharing of hazards and incidents so preventative measures can be implemented. A 'systems approach' is needed to understand and address the issues identified by the nurses. The nurses showed awareness of error provoking situations, this wealth of expertise could be tapped and sharpened. It has been proposed that some incidents, that have bypassed all the systems defences, can still be diverted at the last moment by front line staff with 'error wisdom'. Reason proposed a model that provides people with *"Basic mental skills that would help them to recognise and, if possible avoid situation with a high error potential"* [2004;p.ii31].

6.7 Study limitations

The thesis focuses on a single step within the IV MUP, and although this made study of the preparation stage practical and achievable, it does not reflect reality. The IV MUP is highly complex and actions in one stage are critically dependent upon actions in the preceding stages. This was addressed by an explicit assumption that the prescription from which an IV dose was prepared was correct and appropriate. However, errors or error producing conditions may originate at earlier MUP stages, remain undetected and unintercepted, and so be transferred through to the preparation stage. This was beyond the scope of the study. Similarly, the IVMPE framework described scenarios for inclusion and exclusion as

IVMPEs, but unless the error at the preparation stage actually reached the patient these were potential IVMPEs.

The Delphi technique (chapter 3) is a qualitative method, so its findings are not generalisable. However, this consensus method was used to gather agreement from experts and it is not expected to provide wider applicability. The methods were robustly applied and clearly described, providing transparency and enabling replication. A number of limitations were identified, the main concerns being pharmacist over-representation within the sample, failure to recruit infection control or microbiology expertise despite using the snowball sampling technique, insufficient piloting of the questionnaire prior to the second Delphi round and failure of the attempted validity checks. Survey administration may have achieved higher response rates had it been issued at a less inconvenient time for the participants, with shorter periods between subsequent rounds. Ideally, criteria from the second Delphi round should have been included in the third round to enable test-retest reliability to be assessed.

The pilot study of the observational data collection tool (chapter 4) showed that the IVMPE definition and framework could be operationalised as an audit tool. This enabled the identification of several potential methodological problems which will need to be resolved prior to use. These included the need for robust observer training covering competency assessment in observational techniques and aseptic methods. The publication of the NPSA injectable alert will aid training as it includes national standards for IV preparation in clinical areas, and will enable identification of unacceptable practice. This will also provide clarity for the audit when coding during data analysis. Previous research has demonstrated that effects bias created by the researcher and research process can be minimised [Dean & Barber, 2001; Bowling, 2002]. Although pre-registration pharmacy graduates were used for the observation it was envisaged that this role was appropriate for pharmacy technicians. This has not been evaluated, but technicians have been successfully used in similar work [Mansfield, 2001; Munro *et al.*, 2003].

Recruitment into the pilot study and in-depth interviews was slower than expected. The effects of researching into this sensitive area must not be underestimated. The requirement for explicit informed consent from participants appeared to be a source of concern. It could be that the information provided identified potential issues that the nurses had not

previously considered. It is likely that improvements in the safety culture would improve recruitment.

The nurses who agreed to be interviewed (chapter 5) were opportunistically sampled, and views may differ from those who did not volunteer. Again this was a qualitative method, so the findings are not widely generalisable. A larger sample size may have provided additional issues that were not identified by this study and would have enabled full characterisation of the categories identified. A key limitation of interview methods is that it addresses participant's perceptions and views, which may differ from reality. However through 'triangulation', by combining research methods, the limitations of each method are addressed [Smith, 2002]. This occurred in the present study as the observations and nurse interviews validated the Delphi study findings and consensus achieved in the Delphi study provides confidence in the item-pool generated in the first round.

6.8 Further work

Agreement on what constitutes an IVMPE in hospital clinical practice and a framework of inclusion and exclusion criteria were agreed. This definition and framework can now be used for observational audit for the quantification of IVMPE. Adoption of this definition and framework would reduce variability in what is considered an IVMPE. Further guidance is needed to enable the audit tool to be used consistently in other settings. Some of the guidance could be prepared centrally, such as listing those medicines where filtration would adversely affect stability.

Nurses are just one of a range of healthcare practitioners who undertake IV preparation. Therefore views of other healthcare professionals e.g. paramedics, doctors, radiographers, perfusionists could be investigated. There are several issues identified within this thesis where further study would provide clarity, such as the role of double checking and eliminating interruptions.

The IV preparation process cannot be addressed in isolation. Consideration should also be given to exploring issue that occur during the prescribing and dispensing stages which affect IV preparation. These research questions could be asked in a multiprofessional environment, such as employing focus groups. This would enable cross boundary issues and solutions to be investigated as healthcare professionals may not always consider

problems or solutions that fall beyond their own professional boundary. Systematic analysis of the IV MUP to identify where failures occur using techniques such as failure mode effect and criticality analyses would allow weaknesses to be highlighted. Solutions and resources could then be targeted at the weak or inadequate defences and prioritised for action.

Future research should clearly distinguish between the IV preparation and administration stages, as much of the current evidence is combined. In addition, it would appear that there are unique concerns within the paediatric and neonatal environment that would benefit from further study. This is because many medicines are provided in adult dose units, which poses risks of tenfold and 100-fold dose errors in neonates. In addition, paediatric and neonatal doses vary according to age and weight requiring a calculation, which introduces additional risks [Perlstein *et al.*, 1979; Schneider *et al.*, 1998]. National review and standardisation of the terminology used for IV medicines preparation is required [Gandy *et al.*, 2002].

The results from this study could be used to inform future qualitative and quantitative work. The resource implications and practicality of solving some of the issues identified warrant urgent attention. The findings from the nurses interviewed suggest that priority should be given to developing solutions to minimise interruptions, to the design and provision of a dedicated workspace, to using needle free devices and to ensuring that all the relevant information required for IV preparation and administration is available in clinical areas. It is also recommended that 'high-alert medications' and those requiring multi-step preparation should be purchased premixed or prepared in the pharmacy department and supplied to the clinical areas in a form ready to administer. It is recognised that ready to administer preparation are more costly; but detailed risk analysis are needed.

6.9 Conclusions

This thesis makes several new contributions to the literature on IVMPE. It provides a practical, multiprofessional, agreed IVMPE definition for hospital clinical areas, with inclusion and exclusion criteria. In line with current opinion, the definition incorporates poor aseptic technique. The definition has also been successfully translated into a data collection tool and its feasibility as an observational audit tool verified in adult and paediatric ward areas. The audit study describes the training and guidance required for

observers, and is suitable for use with previously validated measures to score the patient consequences of the error.

This audit tool provides a valuable mechanism for organisations to assess IV medicine preparation practice in clinical areas against safe practice standards. This allows identification of any deficiency to enable generation of a prioritised action plan. This could be used as a medicines management assurance measure for the Trust Board.

An insight has been gained into the concerns and difficulties that nurses encountered during IV medicines preparation in hospital clinical areas. Attention should be given to using a human factors approach to understanding and minimising the potential for error in these settings. This requires action at an individual, organisational, professional body and national level. With the NPSA patient safety alert on the 'Safer use of Injectable Medicines in Near-Patient Areas', due to be issued in 2006, IV medicines preparation will be under scrutiny. Therefore, the findings of this thesis are particularly timely. The NPSA tool provides a mechanism for pro-active risk evaluation and describes the organisational framework and standards required for injectable therapy. When combined with the audit tool developed in this thesis, this would allow identification of whether the framework has been implemented and embedded in practice.

The results from the nurses interviewed in this study indicate that priority should be given to:

- Developing solutions to minimise interruptions.
- The design and provision of a dedicated work space.
- Reviewing the availability of needle free devices.
- Reviewing IV training and competency.
- Providing an SOP for IV preparation.
- Ensuring that all the relevant information required for IV preparation and administration is available to staff in their clinical areas.

In order to address these concerns commitment and investment at individual, local, managerial and organisation level is required to further embed a safety culture. Actions are required that clearly demonstrate cost is not the over-riding NHS concern and that patient safety is paramount. Healthcare professionals need to work in partnership with

pharmaceutical manufacturers to enable them to design products that are simpler and easier to use. Ultimately, it in unrealistic that IV preparation could ever be error free, however it should be the goal of all those involved in this critical patient safety area.

Chapter 7

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List of Appendices

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