DRUG ERRORS IN ANAESTHESIA: TECHNOLOGY, SYSTEMS AND CULTURE.

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ABSTRACT

Annually in Britain, iatrogenic harm results in patient deaths, increased morbidity, and millions of pounds spent on additional healthcare. Errors in the administration of drugs have been identified as a leading cause of patient harm in major international reports,[1 2] and the literature also suggests that most practicing anaesthetists have experienced at least one drug error.[3 4]

Methods of conventional drug administration in anaesthesia are idiosyncratic, relatively error prone, and make little use of technology to support manual checking. While there is support for the use of double-checking during anaesthesia practice, the availability of a second person during every drug administration, and issues around hierarchy and recognised automaticity in checking[5] can potentially be the limitations. Currently there has been little work carried out in the UK in relation to the use of double checking protocols and there remains a need for a robust check that can be implemented within the National Health Service (NHS).

The first study explored the feasibility of introducing a double check methodology, either second-person confirmation or electronic confirmation into clinical practice within the NHS. This was the first study of this nature within the NHS and explored the attitudes, barriers and benefits of each method.

The second study was designed to explore the beliefs and attitudes of anaesthetists and Operating Department Practitioners (ODPs) on introducing technology which is designed to reduce drug error. This study also explored in greater depth the culture issues raised in the first study and the impact of introducing the electronic confirmation on the anaesthetist's workload.

The findings suggested that while many participants acknowledged that the process of second person double checking was an important factor to minimise the opportunity of any unsafe medication administration, the process of second person confirmation could be prone to human manipulation and could alter the behaviour and practice of the anaesthetist, resulting in a reluctance to adopt it.
The electronic confirmation method was found to be more feasible. It did not rely on the presence of a second person at the time of drug administration, and did not impact on the anaesthetist's workload.

This thesis has shown that technology was more readily accepted and seen as more feasible to use by anaesthetists within their clinical practice. However, these studies have also shown that the culture and beliefs of the organisation and individuals, in particular of 'blame and shame', has such a strong influence that it continues to prevent a true safety culture developing into an open culture of reporting incidents, recognising that drug errors remain a problem, and that corrective measures are required to prevent them.

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LIST OF PUBLICATIONS

Papers

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Abstracts

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ABREVIATIONS

AAGBI	Association of Anaesthetists of Great Britain and Ireland
AfPP	Association for Perioperative Practice
AIMS	Australian Incident Monitoring Study
BWS	Borg Workload Scale
CAA	Civil Aviation Authority
CODP	College of Operating Department Practitioners
DOH	Department of Health
DSSQ	Dundee Stress State Questionnaire
ERAA	European Regions Airline Association
GMC	General Medical Council
IOM	Institute of Medicine
NASA	National Aeronautics and Space Administration
NASA-TLX	NASA Task Load Index
NHS	National Health Service
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
ODP	Operating Department Practitioner
PDA	Personal Digital Assistant
PIS	Participant Information Sheet
QHCAC	Quality of Health Care in America Committee
QUiC	Quality Interagency Coordination Task Force
R&D	Research and Development department
RCT	Randomised Controlled Trial
RCoA	Royal College of Anaesthetists
REC	Research Ethics Committee
SWOT	Strengths, Weaknesses, Opportunities, Threats
TSCSC	Trent Simulation & Clinical Skills Centre
SAC	Safety Assessment Code
SALG	Safe Anaesthesia Liaison Group
VAS	Visual Analogue Scale
VASER	Validating Anaesthesia Simulation-based Error Research
VLT	Vigilance Latency Task

CHAPTER 1 – INTRODUCTION

1.1 Background

1.1.1 The Government's promise of a better National Health Service

In December 1997, the Government published *The New NHS: Modern, Dependable;*[6] a White Paper with the agenda of providing a ten year modernisation strategy for the National Health Service (NHS). "This White Paper explains how the Government will build a modern and dependable health service fit for the twenty first century".[6] The paper went on to state that there would be a guaranteed national standard of excellence for patients providing assurance for the quality of services provided. Across the country these changes were expected to result in a more constant and reactive service. The quality the government was striving for was, in the broadest sense: doing the right things, at the right time, for the right people, and doing them right - first time.[6] It was expected that as a result of this paper, the NHS would now have a clear direction to move in, in order to become a modern and dependable service.

1.1.2 Patient safety issues in the United States of America

In the United States of America (USA), patient safety was also coming to the forefront of the political agenda. In 2000 the document "*To Err is Human: building a safer health system*"[2] was published following the formation of the Quality of Health Care in America Committee (QHCAC), within the Institute of Medicine. The Institute of Medicine works outside the government framework to ensure scientifically informed analysis and independent guidance. They provide unbiased, evidence-based, and authoritative information and advice concerning health and

science policy to policy-makers, professionals, leaders in every sector of society, and the public at large.[7]

The QHCAC was created to develop a strategy for improving quality in health care. The report addressed issues relating to patient safety, outlining a national plan for reducing errors in health care and improving patient safety in the USA. The paper stated that health care was a decade or more behind other high risk industries in focusing its attention on ensuring basic safety.[2]

It was recognised by the committee that there was still much to learn about the types of errors perpetrated in health care and their causes, but it was essential that patients should not have to worry about being harmed by the health system itself.[2]

1.1.3 Issues of quality in health care still present in Britain

In Britain, following on from *The New NHS: Modern, Dependable,*[6] In 2001 the Department of Health published the document '*An Organisation with a Memory';*[1] this was in response not only to the realisation that the NHS was still failing to provide the appropriate quality of care, but that they were failing to prevent serious incidents where patients were being harmed or experiencing very poor outcomes.[1] It had also become apparent that the NHS was failing to learn from its mistakes when they did occur; "Amidst this major and comprehensive range of measures to assure and improve quality in the NHS, there is one remaining weak link. The NHS has no reliable way of identifying serious lapses of standards of care, analysing them systematically, learning from them and introducing change which sticks so as to prevent similar events from recurring".[1]

It is essential in the modern health service, which involves the use of some of the most complex and advanced technologies in existence, safety practices keep pace and respond quickly to any errors that occur. However, some aspects of medical practice have remained unchanged for many decades[8] and in this respect the NHS still lags behind other high risk sectors, such as aviation and the nuclear industry.[1]

1.1.5 The National Patient Safety Agency

In 2001 the NPSA was formed and charged with the responsibility of formulating solutions for existing problems and developing the National Reporting and Learning System (NRLS).[9] The NRLS aims to identify and reduce risks to patients receiving NHS care and leads on national initiatives to improve patient safety. It does this through feedback and guidance which it provides to healthcare organisations in order to improve patient safety. These include alerts to address specific safety risks, tools to build a strong safety culture and national initiatives in specific areas such as hand hygiene, design, nutrition and cleaning.[10]

It is increasingly accepted that adverse outcomes are often due to system failures and that by addressing the intrinsic problems, inherent in some systems, the error may have been prevented or actions could have been taken to mitigate the circumstances.[1]

1.2 Understanding the Causes of Failure

There are two approaches to human error described in the literature. The person-centred approach and the system approach.[11] Reason[11] describes the different models of error causation ascribed to each and the philosophies underpinning them.

1.2.1 The Person-Centred Approach

The Individual is responsible for causing errors

The person-centred approach remains the longstanding tradition within health care today despite the efforts of many to move away from it.[11] The focus is on the unsafe acts of people at the 'sharp end' such as nurses, doctors and pharmacists. The belief that these unsafe acts originate from aberrant mental processes, such as forgetfulness, poor motivation, carelessness, negligence and recklessness leads to corrective measures targeted at the individual rather than the situation and inevitably falls within the control of management.[1 11] Supporters of this approach view errors as moral issues, assuming that bad things happen to bad people.[11] Blaming individuals is emotionally more satisfying than targeting institutions and trying as far as possible to dissociate an individual's unsafe actions from any institutional responsibility is clearly in the interests of managers.[11]

However, by focusing in on the individual the error is disconnected from its system context. As a result two important features of human error tend to be overlooked. Reason suggests it is often the best people that make the worst mistakes, "error is not the monopoly of an unfortunate few" and goes onto say that far from being random, mishaps tend to fall in recurrent patterns.[10] The same set of circumstances can provoke similar mistakes, regardless of those involved, the quest for greater

safety is seriously impeded by an approach that does not pursue and eliminate the error triggering attributes within the system at large.[11]

1.2.2 The System-Centred Approach

The system is responsible for causing errors

The basic presumption in the system-centred approach is that everybody is fallible and errors should be anticipated even in the best organisations. As Reason[12] and Merry and Webster[13] describe, an error is an unavoidable trait of human behaviour, no amount of proficiency or expertise will eliminate it.

Within the system-centred approach, errors are seen as being created and triggered by elements inherent within the system. These elements include the organisation's attitude towards safety as a whole, the culture it promotes and the position management takes to risk and chance.[1] Corrective actions are based on the belief that although we cannot change human nature, we can change the working environment to lessen the impact any intrinsic characteristics may have on the production of errors.

All potentially hazardous technologies should possess some form of built in barrier or safeguard that becomes interjected between the source of the hazard and the potential victims or losses that would occur should that risk become realised. When an error occurs, the central focus should not be on who made the error but how and why those defences failed. What were the factors that led to the creation of those conditions which triggered the error? The defences can be categorised by their characteristics, they are either 'hard' (physical containments, automation and engineered safety features) or 'soft' (the procedure, protocols, administrative

controls and people at the sharp end). The human element of the system can weaken or create gaps in these defences in two ways: by active failures and latent conditions. Nearly all adverse events involve a combination of these two sets of factors.[11]

1.2.3 Active Failures

1.2.3.1 Slips, lapses, mistakes and violations

"Knowledge and error flow from the same mental source, only success can tell one from the other"

[Ernest Mach 1905[14]]

Cognitive psychologists, over the past decade, have expanded our understanding of human error, theories of consciousness, memory, attention and performance greatly, all of which are fundamental to the understanding of medical error research. An active failure can be described as the 'unsafe acts' of individuals, such as doctors or nurses, leading to the failure to perform an action as required.[14 15] These active failures can be divided into slips, lapses, mistakes and procedural violations.

Slips

A slip results from a failure to execute an action, whether or not the plan behind it was adequate to reach its objective. Slips are said to be skill based, occurring during the execution of smooth, automated and highly integrated tasks that do not require

conscious control or problem solving, therefore a slip can be associated with paying insufficient attention.[14 15]

Lapses

The distinction between a slip and a lapse can be very subtle. Lapses involve memory failure, and may only be apparent to the person who experiences them.

Slips and lapses occur when actions do not go to plan, mistakes happen when a plan proves inadequate. The individual is aware of the problem and begins to use rules or knowledge to solve it. A mistake occurs when the necessary knowledge or rules to solve the problem are lacking. A rule-based mistake can occur when normally good rules fail to be applied or are misapplied, or when bad rules are applied. These rules may originate from the individual or from protocols drawn up by external bodies.

Mistakes

Knowledge based mistakes can be thought of as errors of judgement, manifesting during 'on the hoof' problem solving. These normally occur when all previously utilised solutions have been exhausted. As human beings, having recognised a pattern or problem as comparable to one faced previously, we quickly provide the first hypothesis which comes to mind and tend to stick with it. If the hypothesis is correct then we enhance our reputation for being decisive, but when it is not we are often slow to change. We prefer to seek confirmatory evidence rather than

putting our hypothesis to the test. This leads to a highly error prone endeavour, especially if an individual lacks knowledge or judgement.[14 16]

Violations

Violations can be described as deliberate breaches of rules or policies. Similar to errors, violations do not inevitably imply harm or disregard of safety. Reason,[17] defines violations as 'deliberate – but not necessarily reprehensive – deviations from practices deemed necessary (by designers, managers, and regulatory agencies) to maintain the safe operation of a potentially hazardous system' - deviations from safe operating practices, procedures, standards, or rules'.

Violations differ from errors in that they stem from considered choices; they are deliberate deviations from standard instructions that seem to offer some element of advantage to the individual.[18] Hurwitz & Sheikh[19] however, suggest that these choices are not made entirely freely and that they are often provoked by 'significant operating restrictions and system faults', Espin and colleagues[20] also argues that 'more rules simply may provoke more rule violations'. Within that violation there is often a rationale; a belief, whether right or wrong, that breaching a rule or regulation is effort saving and will not cause significant harm to the patient.[19]

According to Amalberti[18] the degree of violation varies according to 'the type of instruction, the nature of the work, and the social and organizational context'. In certain situations a certain level of flexibility is tolerated, or even expected. An

example would be evidence based medicine, a set of guidelines for practice rather than a compulsory set of instructions. Custom and culture can reinforce people's beliefs and decisions about whether a regulation should be breached or not. On the other hand, violations can stem from recklessness on the part of a health professional, who chooses purposely to violate a regulation.[19]

1.2.4 Latent Conditions

1.2.4.1 The managements influence on error creation

Latent conditions can be compared to 'resident pathogens' in the body. By themselves, they are often harmless, lying dormant undetected for long periods before combining with local factors and active failures to infiltrate or totally circumvent any defences in place.

Latent conditions arise from critical decisions made by designers, builders, procedure writers and top level management. All of these decisions have the potential for seeding pathogens into the system, even good ones (hence the term latent condition rather than latent failure).[11 21] Latent conditions have two types of adverse effect: they can translate into error provoking conditions within the workplace, such as time pressure, excessive fatigue, staff shortages, lack of experience and inadequate equipment. Or they can create long lasting holes or weaknesses in the defences arising from untrustworthy alarms and indicators, unworkable procedures, design and construction deficiencies, etc. Unlike active failures, whose precise forms are hard to predict, latent conditions are always present.[11] They can therefore, theoretically, be identified and removed before they cause an adverse event. Understanding this leads to proactive rather than reactive

risk management.[11] However, the process of addressing these latent conditions can strike at the heart of the organisation's culture or the core management philosophy. Consequently, attempts to deal with such issues are often problematic as they require fundamental changes to the core beliefs and values of senior staff within the organisation.[21]

1.2.4.2 How errors get through the barriers

Reasons' 'Swiss cheese' Model of system accidents

As already discussed, key features of the system approach are the defences, barriers and safeguards that are inherently present within it. There are many defensive layers built into high technology systems, some are engineered such as alarms, physical barriers and automatic shutdowns, some rely on people, such as surgeons, anaesthetists, pilots, control room operators, while others depend on procedures and administrative controls. The primary function of all these defences is to ensure the protection of assets and potential victims from local hazards.[1 11]

Reason[11] compared the causation of accidents within a system to a piece of 'Swiss cheese'. Ideally all the defensive layers present within the system should be intact, in reality though; they are more like slices of Swiss cheese – full of holes. Unlike the cheese however, these holes are constantly opening, shutting and shifting their location. These holes appear due to active failures and latent conditions, and although the presence of holes in one slice does not normally lead to disaster, the opportunity for disaster arises when these holes line up briefly to allow a window of accident opportunity.[1 11 14]

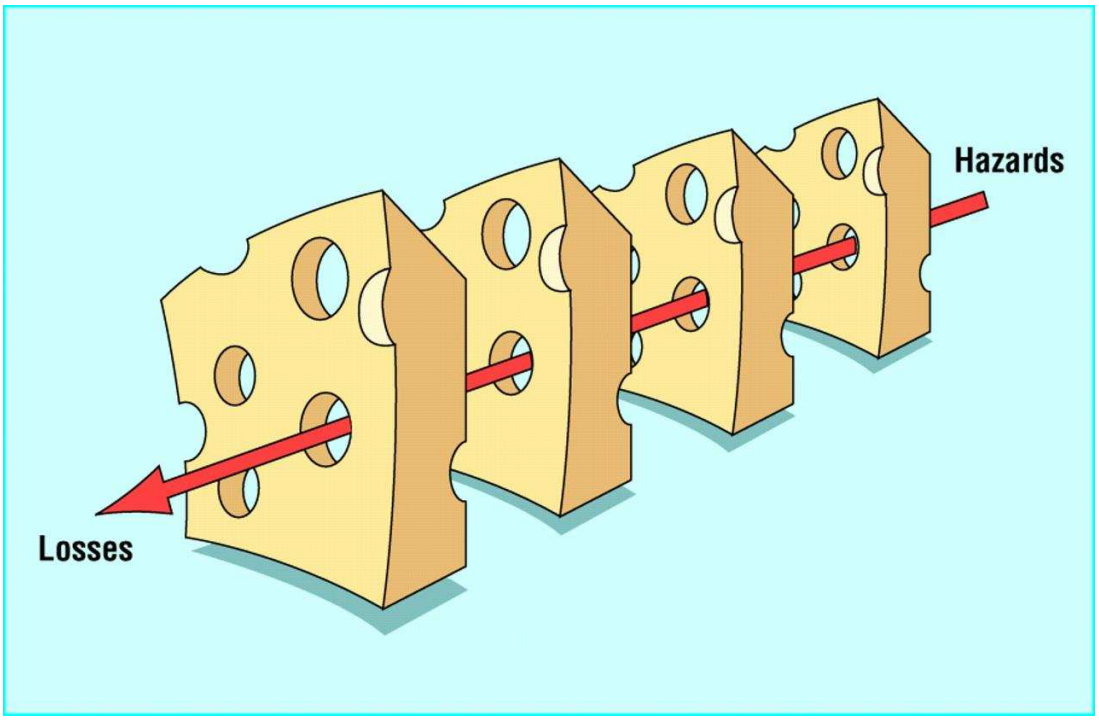

Figure 1: The Swiss Cheese Model of accident causation:
Defences, barriers and safeguards may be penetrated by an accident trajectory.

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Within well defended systems such as those found in aviation and nuclear power plants, accidents are rare due to the sheer number of barriers and safeguards in place.[1] However, within many fields of clinical practice there may exist, only a few slices of protective measures designed to keep danger away. It can be said of health care that the human elements are often the last and most important defences against a disaster occurring.[1]

1.2.5 Interaction and Coupling

1.2.5.1 Why is it necessary to understand interaction and coupling?

Almost any organisation will have areas that interact under closer inspection. However as systems grow, whether they are aviation, nuclear or health care, they become more and more complex and encounter more and more obscure and unpredictable interactions.[22] Charles Perrow[22] stated that certain characteristics of a system can make it either inherently safer or more dangerous; he described these two elements as interaction and coupling.

Interaction

Interactions can be described as being either complex or linear.

If there are numerous choices and intertwining parts at any point during the process to complete the selected task the interaction can be characterised as complex. Complex interactions were not part of the original system design; they are unexpected, baffling and difficult to plan for.[22]

Linear interactions on the other hand follow an independent series of steps to complete the designated task. They are familiar interactions that even if something happens that is unexpected the interaction is visible and so can be rectified. Complex interactions by their nature are more at risk of failure than linear interactions due to their inherent complexity which can lead to unexpected interactions between the different elements within the system.[14]

Coupling

Systems can also be described as either being tightly or loosely coupled.

A system is tightly coupled if there is a high risk of serious consequences resulting from a system failure or error. A tightly coupled system does not have the ability to wait for an error or failure to be rectified, it cannot compensate and so accidents result more readily.[8]

Loosely coupled systems as their name implies are more flexible and therefore allow greater opportunity for any mistakes to be rectified avoiding serious outcomes. Loosely coupled systems, can absorb impacts and failures without becoming unstable.[8 22]

1.2.5.2 Recovery from Failure

Since all systems can fail, it is critical that recovery is possible and that any failure or error does not spread causing catastrophic outcomes. Because of this most systems tend to have safety devices designed in to prevent such incidents spreading.

Tightly coupled systems, however, have to have safeguards built in at the design stage. All possible interactions have to be thought of in advance and buffered against as there is little scope to rectify an error once it has happened.

Loosely coupled systems on the other hand have the luxury that mistakes and failures can be repaired more easily, they allow for alternative routes to be taken even though they were not predicted in advance.

The same can be said for the substitution of staff, equipment and techniques. In tightly coupled systems there is little opportunity to replace faulty equipment, try

alternatives or substitute staff, whereas in loosely coupled systems all of these routes may be possible.

The key safety design of a nuclear power plant is to prevent a catastrophe; these systems are designed with as many buffers and safeguards as possible to prevent errors becoming disasters. Why then should the health system rely solely on the human element, in this case the anaesthetist, to ensure safe system performance?[8]

1.2.5.3 Are there really similarities between an anaesthetised patient and an aircraft or nuclear power plant?

Within the literature there have been many who have likened anaesthesia to the aviation industry.[16 23] Both anaesthetists and pilots are highly trained professionals who are usually determined to maintain high standards, both externally and internally imposed, whilst performing difficult tasks in life threatening environments. They both use high technology equipment and function as key members of a team of specialists, although not always with colleagues of their choosing, and are sometimes forced to operate at a time and under conditions which are far from ideal. They both exercise high level cognitive skills in a most complex domain about which much is known, but where much remains to be discovered.[16] Webster[8] however prefers, in terms of complexity and coupling, to compare an anaesthetised patient with a nuclear power plant; a highly complex, unpredictable system with many unknown failure modes.

1.3 Safety Culture

1.3.1 The Safety Culture

'To err is human, to cover up is unforgivable, and to fail to learn is inexcusable.

[Sir Liam Donaldson, Chief Medical Officer[24]]

Different safety cultures have been described in the literature. One definition from the NPSA suggests that a safety culture fosters a willingness to report and learn from errors.[25] There is evidence that the possession of a shared set of beliefs, attitudes and norms in relation to what is seen as safe clinical practice has a positive and quantifiable impact on the performance of organisations.[25] However, a culture that apportions blame onto the individual and ignores the role of the underlying system encourages people to cover up errors for fear of retribution. This culture of blame also prevents the identification of the true causes of failure.[1]

1.3.2 The importance of a safety culture

A key issue within an organisation is the safety culture, this is important for two reasons.

Firstly, the personnel within the organisation are constantly changing; the safety culture that exists within it does not. Secondly, the culture is as widespread as the interventions and safeguards the organisation can put in place and so can influence for good or bad the impact these initiatives will have.[1]

It has been argued that safety cultures can be established by identifying and putting in place their key components. The process can be seen essentially as one of collective learning, or of a constant and active awareness of the potential for

failure.[1] It would be unfair to suggest that the NHS as an organisation is incapable of achieving this, but the literature suggests that this process takes a long time and the implementation and take up of initiatives in patient safety can be patchy.[1]

1.3.3 The aviation industry's approach to safety culture

In the aviation industry, safety analysis is well established and based on a systems approach.[22 26] The key focus of the system is not just ascertaining and subsequently learning from the accidents or serious incidents, but also from the minor incidents or near misses, some of which might have the potential to lead to more serious outcomes.[1]

During the 10 year period from 1998 – 2007 the Civil Aviation Authority received 42, 400 reports of incidents involving large UK public transport aircraft. Of these incidents 132 were reportable accidents of which 5 were fatal.[27] These figures highlight that the majority of information gathered for educating and training within the aviation industry was not gained from the major accidents but from the minor incidents that had the potential to escalate into catastrophic outcomes.

The aviation industry does not use evidence based practice to produce a reduction in mortality or morbidity. It utilises many logical and practical measures to establish a robust safety culture. When dealing with a process with rare but catastrophic consequences, it may be impossible to prove statistically the benefit of some safety measures. This could be applied to many practices in anaesthesia, where the

number needed to treat to reduce mortality may be large because mortality is rare.[28]

1.3.4 Official response to error

Over the last 20 years the incidence of doctors being charged with manslaughter has shown a distinct increase,[29] and the literature advocates that if safety rules have obviously been violated then the criminal prosecution of a doctor is justified.

Over the last two decades there have been several independent inquiries involving NHS Hospitals and Primary Care Trusts. The Bristol Inquiry[30] was a particularly influential catalyst in putting patient safety and quality improvement high on the agenda in the NHS.[31]

More recently two reports which followed concerns about standards of care at the Mid-Staffordshire NHS Foundation Trust - the Robert Francis Inquiry report[32] and an investigation and report published by the Healthcare Commission in March 2009,[33] stated that "The culture of the Trust was not conducive to providing good care for patients or providing a supportive working environment for staff."

The Francis report[32] cited a number of factors that contributed to the culture inherent within Mid Staffordshire NHS Foundation Trust that compromised patient safety:

- The attitudes of patients and staff; a lack of compassion and an uncaring attitude shown by some staff towards vulnerable patients,
- Bullying and an atmosphere of fear of adverse repercussions,

- Target-driven priorities with a high priority being placed on the achievement of targets.
- Disengagement from management by the consultant body.
- Lack of trust in management leading to reluctance to raise concerns.
- Low staff morale due to financial constraints and staff cuts.
- Isolation; the Trust and its staff carried on much of its work in isolation from the wider NHS community.
- Lack of openness.
- Acceptance of poor standards of conduct with insufficient attention to the maintenance of professional standards.
- Reliance on external assessments and denial of the recent criticisms were also reported by the inquiry.

The Francis report went onto say that "While benchmarks and data-based assessments are important tools, these should not be allowed to detract attention from the needs and experiences of patients. Benchmarks, ratings and status may not always bring to light serious systemic failings."[32]

1.3.4.1 Previous Cases

As previously mentioned the Bristol inquiry[30] reported that between 1990 and 1995, despite an anaesthetist continuously raising concerns about poor surgical quality outcomes, cardiac surgeons at the hospital continued to operate on newborns until they were eventually forced to stop by the Department of Health. A subsequent public inquiry concluded that thirty-five deaths had been avoidable.[31 34]

Two of the three cardiac surgeons were struck off the medical register but no criminal prosecutions were brought.

In 2002[35] Dr Mulhem was convicted of manslaughter and sentenced to an eight month custodial sentence following the fatal administration of Vincristine intrathecally, instead of intravenously, to an 18 year old oncology patient. Previously in 1999[36] two doctors, working in a different NHS Trust, were cleared of manslaughter after a 12 year old boy was incorrectly injected with the same drug. In 1998[37] a GP was charged and convicted of manslaughter for administering a dose of diamorphine to a patient that was ten times the recommended maximum.

In January 2000, GP Dr Harold Shipman was convicted of murdering 15 of his patients. The subsequent independent public inquiry into his crimes found the number of patients killed by the former family doctor to be at least 250 over a 23 year period. Whilst this case is one of deliberate overdose of diamorphine with the intention to murder and not a medication error, it has impacted on the system in which medical professions work within. The inquiry has published six reports which made a number of recommendations for the reform of various British systems. It called for coroners to be better trained and underlined that better controls on the use of Class A drugs by doctors and pharmacists were needed. Specifically the fourth report called for stringent controls on the use and stockpiling of controlled drugs such as diamorphine, and the fifth report on the regulation and monitoring of GPs criticised the General Medical Council (GMC) for failing in its primary task of looking after patients because it was too involved in protecting doctors.

Dame Janet Smith who chaired the inquiry said of the GMC that “the organisation's constitution should be changed so the GMC is no longer dominated by elected members.” She also stated that the GMC should also be directly accountable to Parliament.

More recently, in February 2008, Dr Daniel Ubani, a Nigerian-born German citizen, was on his first UK shift as a locum GP when he injected a patient, David Gray, with 100mg of diamorphine – 10 times the recommended maximum dose. Dr Ubani had flown into the UK the day before and had only a few hours' sleep before starting a 12-hour shift.

Dr Ubani was struck off the general medical register by the GMC in June 2010 but is still allowed to practice in Germany where he normally resides.[38] William Morris, the coroner in this case, called the death of David Gray "gross negligence and manslaughter" and called for a review of European regulations which allow free movement of doctors, a national database of overseas doctors applying to work in out-of-hours services in the NHS, and more consistent standards in monitoring by local health chiefs working for primary care trusts.[39]

Niall Dickson, Chief Executive of the GMC, said: "On the general issue of doctors coming to work here from the European Union, the GMC remains extremely concerned that the current arrangements do not provide patients with the protection they need. He went on to say that "Patient safety must come first and we need to plug the gaping hole in our current procedures. As the guardian of

standards for doctors working in this country, the GMC must be able to assess the language and clinical competence of doctors who come from Europe, as we already do for doctors coming from the rest of the world".[40]

Dr Ubani was charged with death by negligence, in Witten, Germany, over Mr Gray's death. He received a nine-month suspended sentence and ordered to pay a fine of 5,000 Euros (£4,370). This prosecution, in Germany, meant he couldn't be charged in the UK for possible manslaughter.[41]

1.3.4.2 The threat of litigation on establishing a Safety Culture

Merry[42] advocates that if the system or other environmental characteristics are recognized as the cause of errors within health care, punishing the member of staff who makes them, without considering these factors, is unlikely to prevent their reoccurrence. In addition, standardised interventions, such as the use of new technology, have been previously shown to have better safety effects than the prosecution of individuals.[4 43]

Chapman[44] also suggests that 'Practicing under the threat of prosecution can only serve to hide errors'. If individual doctors are singled out for punishment it will become much harder to foster an open culture, interfere with independent safety investigations and destroy the willingness of people to voluntarily report errors and violations. This in turn will lead to faults in the system remaining hidden, and potentially more patients dying.[29 43-47]

The Bristol Inquiry[30] stated that 'the culture of blame is a major barrier to the openness required if sentinel events are to be reported, lessons learned and safety

improved. The system of clinical negligence is part of this culture of blame. It should be abolished.'

Charging doctors with manslaughter following a medical error may be an emotionally satisfying way to demand retribution; however, by putting the blame on the professional, the organisation and anyone else involved are let off the hook. More significantly, it may not give the principal victims self-assurance that a comparable incident will actually be prevented in the future.[43]

1.3.5 Critical Incident Reporting

Incident reporting systems are considered useful tools to learn from adverse events, errors and near misses within healthcare and other high risk industries. They have been described as a key prerequisite for the NHS in the effort to improve the quality of services and patient safety.[1 6 23] The belief is that the learning derived from incidents and near misses, rather than pretending the mistake did not occur, can lead to improvements in safety.[48-50]

The investigation of critical incidents was first used in the 1940s by Flanagan within the aviation setting.[51 52] In 1978, Cooper & Colleagues[53] used a 'modified critical incident technique' where they obtained details of preventable events from interviewing anaesthetists.[52] It is now standard within anaesthetic departments to have systems in place to record, discuss and disseminate information about adverse events and near misses, with the hope to learn from these "free lessons" on latent failures, identifying potential threats and improving patient safety.[12 49 50 52]

Evans and colleagues found that more than 90% of consumers believed that healthcare workers should report errors, even when the outcome of the error was

temporary and had no long term health effects on the patient.[54] In the UK in 2001, the NPSA set up the NRLS for the NHS. This is a generic system and covers all specialities and since its conception, has received over 4 million incident reports.[52] However as already discussed, previous research suggests that many incidents go unreported, compromising the effectiveness of such schemes.[55-59] In addition, substantial variation in incident reporting behaviour has been shown between different professional groups, where doctors are less likely to report an adverse event than nurses and midwives.[60-62]

1.3.5.1 Critical Incident reporting in Anaesthesia

The Royal College of Anaesthetists (RCoA) and the AAGBI have recently worked in partnership with the NPSA to develop and launch a speciality specific critical incident reporting system for anaesthesia.[52] The new system has been described as incorporating most of the features of a potentially successful system, in terms of data capture, analysis and feedback.[52 63] It is clear though, that clinicians will not waste their time reporting unless they can see a tangible response and improvement to quality and patient safety. There also needs to be the assurance that they will be at no risk of retribution.[63]

1.3.6 The Safety Culture within anaesthesia

Anaesthetists have a long history of involvement in patient safety. Over 20 years before the publication of 'an organisation with a memory'[1] and 'to err is human'[2] the Association of Anaesthetists for Great Britain and Ireland (AAGBI) had established a safety committee to investigate patient safety issues.[64]

Leape and colleagues[65] write that the current practice in anaesthesia provides an outstanding example of how a high level of safety can be achieved in health care. Mortality from anaesthesia has declined 10-fold in the past several decades as the result of a concerted effort to improve safety.

Anaesthesia safety was achieved by applying a whole host of changes that made sense, were based on an understanding of human factor principles, and had been demonstrated to be effective in other settings. Safety they showed was doing a lot of little things that, in aggregate, made a big difference.[65] The NHS is now founded on evidence based practice, so convincing managers and the medical profession to accept changes without any proof that they make a difference is becoming extremely difficult. Furthermore as Webster[8] states, delivering anaesthesia with a safety record similar to that of the aviation industry is proportionally more difficult because aircraft are far less complex than an anaesthetised patient.

CHAPTER 2: MEDICATION ERRORS IN ANAESTHESIA

2.1 Medication Error

"Everything that happens once can never happen again, but everything that happens twice will surely happen a third time"

Paulo Coelho [The Alchemist][21]

2.1.1 Medication Safety a universal goal

Medication error is not the sole plight of the NHS; they occur in all health care settings on an international scale.[66] Improving the prescribing, dispensing and administration of medication is of precedence to governments across Europe, Australasia, North America and numerous other countries.[66] The Government in 2001 published the paper *Building a safer NHS for Patients* that defined their goals for improving patient safety. Within the paper it described four key areas that needed decisive attention of which one was the reduction of serious medication errors by 40%.[21]

The publication *Building a safer NHS for Patients – Improving Medication Safety*[66] states that "medication errors are consistently reported to account for between 10% and 20% of all adverse events".

2.1.2 What is a medication error?

Medication error is not the result of adverse events occurring from the correct prescribing or administration of a drug, it is the result of an omission or oversight, a

slip or a lapse when the medication was prescribed, dispensed or administered which would otherwise have been avoidable.[14 66]

Although medication errors may not necessarily result in injury, it is an important indicator of an organisation's medication safety and therefore should not be ignored.[66]

2.1.3 The incidence of medication error

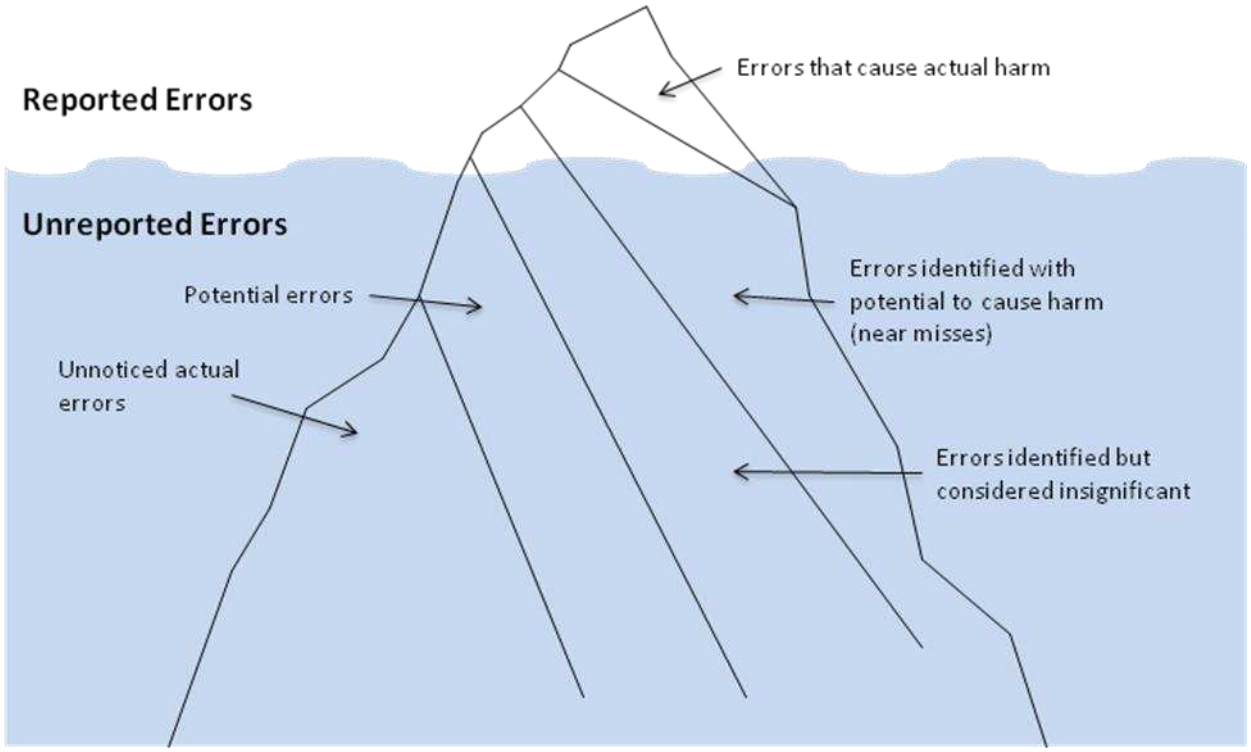
The literature suggests that within the hospital environment, medication error is one of the leading causes of harm to patients.[67 68] In 2000 the paper 'to err is human: building a safer health system'[2] shocked the health community when it reported that more than one million medical mishaps occurred each year in the USA resulting in 100 000 patient deaths, 77 000 of which were due to adverse drug events.[69] Amongst the first 4000 reports to the Australian Incident Monitoring Study (AIMS) there were 1199 reports involving drug incidents[70] and in the UK the NPSA received on average 99,000 reports of adverse incidents per month between October 2009 and September 2010 and of these reports, 10600 were medication related.[71] However as Osbourne and colleagues[72] and Horns and Loper[73] suggest, medication errors are underreported and these figures may just be the tip of the iceberg.

2.1.4 Underreporting of medication error

Bates[55] stated that 'the evidence suggests that for every medication error which harms the patient there will be 100, mostly undetected errors, which do not' [Fig 2]. Errors may be unreported for several reasons, the continued emphasis on blaming

the individual when the system is at fault, fear of the consequences of reporting the error, the perception that the patient is unharmed by the incident or the lack of awareness that an error has occurred.[66] Leape[56] suggests that only the most serious cases emerge, while others are covered up or discussed in private.

Figure 2: The Medication Error Iceberg



2.1.5 Incidence of Drug Errors in Anaesthesia

The complex process of administering intravenous drugs in anaesthesia can be hindered by pressures of urgency, poor communication and fatigue.[28, 74] Studies have shown that a single drug administration can involve up to 40 individual steps; it is perhaps of greater surprise then that more errors do not occur.[28, 75]

Despite literature spanning more than two decades on the incidence of medication error in anaesthesia, it remains a global problem.

AIMS collected data on critical incidents from 1988 to 2001. Critical incident reporting is widely recognised in both medical and non-medical fields as being an important tool in the identification of system based errors.[28] It was first used within anaesthesia in 1978 by Cooper and colleagues[76] and since then most health care systems in the developed world collect critical incident data. The data is used for auditing work practice, for correction of factors contributing to the incident and for identification of recurrent problems.[76]

In 1993 Currie and colleagues[77] evaluated the first 2000 incidents reported to AIMS and found there were 144 drug errors reported within anaesthetic practice. Abeysekera and colleagues[28] reanalysed the AIMS database between 1988 and 2001 which was by then much larger and found 896 incidents involving drug error within 8088 reports. More recently Catchpole and colleagues[9] analysed data from a two year period, January 2004 to February 2006, from the NRLS in the UK and found that within the 12606 reports on the database 1120 related to medication incidents within anaesthesia.

Other authors across the world have analysed the total number of drug error incidents over periods of time within anaesthesia, the results of which can be found in table 1.

Table 1: Incidents of reported drug error within anaesthesia

Authors	Country	Time Line	Total Number of Anaesthetics	Total reported drug errors	% Rate of error
Fasting and Gisvold [78]	Norway	Sept 1996 to Oct 1999	55,426	63	0.1
Hintong et al [79]	Thailand	Feb 2003 to July 2004	202699	40	0.02
Khan and Hoda [76]	Pakistan	Jan 1997 to Dec 2002	44 874	165	0.37
Llewellyn et al [80]	South Africa	April 2005 to Jan 2006	30 412	111	0.36
Sakaguchi et al[81]	Japan	1993 to 2007	64 285	50	0.078

2.2 Types of medication error reported in anaesthesia

2.2.1 What is the most commonly reported error?

The most commonly reported error within the literature is choosing the wrong drug or wrong dose.[69] These types of errors are not new; they have been reported by several authors over the last decade.[56 82-84] Analysing the data from the AIMS database, Abeysekera and colleagues[28] found that 452 incidents out of 896 incident reports (50%) involving drug errors concerned syringe or drug preparation error or pre-error. Abeysekera and colleagues[28] defined pre-error as 'an incident that may have led to a drug error, but in which no drug was given'. These incidents included syringe swaps, wrong ampoule or labelling errors. 37% of all these errors were due to syringe swaps. Syringe swap refers to incidents in which two syringes are inadvertently confused or interchanged and the wrong drug nearly or actually administered.[53] These results are comparable with the findings of Fasting and Gisvold[78] (44%), Currie and colleagues[77] (40%) and Llewellyn and colleagues[80] (21%), however syringe swaps errors were reported as being far more prevalent in the THAI study,[79] which accounted for 70.7% of drug errors, and by Orser[3] who reported 70.4% of syringe swap errors in a Canadian study.

2.2.2 When do drug errors occur?

There is little evidence within the literature at what point during the anaesthetic process drug errors are most prevalent. Hintong and colleagues[79] found that drug errors occurred more frequently during induction of anaesthesia (63.4%). Fasting and Gisvold[78] also found similar results with 70% of drug errors occurring during the induction phase compared with only 16% during the maintenance phase. However,

conversely Llewellyn and colleagues[80] found in their study that the majority of errors occurred during the maintenance phase. They suggest this may be due to the increased vigilance of the anaesthetist at the beginning and end of each anaesthetic or may just reflect the fact that the maintenance phase is longer allowing more opportunity for error to take place.

Inferences could be made from other reports that this phase is most prone to syringe swap errors, the majority of errors reported involved induction drugs.[28 53 77 85] Hintong and colleagues[79] suggests the reason for this could be due to multiple and varied drugs being given all within quick succession.

There is also disagreement within the literature on the incidence of error related to emergency situations. Hintong and colleagues[79] found no increase in the risk of drug errors occurring during an emergency whereas Abeysekera and colleagues[28] found that over half the drug errors reported to the AIMS database occurred during emergency procedures. There is little further evidence to support either of these claims within the literature and would therefore benefit from further investigation.

2.2.3 Which drugs are most commonly implicated in errors?

Despite the literature reporting incident rates for drug errors for nearly two decades now, the same drugs are implicated time and time again. Currie and colleagues[77] back in 1993 reported that out of 144 incidents of 'wrong drug' reported in the first 2000 incidents to AIMS, the drugs most commonly implicated were non-depolarising relaxants (44 incidents) of which 29 incidents were due to syringe swap errors, followed by opioids (27 incidents) of which 19 incidents were due to syringe swap errors. Since then other studies have reported similar findings;

Fasting and Gisvold[78] found non-depolarising relaxants (32%) and depolarising relaxants (21%) responsible for the most syringe swap errors. Cooper and colleagues[53] stated that 'relaxants or their antagonists were almost always involved in syringe swap errors' with a total of 17 incidents out of 19 involving this class of drug.

Abeysekera and colleagues[28] reported that neuromuscular blocking agents accounted for 39% of syringe swap errors out of 8088 reports within the AIMS database. Hintong and colleagues[79] found similar with 31% of syringe swap errors involving muscle relaxants, followed by opioids (26.8%) as did Khan and Hoda[76] who reported 41% and Llewellyn and colleagues[80] reporting 26% of incidents related to neuromuscular blocking drugs. Muscle relaxants are perhaps more at risk of errors because they are frequently drawn up in the same size syringe as opioids, another drug implicated in syringe swaps, and then placed next to each other in the same drug tray ready for induction.[76 79]

However a more recent paper on drug error incidents in anaesthesia found that antibiotics (27%) were more prevalent in syringe swap errors than muscle relaxants (9%).[86] The authors suggested this may have been due to communication errors; antibiotics were not prescribed and were given on the basis of a verbal order from the surgeon.

2.2.4 Do drug errors actually cause harm?

Incidents of drug error in anaesthesia have been reported now for many years and most anaesthetists admit to having been involved in at least one drug error during

their career[28 87 88] however despite all of these reports there fortunately remains an absence of serious harm reported from drug error incidents.

The mortality rate reported within the literature has ranged from no deaths due to drug error[80 88] to 0.3% - 1.5%[3 9 28 70 77] to a mortality rate of 2.5% - 4.8%[78 79] Hintong and colleagues[79] only found 1 case of death caused by drug error and Fasting and Gisvold[78] only found 3 deaths resulting from drug error. Both these studies had small numbers of drug errors overall and so this may account for the higher mortality percentage rates.

It has been suggested that more time and money has been invested in aviation safety compared with healthcare because errors in healthcare occur one at a time. Individual drug errors are less likely to attract public attention compared to an aeroplane crash in which many lives are lost suddenly and concurrently.[89]

Deaths from drug errors will continue to be reported. However, as suggested previously, the reported incidence of minor drug errors or 'near misses' is likely to be the tip of the iceberg. As Merry[89] suggests, often, only the anaesthetist knows that the wrong drug has been given.

2.2.5 Situations associated with error

Fatigue, distraction, inattention, haste and communication have all been cited as causing or contributing to medication error within anaesthesia.

Abeysekera[28] found that within the AIMS incidents fatigue contributed to 11% of Syringe Swap errors and 10% of ampoule labelling errors, Webster[88] found similar. Distraction has been implicated in 16% - 25% of medication errors[28 88] whereas inattention contributed to 5-13% of errors within two studies[79 88] but was a far

greater cause within the AIMS database where 58% of syringe swaps and 41% of ampoule labelling errors were attributed to inattention.[28] Haste has a similar wide ranging consequence with 12 – 40% of errors being attributed to it.[28 79 88]

Currie[77] however stated that none of these factors appeared to influence whether the wrong drug was actually given within the first 2000 cases within the AIMS database.

2.3 Methods to reduce drug error

2.3.1 Literature

In 2004 Jensen and colleagues[90] published a literature review of strategies for preventing drug administration errors in anaesthesia. Recommendations were classified as strongly recommended, recommended, possibly recommended and unclear. From reviewing 98 references the authors produced recommendations that would be likely to prevent drug error incidents from occurring.

Ranked in order of strength the following were strongly recommended and will be discussed in more detail: the label on any drug ampoule or syringe should be read carefully before the drug is drawn up or injected, legibility and contents of labels on ampoules and syringes should be optimised, syringes should always be labelled, formal organisation of drug drawers and workspaces should be used and labels should be checked specifically with a second person or a device.

Jenson and colleagues[90] also recommended that errors in intravenous drug administration should be reported and reviewed and similar packaging and presentation of drugs contribute to error and should be avoided where possible.

They went on to 'possibly recommend' on the strength of the evidence the use of pre-filled syringes, the anaesthetist always drawing up and labelling the drugs they will be giving, and the use of colour coded labels. They found it unclear from the literature as to whether coding by syringe position or size, or by the needle on the syringe should be used as means to prevent error.

2.3.2 Reading labels carefully

One of the final safeguards in preventing drug error is ensuring the label is read accurately before giving the drug to the patient.[78 91] This process applies to the label on both the ampoule and the syringe.

Currie and colleagues[77] found that that if the wrongly selected drug was in the ampoule there was a 58% chance of the drug being administered to the patient, however if it was in the syringe there was a 93% chance of administration. They strongly believe that it is vital to take great care when reading the ampoule to ensure the correct drug is chosen, and their findings suggest that re-checking the ampoule was the most effective technique at preventing error. This is supported by Hintong and colleagues[79] and Webster and colleagues[88] who found that between 17% and 29% of medication errors were due to a lack of re-check prior to administration.

Within clinical practice it is often the case that the anaesthetist will draw drugs up into particular sizes of syringe, this usually correlates to the volume of drug but indirectly it becomes used as an unconscious check of whether the correct drug has been chosen. Bergman and colleagues[92] stress that labels should be checked

carefully and the size of the syringe should not be relied on as confirmation of the correct drug to be administered.

2.3.3 Legibility of ampoules and syringes

While there are multifarious causes of medication error, labelling and packaging of drugs is increasingly being blamed for their cause.[93] Within the first 2000 reports to the AIMS database Currie and colleagues[77] found that 54% of errors were associated with the wrong ampoule being chosen due to similarities of design. In the paper published by Orson and Oxorn in 1994[91] they recommended in order to minimise drug error that whenever possible, each drug available should have "distinct and unique markings". However, even today, ampoule labelling and drug packaging continues to be ambiguous and a potential source of error. As Llewellyn and colleagues[80] state, there is an urgent need for an international standard for drug labelling. The NPSA have gone someway to tackle this problem by issuing manufacturing guidelines to pharmaceutical companies for medications dispensed within the NHS,[94] these guidelines however were only issued in 2008 and more time is needed to evaluate how effective this move has been in preventing error in clinical practice.

Garnerin and colleagues[95] describe labels as representing the 'main user/drug interface'. Other studies[96 97] have suggested that drug name, type face, colour coding or the phrasing of the drug strength can all compound the frequency of drug errors. It is suggested that people tend to see what they expect to see, recognising words by their shape and not through reading the letters individually.[98 99] There are several drugs that have similar names, they either look very similar or sound very

similar. Combine this with poor legibility of the label and it leads to increased risk of false identification of the drug.[95 100 101]

Several methods have been advocated to reduce the false recognition of drug names; these include the use of TALLman lettering, where part of the drug name is in capital letters.[102 103] Merry and colleagues[100] suggested including both the class name and the name of the drug on highly legible labels, while Garnerin and colleagues[95] found that by displaying the concentration, quantity and volume at fixed locations on the label further improved human functioning.

2.3.4 Syringe labelling

Nearly two decades ago Currie and colleagues[77] recommended that it should be policy for every syringe to be labelled as the drug is drawn up into it. In 2009 Llewellyn and colleagues[80] reiterated this recommendation in stating that the education of anaesthesia trainees should ensure they systematically label syringes in their daily practice. Bergman and colleagues[92] also proposed that drug error would be reduced if syringes were labelled immediately upon drawing up. However, there is the argument that if a drug is being given as soon as it is drawn up there is no need to label the syringe. In some cases this may be acceptable, but there is always the opportunity for distraction, especially if there is more than one drug involved or if there is more than one anaesthetist working together.[77]

2.3.5 Formal organisation of drug drawers and workspaces

Within the first 2000 reported incidents to the AIMS database Currie and colleagues[77] attributed one fifth of errors to the use of location for selecting the

correct ampoule. The practice of taking the ampoule out of its original packaging and placing it in a tray ready to be draw up reduces further any indicative characteristics used for identification.

Reason[104] proposed that safety could be improved through the reduction of complexity by making a process simple and linear. Currie and colleagues[77] suggested the use of standardising the layout where drugs are placed for drawing up, through the use of a template that is colour coded to the class of drug. Orser and Oxorn[91] also recommended that drugs, which are not in regular use, should not be left to collect in the drawers or on top of the anaesthetic machine.

Merry and colleagues[105] have designed a new drug administration system with the intention of reducing error in anaesthesia through standardisation. The new system utilises plastic trays that have been designed to expedite the placement of syringes and ampoules. The number of trays used for each anaesthetic is not limited and is relative to the amount of drugs needed. Merry and colleagues[105] describe the layout as having an 'active area' used for the syringes in current use, a 'used area' for used ampoules or syringes which ensures they are kept in an orderly fashion and a 'prompt area' where drugs that may be needed later in the anaesthetic can be stored. The system, if used as intended, generates a physical record of the drugs used within the anaesthetic and through inspection alone it should be obvious which drugs have or have not been administered. The drug drawers are arranged in a similar layout to the trays, the authors suggest the use of two drawers to prevent congestion and ensure potentially hazard drugs are kept separate from the more commonly used ones. They go on to suggest standardising the placement of drugs, left to right, to reflect the frequency of drug class used. The recommended order in

which the drugs are placed from front to back in the drawer is dependent on the frequency of use within the individual class of drug in question, the most popular choices being sited nearer the front.[105]

2.3.6 Double checking

One of the recommendations from Currie and colleagues[77] was if there was more than one anaesthetist involved in the administration of drugs, the drug should always be double checked with their colleague. Bergman[92] also suggested that the frequency of drug errors would be reduced if the contents of the syringe were double checked immediately upon drawing up.

Within the literature there have been several studies[90 106-108] that suggest errors can be reduced through double checking. The white paper 'Building a safer NHS for patients'[66] recommends that ideally, all intravenous drug administration should be checked by two qualified practitioners.[66] Toft[64] suggests one way to reduce the risk of a drug being given inadvertently is through the use of an 'explicit appropriately configured verbal double checking protocol'. He goes onto to say that the expectation is that if one person misses an error the other will detect it. The results of the study by Jensen and colleagues[90] suggested that double checking could have prevented 58% of the errors reviewed, which made it the most effective single measure in their review. However, Orson and Oxorn[91] despite strongly accentuating the need to double check before administering a drug, stop short of actually stipulating whether that check should involve a second person or device.

There are however critics of double checking as a method to reduce error. Leape described double checking as a 'sacred cow' that saps time and is ineffective,[109]

while O'Connell[110] believes the benefits of double checking as opposed to single checking remains undetermined. Verbal double checking does not always prevent errors from being made or serious incidents from occurring, there are several issues that can impact on the safety of the check. There is the issue of 'diffused responsibility' where two people are supposed to be responsible for the same task but in reality neither person is truly responsible, or the problem of both members of staff relying on the other to be rigorous, resulting in neither giving the task their full attention, involuntary automaticity can also impact on the robustness of the check being undertaken.[5 111-113]

In an attempt to address human factor issues that can inherently impact upon a two person double check, Merry and colleagues[100] designed an electronic system to execute the double check prior to administration of the drug. The authors suggested the anaesthetist's attention would be regained through listening to the information articulated when the syringe is passed over the bar code reader immediately prior to administering the drug, providing a "computerised two person check" which is prompt, definitive and not prone to human susceptibility.

2.3.7 Involuntary automaticity

Involuntary automaticity can have a significant impact on the accuracy of a double checking protocol. It can provoke the health care professionals who performed the double check to fail to recognise any errors present within the system and thus provide a false sense of security in regards to the patient's safety.

Automaticity is a term with its roots in psychology; it can be described as the thoughts and processes that take place primarily without the need for conscious

regulation or scrutiny. These processes are rapid and extremely useful; they provide the scope to carry out tasks efficiently without a great deal of effort.[5 114]

The drawbacks of automaticity manifest in procedures which are highly familiar, but require close attention, such as verbal checklist procedures. Repeatedly using identical checking procedures can unintentionally lead to a ritualistic chant of the checklist items, which in turn could lead to 'the literal meaning of the message being ignored'.[115] This behaviour, however, is not calculated but unconscious and involuntary. Although the task actually requires careful attention, once under the influence of involuntary automaticity, the diligence of the individuals undertaking the check is only cursory, this in turn leads to an increased risk of any errors that are present being overlooked.[5]

2.4 Aims and Objectives

The overall aim of this thesis is to explore issues surrounding drug errors in anaesthesia, in relation to technology and systems designed to reduce such errors and the inherent culture within anaesthetic practice that impacts and influences the subsequent compliance with these proposals.

Currently there has been little work carried out in the UK in relation to the use of double checking protocols. Ross and colleagues[106] found that following the introduction of a two person check for all drugs dispensed from pharmacy, errors were reduced from 9.8 per year to 6 per year. The British Committee for Standards in Haematology, Blood Transfusion task force[113] recommended that one member of staff should be responsible for carrying out the identity check of the patient and the unit of blood; however Watson and colleagues[116] found that very few hospitals had implemented the system of single checking by 2006 in preference over a double checking system.

Increasingly technology is seen as the way forward in providing the means to improve patient safety[100 116] and although these systems do play an important role not all hospitals or health care providers will be able to afford to introduce them. There still remains a need for a robust check that can be implemented within the National Health Service. Manual double checking presently takes place on an ad hoc basis and as previously discussed, technology specifically designed for use within anaesthesia has been developed, but is not currently installed within any NHS hospital Trusts.

Investigating two methods of double checking anaesthetic drugs given by injection was a priority area agreed by the NPSA and the RCoA for the 'improvement through partnership' collaborative project aimed at improving patient safety through working directly with clinicians. This qualitative study (Chapter 4) involves seven NHS Trusts across the UK and evaluates the feasibility of introducing a manual two person double check or an electronic bar-code double check using the SAFERsleep™ system into clinical practice. This is the first study of this nature within the NHS and gives an insight into the benefits, barriers and practicalities of introducing these systems as seen from the viewpoint of the clinicians who will use them.

Following on from this study (Chapter 5) the cultural issues and attitudes of anaesthetists and other professional groups towards drug errors and methods of preventing them will be explored in greater depth. This will be achieved through integrating my research aims into a larger international study seeking to validate anaesthesia simulation-based error research (VASER).

The aim of my research (Chapter 5) is to explore the beliefs and attitudes of anaesthetists and Operating Department Practitioners (ODPs) taking part in error research, and their views on the introduction of technology designed to reduce errors. Also, as part of the VASER study I will assess the workload of the participating anaesthetists in order to evaluate whether the SAFERsleep™ system adds further workload to the simulated clinical scenarios.

In addition I will explore the beliefs and attitudes of anaesthetists and ODPs that did not participate in the VASER study in order to further judge the cultural effects of drug error within anaesthesia and their subsequent reporting.

The thesis is divided into individual chapters addressing these objectives. However, the following chapter, Chapter 2, details the methodology and methods used within both of these studies (Chapter 4 & Chapter 5).

CHAPTER 3: RESEARCH METHODOLOGY & METHODS

3.1 Introduction

In Chapter One the incidence of medication errors in anaesthesia and methods to prevent them were discussed. In order to understand in depth the anaesthetists' perspective and the feasibility of introducing methods aimed at preventing medication errors I have chosen to adopt a qualitative approach. Chapter 2 describes the methodological issues related to the current thesis and the methods used to collect data for the studies presented later in Chapters 3 and 4. I will discuss the theoretical basis for these research projects and what characterises qualitative research. This chapter will also address the chosen research methods for this study, including methods of data collection and analysis using grounded theory. The chapter concludes by addressing ethical issues present within both of my studies.

3.2 The Nature of Qualitative Research

"*We can see social theory as a sort of kaleidoscope – by shifting the theoretical perspective the world under investigation also changes shape"*[117]

Alderson[118] advocates that theories are at the core of practice, planning and research, and their scope powerfully influences how evidence is collected, analysed, understood and used. The choice of methods used is often determined by the specific theoretical or methodological approach adopted.[119]

Reeves and colleagues[120] suggest that theories provide researchers with different "lenses" through which to consider complicated problems and social issues. Unfortunately it is impossible to study everything. The theory chosen helps to determine what problems are given priority, what directions are considered most

profitable to search for answers, and what types of data are collected. Overall theories establish a framework for answering the question why.[121]

Differing theoretical traditions, within qualitative research, are allied to a divergent mix of research questions, data collection methods and analytical techniques.[122] Common to all research projects, choosing the most appropriate method suited to the line of inquiry is vital to achieving the desired results.[123 124] Researchers justify their use of a particular method for capturing data and subsequent analysis under the banner 'Methodology.' Rice & Ezzy[124] go on to state that 'where research methods describe how you plan to go about collecting and making sense of data, a methodology describes and justifies why you have chosen this particular research method.'

3.2.1 Developing a Methodology

Qualitative research aims to provide an in-depth understanding of the meanings and interpretations people assign to their own actions, to the actions of others and to situations and events.[122 125] The qualitative researcher's skill lies in looking beneath the routine, everyday, taken for granted aspects of the settings under study.[122 126 127] Methodologies can be defined in broad terms such as 'qualitative' or narrowly such as 'grounded theory'.[128] The methodology defines how a phenomenon is studied. This overarching term incorporates the choices made about which population is chosen, the methods of collecting data, the analysis used and how the study is actually planned and executed.[128] Sarantakos[129] defines methodology as a strategy that translates ontological and epistemological principles into guidelines that show how research is to be conducted. Researchers adopting a

symbolic interactionism, phenomenology or ethnomethodology paradigm will approach the research question through a qualitative methodology that utilises a more flexible design and qualitative methods.[129]

3.2.2 Major characteristics of qualitative research

Qualitative research is concerned with the collection and analysis of data that are not in the form of numbers. Unlike quantitative research which is seen as objective, focusing on the collection of facts, qualitative research focuses more on exploring occurrences and illustrations that are subjective but considered as interesting or illuminating. In other words, it aims to realize depth rather than breadth.[130]

A review of the literature on qualitative research methodology suggests a number of distinguished characteristics. First of all, qualitative research takes place in the 'natural setting',[129 131] where descriptions and accounts of the phenomena under study are to be found. This characteristic is related to another characteristic described by Bryman[132] as 'seeing through the eyes of the research participants'. The second feature of qualitative research is that it aims at collecting 'naturally occurring data' through using observation rather than experiments, and unstructured rather than structured interviews.[128] Traditional data collection methods include observations, interviews and documents. The data collected is often in the form of texts (or words) and images (or pictures) rather than numbers.[131] Another distinguished characteristic of qualitative research is that it is inductive, hypothesis-generating research rather than deductive, hypothesis testing one.[133]

The above mentioned characteristics of qualitative research, however, give rise to criticisms which are presented in the next section.

3.2.3 Limitations of qualitative research

As mentioned above, adopting a qualitative methodology allows the researcher to foster an understanding of the values, beliefs and behaviours of individuals under study. However, qualitative methodology has been criticised for a number of reasons. These include the way it perceives reality, people and research; the methods it uses; the politics it supports; and the relationship it establishes with the researched.

First of all, qualitative research is often criticised for being 'too subjective'.[132] The qualitative findings are criticised in respect of the influence the researcher's own beliefs about what is significant and important may have had on the data collection, as well as the potential relationships developed between the researcher and those being studied.[132] The researcher's previous experiences might also bring some biases to the research. These biases, as described by Sadler,[134] can be related to the researcher's background knowledge, prior experience, emotional makeup, or world view'.

The second limitation of qualitative research is that there are problems of generalisation.[132] The findings may not be generalisable beyond the population being studied. Within the study findings, however, you would expect a detailed description of the context of where the research was carried out, the methods used, the procedure for data collection, and the knowledge base for data analysis. This

will ensure that those reading the research findings have enough information to judge whether or not the findings are transferable to other contexts.

Bryman[132] also suggests that interpretation will be greatly influenced by the personal preferences of the researcher; this in turn impacts on the ability of the research to truly see through the eyes of the researched and to interpret events from their point of view.

An understanding of the strengths and weaknesses of qualitative research therefore is crucial for the researcher. Such an understanding will enable the researcher to plan and design the research project in order to make the most of the strengths and to be honest and open about the weaknesses.

3.3 Sampling

3.3.1 Purposive Sampling

Sampling strategies and the adequacy of the chosen sample, as with all research projects, can have serious knock on effects to the scientific accuracy of the research, typically judged in terms of validity and reliability.[135] In contrast to the random sampling strategies of quantitative research, qualitative research requires in-depth study and smaller samples that identify and include those information rich cases. Sampling is therefore driven by the emerging categories and hypotheses, the need for theoretical elaboration and by the researchers need to ground developing theory in the empirical data.

The sampling strategy, for both of my studies, was guided by my research question but also by pragmatism. I adopted a purposive sampling strategy, which I believe contributed to the credibility of the research. Purposive sampling involves selecting groups or categories to study on the basis of their relevance to your research questions, your theoretical position and analytical framework, your analytical practice and most importantly the argument or explanation that you are developing.[136]

Purposive sampling began, in my first study, with the choice of NHS Hospital Trusts selected. These were chosen to represent a range of NHS secondary and tertiary referral centre Hospitals, geographically spread across England and Wales. Participants were selected from the qualified anaesthetists and ODPs, who were willing to participate, working within the theatres at these NHS hospital trusts.

Purposive sampling is integral to the constant comparative method of data collection and analysis. Individuals are added to the sample until theoretical saturation is reached; that is, an exhaustive range of elements that formulate the theory is fully described by the data. It was possible for me to review decisions about sampling during the research process through the use of purposive sampling. On analysing the data from the focus group in the second of my studies, I went on to hold a second focus group with anaesthetists and ODPs that had not participated in the initial study. This allowed me to explore further the perceptions of drug errors within anaesthesia and their subsequent reporting, and the use of technology in anaesthetic practice in a group that were not research or technology focused.

3.3.2 Sample size

Given that an individual person can generate hundreds or thousands of concepts, large samples are not necessarily needed to generate rich data sets.[122 123 135 137] In qualitative research, the sample size is not determined by the need to ensure generalisability, as in quantitative research, but rather by the desire to investigate the chosen topic fully and to provide information rich data.[136] There are no closely-defined rules for the sample size in qualitative studies, however, there are widely accepted considerations related to the sampling decision.[138]

Determining an adequate sample size in qualitative research is in the end down to the researcher's individual judgment and experience in assessing the quality of the information collected against the purpose to which it will be put.[139]

Sampling in qualitative research usually relies on a small number of participants with the aim of studying them in depth. However, the sampling strategy has to be adequate to answer the qualitative research question. Generating too small a sample can make it difficult to justify the claim of achieving theoretical saturation. Conversely, too large a sample may not permit a deep, case-orientated analysis, which is a core principle of qualitative research. In order to saturate any given theory it is extremely difficult to predict what sample size will be needed, however the literature reports a grounded theory study sample sizes ranging between 10 and 60 persons.[123 135] In the first of my studies 36 consultant anaesthetists, three trainee anaesthetists, 15 ODPs and seven nurses participated and in the second of my studies 20 anaesthetists and 20 ODPs participated overall in order to achieve theoretical saturation.

3.4 Research Methods

3.4.1 The research methods

A research method can be described simply as the approach for collecting data and can be associated with a diverse range of research designs.[132] The research design provides a framework for collecting and analysing data, but the research method is the tool for collecting that data, for example participant observation or semi-structured interviews.[132]

In the next section, I will look at each of the methods used in my research.

3.4.2 Questionnaires

Within the second of my studies I utilised a Likert-scale questionnaire. This was used to gain a baseline measurement of the intensity of participants' feelings, agreement and/or discord around the subjects of drug errors in anaesthesia, levels of harm caused and the use of technology as a preventative measure. Initially 10 anaesthetists and seven ODPs completed the questionnaire; it was later distributed to a further 10 anaesthetists and 10 ODPs that did not participate in the original study.

Bryman suggested that the self completion questionnaire and the structured interview are very similar methods.[132] The apparent difference between the two methods is the absence of the researcher with the self-completion questionnaire; instead, the questionnaire relies on the participant to read each question and answer them independently. However, because there is no researcher to clarify the questions, the questionnaire must be clear and easy to answer. As a result

questionnaires need to be designed to be succinct to prevent 'respondent fatigue', have fewer open questions to ensure ease of answering and easy to follow to reduce the chance of questions being omitted.

The advantages of using questionnaires, as described in the literature, is the ability for the researcher to gather consistent and sufficiently accurate data in a straightforward, cost efficient and convenient manner.[132 140]

Wilson[141] argued that the principal advantage of using self completed questionnaires, compared to interview-led methods, was the ease of administration and the reduced costs of implementation. Secondly, self completed questionnaires reduce the possibility of the researchers own personality influencing the responses from the participants. Research by Sudman and Bradburn[142] suggested that self completion questionnaires worked better than personal interviews when a question carried the possibility of such bias. Wellington[143] suggested that self-completed questionnaires may provide a richer, more truthful account than data collected through interview,[143] while Bryman[132] conferred when he suggested that there is a tendency within the interview situation for respondents to under-report situations that are sensitive or induce anxiety.

In addition, self completed questionnaires are convenient as they can be completed at a time and pace that suits the respondent.[132] Another advantage of the questionnaire, as stated by Wellington[143] is that self completed questionnaires are often associated with the collection of quantitative data. Thus allowing the data to be inputted straight into a spreadsheet in a numerical format and analysed quickly.

The questionnaire, however, suffers from a number of disadvantages. Firstly the questionnaire does not allow the opportunity to probe respondents to elaborate their answers or prompt if they are having difficulty answering a question. It is therefore vital that questions are clear, unambiguous and easy to answer.[132] Another disadvantage of the questionnaire, according to Bryman,[132] is that any questions that are not viewed as important by the participant are likely to be ignored or worse still the whole questionnaire is assigned to the waste paper bin. To avoid this happening and reduce the risk of missing data, since respondents may skip questions that appear to be irrelevant or boring to them, the questionnaire should not be overly long and ask too many questions.

I encountered a couple of the disadvantages of using questionnaires that have previously been described in the literature.[132] Firstly the problem I encountered was missing data; where respondents fail to answer all the questions. The second problem was the failure by 3 ODPs to complete the questionnaire. Low response rates to questionnaires can lead to the risk of bias, it has been argued that those who do not return the questionnaire may have different responses from those who do.[132] In an attempt to prevent this happening further, I decided that when I handed the questionnaires out I would advise the respondent I would be collecting them later on in the same day. This enabled, I believe, a greater response rate than I would have otherwise had.

In summary, every data collection method has inherent strengths and weaknesses and so it is difficult to say that one method is superior to another. Depending on

the nature and context of the research, the researcher must decide what method or methods are most appropriate to gain the greatest understanding of the phenomenon under study. The information from questionnaires, in triangulation with the interview and focus group data, gave a deeper understanding and description of medication error within anaesthesia.

3.4.3 Interviews

Semi-structured interviews were utilised within the research methods of my second study (Chapter 5). The requirement for depth of knowledge rather than breadth was the determining factor in use.

Interviews are utilised widely in qualitative research. Green & Thorogood[144] describe the process as 'a conversation' which the researcher directs in order to gain greater insight into the area under study. Typically qualitative researchers make use of unstructured or semi-structured interviews, which may also be referred to as in-depth or qualitative interviews.[144 145]

In semi-structured interviews, the researcher decides the outline in terms of the topics covered, often referred to as an interview guide, but the responses from the interviewee's determines the variety of information produced about those issues, and the relative significance of each of them.[132 144] Mason[136] describes qualitative interviewing as involving 'the construction or reconstruction of knowledge more than the excavation of it' therefore, they can be a valuable tool in unearthing group norms and assumptions that may seldom be discussed openly in daily practice.[146]

Semi-structured interviews were conducted with three consultant anaesthetists and one ODP. The interviews were carried out face to face, and were held in a separate meeting room within my department, with the exception of one. The interview with one of the anaesthetists' took place in their office, as it was more convenient for them. Each interview lasted approximately thirty minutes.

In order to allow the opportunity for me to follow up on any interesting points raised during the interview, all the interviews were audio recorded, with the permission of the interviewee. This allowed me the freedom not to take notes, which could have been more of a distraction than an asset. Recording the interviews also meant they could be easily transcribed for data analysis.
The interview questions investigated the perceptions of drug errors within anaesthesia, the quality of the anaesthetic record produced and the preparation of drugs [Appendix I].

The interviews probed the advantages and disadvantages of current clinical practice against utilising the new electronic system, particularly concentrating on the quality of the anaesthetic record produced and the preparation of drugs using both systems. I was particularly interested in the accuracy and time taken to complete both the electronic and the paper anaesthetic record, and the views of the participants about each completed document. I also explored how useful participants found the electronic system and the overall usability of the system compared to the standard paper record.

Drug preparation using the SAFERsleep™ system was very different to current clinical practice in that the majority of the drugs were pre-filled and pre-labelled and presented in a specially designed drugs trolley. Standard practice is for drugs to be stored in a cupboard and for the anaesthetist to draw up their own drugs and label them. The interview questions were designed to explore the participants understanding and perceptions of the time taken to prepare the drugs within each scenario and their thoughts on having drugs available in a pre-filled format. I also explored the feelings on the potential for distractions within both systems and possible ways to prevent them.

Finally, the interviews also gave me a chance to explore perceptions of drug error within anaesthesia and their subsequent reporting and whether the participants thought that drug errors were an issue within anaesthetic practice. I also went on to explore participant's views on when an error would be reported in their opinion and if this is influenced by the potential harm to the patient or not. Following on from this I asked whether technology has a place in preventing error and if so what would be the ideal system requirements in order to achieve this.

3.4.4 Focus Groups

Like interviews, focus groups are an adaptable method of collecting data for a wide range of qualitative research studies.[122] Focus groups were utilised in both of my studies. A focus group has been described previously as a group interview, brought together to discuss a particular issue under the direction of a facilitator, who has a list of topics to discuss;[132 144] the focus groups I ran typically had five to eight participants and lasted approximately one hour. Conducting a focus group can

involve a great deal of work. In order to concentrate solely on facilitating the group and not having to worry also about taking notes, I aimed to have the help of another member of the research team at each focus group. Hand written notes were taken at all focus group interviews, as well as being audio recorded, as a back-up in case the tape recording failed for whatever reason.

I utilised a schedule to ensure consistency within all the related focus groups [Appendix II, III, IV, and V]. This was not so prescriptive that it stifled further discussion of new and interesting themes emerging from the dialogue, but kept the focus of the enquiry around the overarching research question.

Focus groups have several advantages. Berg[147] suggests that focus groups are valuable in situations where there is only a limited amount of time available to the researcher to collect data from a group or setting. While other authors suggest that the focus group creates a safe environment for the sharing of experiences.[148-150] They allow the opportunity for participants to raise issues, within the scope of the research question that they deem to be important and significant. Green & Thorogood[144] suggest that the focus group allows the researcher the extra opportunity to utilise the interaction between the participants of the group and not just the interaction between the researcher and the individual participant. It is an excellent tool for allowing participants to build upon one another's comments, stimulate thinking and discussion. This can in turn lead to new ideas being generated and widening the scope of the analysis. It also allows the opportunity for the moderator to clarifying any issues arising and seek a more detailed response.[151]

The potential for producing a huge amount of data over a relatively short space of time is great,[144] while Schneider and Palmer[152] note that although the focus group data does not necessarily provide a more valid report of reality, it did provide rich and meaningful data.

The reason I chose to use focus groups within my research was to explore how individuals collectively make sense of the phenomenon I was studying and to understand why people feel the way they do about it. Bryman[132] suggests that individuals make sense of a situation not in isolation, but through interaction and discussion with one another. Focus groups reflect how meaning is constructed in everyday life; Wilkinson[153] suggests this makes them more naturalistic than one-to-one interviews.

Limitations of using focus groups have been previously discussed in the literature. The advantages of utilising focus groups can also be their limitations.[144] It is much harder to ensure confidentiality with focus groups than it is for interviews.[122] While another potential drawback is the dynamics inherent within the group. An intrinsic disadvantage is the susceptibility to bias; within the focus group, the goal is to let people spark off one another, suggesting dimensions and nuances of the original problem that any one individual might not have thought of.[154] This is useful way to stimulate discussion and may also have a quality control effect where participants check each other's statements. However, the dominance of particular group members, especially overly dominant, judgmental or aggressive participants or the moderator, influencing the beliefs of individuals or the group could easily bias the discussions or deter others from speaking about sensitive issues.[122 144]

In addition, time can be lost due to digression onto irrelevant issues; therefore skilful management of group discussions is paramount to achieve the most from the group.[151] Schneider & Palmer[152] suggest that a poor facilitator will ask leading questions, which in turn, suggests they are looking for certain answers. Proficient moderating is also vital to ensure ease of analysis, too many people talking at once makes it almost impossible to transcribe the discussions from the audio recording. This was something I was acutely aware of and tried to ensure during the focus groups I moderated, allowing individuals the opportunity to finish what they were saying without being interrupted. Despite the many advantages of focus groups, they should not be viewed as an easy alternative to interviews. They collect a quite different type of qualitative data and do not allow for in-depth exploration.[122]

3.4.5 Reflective Diaries

Reflective diaries were distributed to all anaesthetists' and ODPs' that participated in the first study (Chapter 4) [Appendix VI]. They were used to provide a medium for the participants to document their thoughts, experiences and feelings of using either of the methods for double checking drugs. Diaries completed by participants are thought to reflect the importance they assign to any given event or behaviour.[122 155]

Comparing the data from the diaries with the observation data was a distinct advantage; it allowed me to look for comparables or outliers that may not have been witnessed during the short observation time. The diaries gave me a more rounded view of the process under study.

There is however always the possibility that participants could use the diaries to their own advantage, describing events that did not take place or to vent their irritation about a process, past or present. I also found a distinct apathy with some participants to complete the diary, something I tried to counteract by encouraging their completion whenever I visited a participating site. This phenomenon has previously been highlighted in the literature as a drawback of using reflective diaries.[122 132]

3.4.6 Observation

'Simple observers follow the flow of events. Behaviour and interaction continue as they would without the presence of a researcher, uninterrupted by intrusion' [156]

Observation captures the routine and often nondescript characteristics of everyday life within the context of their occurrence; it allows direct access to what people do, as well as what they say they do.[144] Mason[136] describes the knowledge generated, through high quality observation, as 'rich, rounded, local and specific'.

Prominent among the tools of qualitative research is observation, characterised by Adler & Adler[157] as the "fundamental base of all research methods". Qualitative researchers use observation as a process by which people interacting in their natural settings are studied so that their behaviours and words can be put into their proper context.[158]

There are several different approaches to observation; depending on the objective of the study, the type of data being collected, and the resources available for the

study. The two main types of observation described in the literature are structured observation and participant observation.[132 159]

Structured observation is a technique of observing which follows clearly formulated rules for how the observation and recording should be carried out.[132] The emphasis for structured observation is on identifying and recording the frequency of events or actions. The suggested advantages of this method are that it is a cost effective method for achieving reliable and easily collected data and while structured observation have the advantage in terms of reliability and validity, the capturing of complex actions, that occur spontaneously, may be missed.[159]

Structured observations allow the researcher to see what people do, however they do not allow for the greater insight into the reason why. The underlying meaning attached to the individual behaviour is lost to the researcher when structured observation is utilised.[159]

Participant observation, on the other hand is inherently more flexible. It is primarily associated with qualitative research and involves the researcher becoming immerged in the setting they are observing in order to understand the motives and actions of the individual as well as the meanings attributed to environmental and behavioural characteristics.[132 159]

When the researcher becomes a 'participant observer' it provides the opportunity for them to develop a degree of trust with those they are observing. However it has to be kept in mind that the observations only represent a 'snapshot in time'.[159]

The biggest criticism of observational methods is not being able to accurately assess the effect being watched has on the individual's behaviour.[159] Webb and colleagues[160] suggested that people change their behaviour when being observed, which they call the 'reactive effect'. However, other authors have suggested that although the reactive effect is more evident in structured observation overall the effect diminishes over time as people become accustomed to being observed.[161 162]

Observational methods were used within both of my studies. As well as my own observations during the first of my studies (Chapter 3), independent observers were also utilised. These consisted of four consultant anaesthetists, three ODPs, two anaesthetic nurses and one sociologist. The main problem I encountered was in defining or selecting what to observe in the short period of time assigned to the observations. It takes time to develop the skills of observation; it is not just a matter of watching and writing down what you see, but of discerning what exactly to look for and how to reflect on it.[144] There is always the risk that if the setting is unfamiliar we impose our own expectations on what is occurring from our previous experiences, alternatively if the setting is one we are familiar with it may be difficult to put aside our professional expectations.[144] For this reason I designed an observation schedule for all the observers to use during their observation periods [Appendix VII, VIII]. Using an observation schedule ensured that everyone had a clear focus of the research question during their observations and it also helped to minimise observer bias.[162] It is also suggested that using a schedule enables large amounts of data to be recorded relatively quickly, ensures consistent record keeping, and may provide other researchers with a tool with which to conduct

replication studies.[122 159] In terms of reliability and validity, utilising an observation schedule has been seen to be a key factor.[159] However, an inherent disadvantage of a highly structured method of data collection is that any characteristics or behaviours that do not 'fit' into one of the pre-defined categories are either missed or are unable to be recorded. In addition, any interruptions during the observation period have the potential to lead to missed or partial data collection.[159]

It is recommended that all observations records are labelled with the time and location as well as any codenames used,[163] therefore the record was purposely designed to include space for these details.

The observers were encouraged to reflect on the observation as soon as possible after the event; as detailed descriptions are 'the heart of any narrative field notes'.[147] There was a section on the schedule specifically for reflections. Observers were encouraged to write down all the things that came to mind about the observation, an irrelevant point to the observer might actually be highly significant to the researcher. Observers were also encouraged to write down any subjective reflections; personal interpretations and remarks about their feelings and experiences of the observation.[122]

One of the limitations of the first of my studies (Chapter 4) could be the lack of inter-observer reliability testing. To mitigate this as much as possible I provided a one to one training of the observers, ensured they had the basic knowledge to go out into the field to observer [Appendix VIII], and was always contactable should they have any queries about the process.

Following my observations I noted any associations I could see between the observations, theories about what was occurring and why, or questions I may have had about different 'actors' and their behaviours. It was important to emphasize to the independent observers that it was alright to ask questions during the observation if they needed clarification on anything they were observing. They were also encouraged to document any 'ad hoc' conversations on the schedule that were in relation to the study.

Observation in the second of my studies (Chapter 5) was more structured. The behaviour of each individual participant was recorded directly into a specifically designed computer programme. The drawback of this approach, however, meant that only pre-defined events were recorded. The option to add free text comments was basic and not suitable for adding great amounts of extra information. This approach was more quantitative in design, in that the resulting data generated could be expressed as variables.[132]

As part of the main VASER study I was lucky enough to go out to Auckland, New Zealand and meet Professor Merry and his study team. During this time I was taught how to use the observation programme and Borg Workload scale, and inter-observer reliability was established.

3.4.7 Workload assessment

As part of the methodology of the second of my studies (Chapter 5), I measured the anaesthetist's workload within the simulated environment.

With constantly progressing technology, work place systems are becoming more complex. Individuals are having to change their decision making and performance in order to meet these dynamically shifting environments, simultaneous tasks demands and time pressures.[164-166] Research concerning the relationship between task demand and mental workload has had a long history, dating back more than 40 years and is recognised as an important issue within the literature.[166-169]

Workload has been described as a dynamic balance between the demands of a task and an individual's reaction to that task. Wickens[158] describes the concept of mental workload as correlating to the demand of the tasks on the person's limited mental resources.[168 169] Young & Stanton[170] define mental workload as follows "the mental workload of a task represents the level of attentional resources required to meet both objective and subjective performance criteria, which may be mediated by task demands, external support and past experience".

Workload is not an intrinsic characteristic, but rather arises from the interaction between the needs of a task, the conditions under which it is accomplished and the expertise, actions, and insights of the anaesthetist.[171-173] Workload demand can be associated theoretically with one of two 'areas'. Firstly, the demand is less than the capacity of the resources available and that there is "residual capacity", this is the optimal situation because it means that the individual will have some spare resources available should anything unexpected happen. Secondly, high levels of workload occur when the demands of the task exceed the capacity of the individual, this in turn can lead to the breakdown of performance. The distinction between

these two areas has previously been referred to as the 'red line' of workload.[166] [174] [175]

Mental workload is an all-encompassing concept, within the human factors literature that is becoming increasingly important. Modern technology is placing more and more cognitive demands, rather than physical demands, upon the individual practitioner. Understanding how mental workload affects performance is therefore imperative.[170] Workload can impact on safety, staffing levels and be affected by automation. Over automation has led to issues such as those described by Endsley & Kaber[176] such as loss of situational awareness and manual skill decay due to complacency and decreased vigilance. Measuring workload is therefore considered important in many high risk environments.[177] [178] The increased likelihood of error and poor performance has previously been associated with raised mental workload.[177] The rationale for measuring mental workload is to evaluate the levels of workload imposed by a task or system with the intention of determining and removing workload-related performance lowering elements. Although various techniques have been used to measure mental workload, most measures can be categorised into one of four types: performance based, subjective, physiological or analytic.[173] Previous studies within the literature have utilised measures that fall within one of these four categories.

Performance based measures determine the individuals workload from the ability to perform a task. The two major categories of primary based measures, described in the literature, are primary task measures and secondary task methodology.[173]

Primary task measures determine the ability of the individual to achieve the primary task. This is usually measured through the speed and accuracy of completing the task. It is assumed that as workload increases beyond the individuals limit for processing information, this will lead to a breakdown in the performance of the primary task.

Secondary task measures, on the other hand, assess the capability of the individual to perform the primary task alongside an additional or secondary task. As part of the international study a Vigilance light was utilised as a secondary task measure (Chapter 5).

3.4.7.1 Vigilance Latency Task

Slagle & Weinger[179] defined vigilance as "a state of readiness to detect and respond to certain specified small changes in the environment". Warm and colleagues[180] suggested that Vigilance performance during an event, such as an anaesthetic, declines over time. They go onto to say that this is due to the cognitive resources available for task performance being depleted at a rate faster than they can be replenished. Many factors have been suggested that can affect vigilance, these include experience, motivation, task complexity, workload and faulty equipment or system design.[179]

As part of the main VASER study data collection methods, the time taken to respond to a 'vigilance light' was utilised as the secondary task measure; an indirect measure of workload or spare capacity.[181] A Personal Digital Assistance (PDA)

computer was attached to the patient physiological monitor screen and this randomly displayed a white circle of light which the anaesthetist had to acknowledge by touching the PDA screen. A specifically designed computer programme within the PDA recorded the time taken (in seconds) to acknowledge the presence of the light.

Figure 3: PDA with Vigilance light illuminated

3.4.7.2 Physiological and Subjective Measures of Workload

Physiological markers include respiration, heart rate, heart rate variability, electrodermal response, eye movements and pupillary responses as indicators of mental effort.[170] These measures have the advantage of being able to be continuously monitored, however the disadvantages include hypersensitivity to environmental interference or from intrinsic interference such as muscle movement, the equipment can also be quite bulky and so quite obtrusive.

Other studies have used subjective measures to assess mental workload. These include the National Aeronautics and Space Administration Task Load Index (NASA-

TLX), the Dundee Stress State Inventory and the Borg Workload scale.[182-184] of which the main VASER study utilised the NASA-TLX.

Bruneau[185] describes subjective mental workload methods as providing a 'self-assessed estimate of workload' because of this the data produced is relative rather than absolute. The advantages described in the literature of utilising a subjective workload measure are ease of use, their relative low cost when compared to objective measures, and their wide acceptance within the research community. However, disadvantages include the possibility that the mental workload score may not reflect the true mental workload level and could be influenced further by biases such as dislike of, or unfamiliarity with the task.[185] In addition, subjective measures require the individual to stop the task at some point in order to tell the researcher their workload score or for the measure to be completed pre and post task.

My second study (Chapter 5) utilised the Borg Workload Scale. This workload ratings scale has previously been used within anaesthetic clinical practice, and is described in greater detail below.

3.4.8 Borg Workload Scale

The Borg workload scale is a 15 point scale previously validated within anaesthesia [Appendix VIX].[181 182 186] The scale ranges from 6 (completely sedentary participant) to 20 (during a full blown OR resuscitation).[187] This scale of 6 to 20 corresponds to a heart rate of 60 – 200 beats per min,[182] and participants ratings of the scale have been found to correlate closely with actual heart rates.[172] The scale is also asymmetric in the attempt to minimise bias caused by the tendency of respondents

to group their answers at the middle or extremes of symmetrical numerical scales. The scale integrates multiple workload constructs, including physical effort, mental effort, and psychological stress.[187]

Workload was assessed both by myself and by the participating anaesthetist. I was prompted by a specifically designed computer programme at random intervals, of between 7 and 15 minutes, to rate workload. I firstly rated the anaesthetist's workload and then recorded the anaesthetist's own estimation of their workload directly onto a laptop computer.

Weinger & Englund[188] suggested that, with increasing anaesthesia workload, primary tasks would be given a much higher priority than secondary tasks, which they described as 'load shedding'. They also suggested that 'information gathering' would be carried out for prolonged periods, which they entitled 'longer than average dwell times'. Finally, it was suggested that the performance of more experienced personnel would be less heavily influenced by workload due to better resource allocation.[181] The results of the anaesthetist's workload are presented later (Chapter 5).

3.4.9 The SAFERsleep™ System

Within the both of my studies (Chapters 4 & 5) the SAFERsleep™ system was utilised. In the first of my studies (Chapter 4) it was integrated into clinical practice at two NHS Trusts for a period of three months, while in the second of my studies (Chapter 5) it was used within the simulated environment. The system consists of a number of safety features previously highlighted in Chapter 1; syringe labelling,

formal organisation of drug drawers and workspaces, and the use of a double check prior to administering the drug.

The following description of the SAFERsleep™ system is in relation to its use within clinical anaesthetic practice relevant to Chapter 4 and Chapter 5.

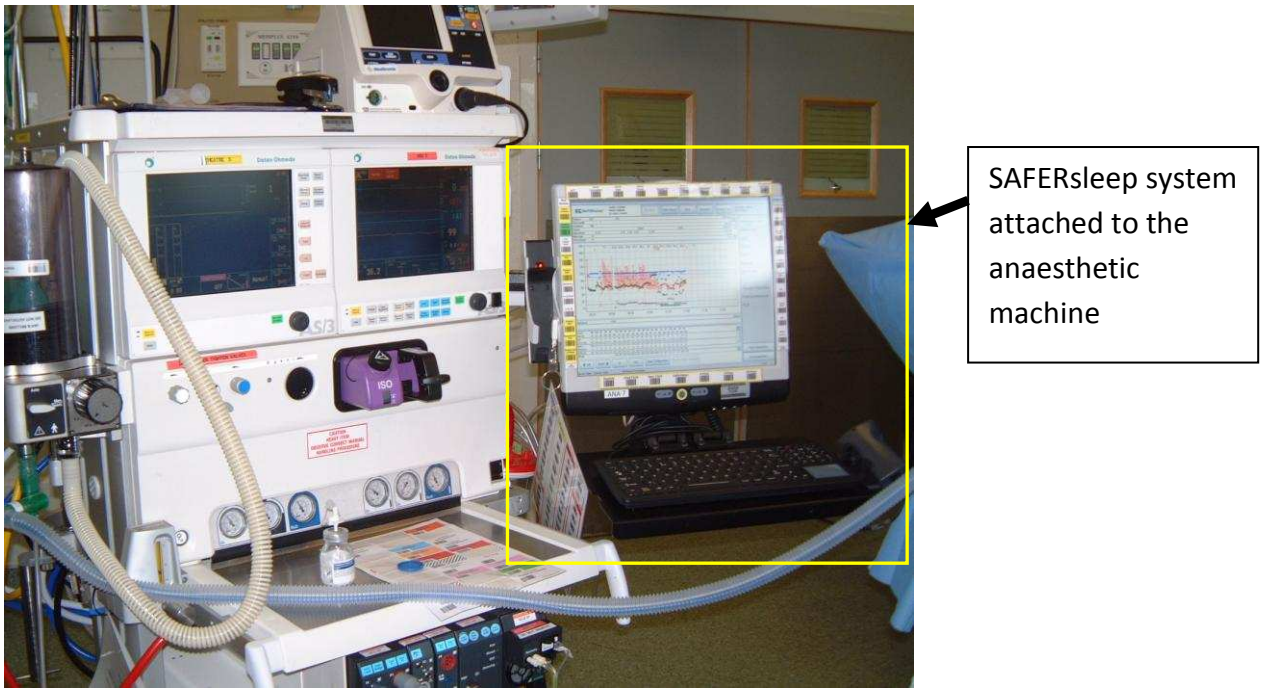


Figure 4: The SAFERsleep™ System in clinical practice.

The innovations comprising the SAFERsleep™ system include:

1) Pre-filled syringes
2) Standardised, more legible labelling
3) A bar-code reader, computer and custom software
4) A purpose designed drug trolley and drug trays
5) Operational rules which promote safe practice

6) An automated anaesthetic record to improve the accuracy and comprehensiveness of anaesthesia recording and reduce the cognitive load on the anaesthetist.

Surprisingly, inconsistent colour-coding, look-alike appearances and illegible labelling remain the status quo on drug containers in hospitals throughout the world.[189]

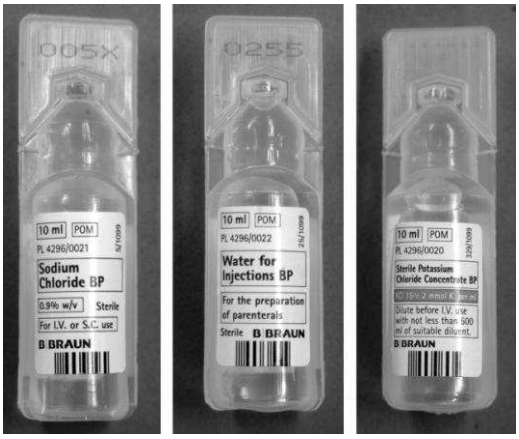


Figure 5: Look alike drug labelling

In The SAFERsleep™ system, all labels (pre-filled syringe labels, flag-labels and user-applied labels) are colour-coded by pharmacological class of drug according to existing international standards for anaesthetic labels[190] [191]and include both the class name and the name of the drug in large clear lettering (e.g. “Opioid Fentanyl”). Details of less importance to accurate drug administration (including those required by regulation) are displayed in smaller lettering.

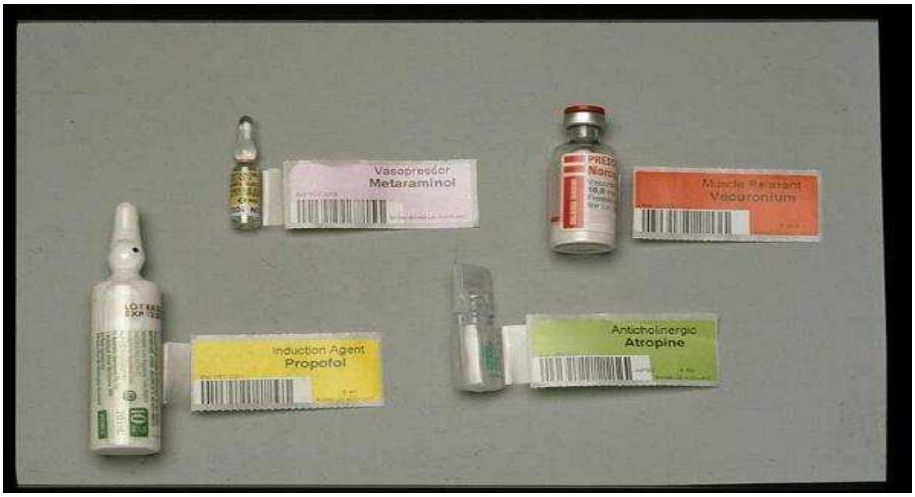


Figure 6: SAFERsleep™ Bar-coded flag labels applied to drug ampoules

With the SAFERsleep™ system, each label also includes a barcode. Custom software interprets scanned barcodes, redisplays the drug name on the computer screen in large type along with its colour-code, and announces the name of the drug using a pre-recorded voice. In this way scanning forces checking and provides two cognitive processes of identification (auditory and visual) and multiple opportunities to detect error. For example, with conventional drug administration methods, dopamine has been mistaken for Dopram (doxapram) with fatal results.[192] However, with the SAFERsleep™ system "Inotrope, Dopamine" on a purple label (and computer display) would be quite distinct from "Analeptic Agent, Doxapram" on a white label (and computer display), and in addition the spoken drug name uses a second cognitive modality (hearing) to reinforce the distinction.

Algorithm-based ("smart") prompts remind anaesthetists to administer prophylactic antibiotics or (if appropriate) provide various warnings (e.g. of expired drug status) in response to scanning. Forcing functions promote the collection of

essential items of information for the record. The custom software also allows the computer to access physiological data from the patient monitors and automatically compiles a complete anaesthetic record, annotated with timed drug administration events.

Workspace organisation in anaesthesia is traditionally idiosyncratic and based on convenience rather than principles of safety.[189] In using SAFERsleep™, the drug trolley drawers and trays are purposely designed to standardise and rationalise the organisation of the workspace and physical tracking of syringes.

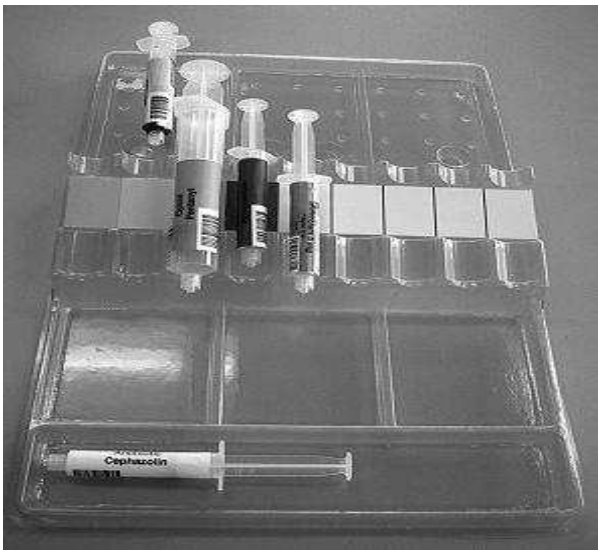


Figure 7: SAFERsleep™ drug tray

Trolley drawer compartments are colour-coded by pharmacological class of drug according to existing international standards for anaesthetic labels in the same way as pre-filled syringes – thus syringe colours match their drawer compartment colours.

Figure 8: Top drawer of SAFERsleep™ drug trolley

In drug trolleys with the SAFERsleep™ system, stocks of pre-filled syringes and ampoules are laid out in drawers from left to right in the order they would typically be used.

Figure 9: Second drawer of SAFERsleep™ drug trolley

Drug administration in anaesthesia has traditionally been decidedly personalised.[100] The SAFERsleep™ system incorporates operational rules to standardise and rationalise this in a manner analogous to a defined pathway of care.

3.5 The Underpinning Philosophy of the Study

3.5.1 Symbolic Interactionism & Grounded Theory

Symbolic Interactionism is a theoretical approach intent on determining how people define reality.[122] The goal of this tradition is to understand 'the complex world of lived experience from the point of view of those who live it'.[193] Grounded theory originates from within this movement;[123 194] Glaser & Strauss[133] set out to develop a more precise and logical method for the collection and analysis of qualitative data. They called this method grounded theory to reflect the foundations of the principle; that data is ultimately grounded in the behaviour, words and actions of those under study.[194]

In line with a constructionist ontological position, which considers reality to be socially constructed and social phenomena and categories are not only produced through social interaction but in a constant state of revision,[132 144] I have chosen to use Grounded theory as the methodology for both of my research studies (Chapter 4 and Chapter 5).

3.5.2 Grounded theory

The term 'grounded theory' although commonly used to describe a specific type of analysis is actually both a method of investigation and the product of

investigation.[195] It is an inductive technique that focuses on the meanings and interpretations of the research participants through the use of highly detailed accounts of social interactions.[122] In order to understand the hidden patterns and relationships within social processes, Strauss & Corbin[196] described six C's explored by grounded theory; causes, contexts, contingencies, consequences, covariance's, and conditions. Within this concept, knowledge of social realities is achieved.[123] Grounded theory encourages researchers to systematically gather and analyse data throughout the research process. The approach is iterative, or recursive, meaning that data collection and analysis progress concurrently, constantly referring back to one another.[132] This process enables the development of an integrated set of theoretical concepts directly from the observed data. The emphasis is on staying close to the origins of the data, ultimately leading to a theory that has emerged directly from within the data.[127]

3.5.3 Grounded theory framework

Grounded theory is quite a unique qualitative method in that it has an apparent 'how-to-do' framework. Glaser & Strauss[133] attempted to frame the procedures they thought informed qualitative analysis, but were never actually written down.[144] This framework is relatively prescriptive in how the data is collected and what analysis techniques are used. Glaser & Strauss[133] argued that you could extract the rules researchers use to, as they put it, 'discover theory from data' and more novice researchers, with practice, would understand how to utilise them.[122] [144] These key features include theoretical sampling, constant comparative method, coding and categorising, memo writing and theory generation.

All of these processes are meant to take place simultaneously throughout the life of the project. Constant comparison and concurrency are seen as fundamental characteristics of grounded theory data collection and analysis. However, complexities of time, resources and access to the research setting may mean the researcher has to remain flexible and adaptable in order to accomplish data fully.[135]

3.5.4 Applications of Grounded Theory

Grounded theory is a method better suited for exploring some questions more than others, especially those that aim to understand the processes by which people construct meanings from their experiences or their 'reality'.[197] According to Stern,[198] grounded theory should be utilised "in investigations of relatively uncharted water, or to gain a fresh perspective in a familiar situation".

It is also important to understand that the original intent of grounded theory was a methodology specifically designed for sociologists.[199] The evolution of grounded theory across a number of diverse disciplines, including social work, health care, psychology and management, has led to alterations of the method in ways that may not be completely compatible with all of the original principles.

3.5.5 Limitations of Grounded Theory

Limitations of using grounded theory have been described previously in the literature. Carvalho and colleagues[200] suggested that the analysis process is challenging for novice researchers as it is very subjective, relying heavily on the proficiency of the researcher and with little specific guidance on finding patterns in the data.[200 201] The hazard of concentrating solely on identifying codes, without

theoretically coding has also been highlighted by several authors.[198 202 203] Constant comparison must continue throughout the process, with emerging themes being grouped on the basis of correlation and diversity.[199]

To reach the point of theoretical saturation is time consuming.[144 200] The constraints of health research, such as the realistic issue of funding, can have an extensive impact on utilising grounded theory to its maximum potential. A major constraint is the flexibility of the sponsor in allowing further collection of data to ensure saturation, or from the results of the initial analysis to change the course of data collection. Most research projects work to tight deadlines and because of this Green & Thorogood[144] question how often theoretical saturation really happens.

An additional limitation has been described as method slurring, where similar yet different qualitative methodologies are confused with grounded theory, e.g. phenomenology,[204] or where studies have been reported in the literature as using a grounded theory approach when theoretical coding has not been utilised.[198 205 206] Stern[198] suggests that although there may be likenesses in all interpretative methods, the frameworks underlying the methodologies were very different. While Baker and colleagues[204] concluded that the failure to clarify qualitative methodologies is culminating in a body of research that is mislabelled.

3.5.6 Constant Comparative Method

As discussed earlier, fundamental to grounded theory is constant comparison. No matter which element of the data you commence coding with, in grounded theory you use constant comparative methods. This process stimulates ideas regarding

incidents, concepts, categories and their properties; it enhances theoretical sensitivity and provides direction for theoretical sampling.[135 195]

Within both of my studies (Chapters 3 & 4) the data was constantly compared. As Charmaz[195 207] describes I compared data with data, data with categories, and category with category to find similarities and differences. Data was compared between earlier and later observations and interviews, and within the same observation/interview. I also compared statements and incidents in different observations and interviews. Data, which had already been coded, was not finished with after its classification but was continually integrated into the further process of comparison.[208]

It was important for me to recognise that if the codes I had generated and defined contrasted with the perspective of those participating I did not reject my observations and ideas and presume they were wrong. Instead the conflicting issues were recorded and the data was re-explored, and further observations were undertaken if necessary, to explore these issues and possibly challenge taken for granted understandings.

3.5.7 Coding & Categorising

The literature differs in that some authors describe three distinct stages, while others describe four stages of the coding process within grounded theory. It must be remembered though that this is not a linear process but ongoing with stages taking place alongside each other during the coding procedure. Charmaz[207] describes coding as the first step in looking at the data through an analytical perspective and directs the researcher to determine the action within the data

transcribed. Jeon[135] goes on to say that 'coding is the defining aspect of analysis within the grounded theory method and is a means by which the quality of emerging theory can be determined.' The phases have been described as open coding, focused coding, axial coding and theoretical coding. Within the coding of my data I used the process described by Charmaz[195] this involved only three phases; Open coding, focused coding and theoretical coding.

3.5.7.1 Open Coding

The process of open coding involved carefully going through the transcribed data word-by-word, line-by-line, incident-by-incident, and as Charmaz[207] described I assigned descriptive codes that were 'active, immediate and short'. Through fragmenting the data in this way it prevented me from ascribing my own perspective, beliefs and emotions, to the data I had collected. By engaging in line-by-line coding, I was able to make a detailed study of the data and lay the basis for the construction of the theoretical perspective. By studying the data in this way, it also allowed me the opportunity to see the participant's words and actions in a new light; this helped in my analysis as I was approaching the data with a different clinical background to those that participated. As Charmaz[195] suggests, you 'attain detachment from your presumptions and your participants' taken for granted conjectures about the data so that you can see it in new light'.

In addition I utilised another member of the research team, Ms Dinah Mathew, a sociologist by background, as well as Professor Mahajan, my supervisor, to open code the initial data. This allowed the coding framework to be verified but also

brought a different viewpoint to the coding and observations due to the different perspective, my expectation of this process was the possibility that the coding might expand in new ways.

I adopted the stance that each piece of data I collected, whether through observation, interview, focus group or reflective diaries could inform earlier data. Any new codes that developed led me to revisit the preceding data; any fresh connections that had been illuminated were explored further.

The descriptive power of the generated theory, through direct connection of the raw data to the theory, is only achieved through the coding process.[195] As Glaser[202] states the conceptual codes serve as 'the building blocks of theory.'

3.5.7.2 Transforming Data into Codes

Within both of my studies, I systematically worked through each transcript, underlining words that jumped out of the data and coding them in a way that preserved the action or meaning. In my first study (Chapter 4) over 150 codes were generated during this process, a slightly smaller number, just over 90, were generated in the second study (Chapter 5). The idea behind coding full transcripts is to elicit ideas and understandings that might otherwise be missed; this immersion in the data allows a deeper understanding of the area under study.[195]

3.5.7.3 Focused Coding

The second key phase in coding is described as focused coding. Following on from the open coding generated within the observation, interview and focus group transcripts, I began to focus the coding and to combine and clarify larger fragments

of data in line with the themes that were emerging from the data. Focused coding has been described as using the 'most significant and/or frequent earlier codes' to sort through vast quantities of data.[195] Focused coding requires judgments about which initial codes make the most sense to categorise your data concisely and absolutely.[195]

As part of the process of focussed coding I met up with both Ms Matthew and Professor Mahajan and we worked through the codes together, bringing our own interpretations to the discussion and this process allowed us to clarify the codes and pinpoint the themes that were emerging from all of our perspectives.

The power of grounded theory coding lies within this intense, active absorption in the procedure. Data is acted upon rather than only passively read; actions, interactions, and viewpoints emerge from the data that had not been considered previously. Focused coding confirms any preconceptions you hold about the focus of study.[195]

3.5.7.4 Theoretical Coding

Theoretical coding is an advanced level of coding that aligns with the codes selected during focused coding. Glaser[203] suggests that these codes weave the splintered story back together. Charmaz[195] goes onto say that if used skilfully, theoretical codes may define your work permitting a sharp analytical influence, conceptualising the relationship between the substantive codes, and moving the story being painted in a theoretical direction. In other words, theoretical codes describe potential relationships forming between the categories originated during focused coding.[195 208]

3.5.8 Memo writing

Memo-writing is a key process in formulating a grounded theory, it promotes the analysis of data and codes early on in the course of the research study.[195] Writing memos' allows the researcher to preserve and elaborate their thoughts, capture the powerful ideas emerging from the data, and define the distinctions and connections made. The use of memos allows you to define further questions and directions to pursue, subsequently leading to the development of theoretical codes.[135 195]

The generation and fine-tuning of the theories that emerged from my data was achieved through the constant writing of memos. This was an integral part of the theoretical sampling, coding and categorising within both studies. Distinctive codes stood out and took shape as theoretical categories as I continued to write my memos. Glaser[202] maintains that in conducting grounded theory research there will be no robust theory without the utilisation of memos.

Charmaz[195] suggests that through writing memos, systematic notes are created to illuminate and expand categories. Memos allowed me the scope and opportunity to make comparisons between multiple variables within the data. It also presented a way for me to document assumptions I made about these comparisons, and provided a way to share these with other members of the research team.

3.6 Rigour in qualitative research

To ensure my findings were credible and robust, it was essential to strive for rigour and data reliability. It is not appropriate to apply the term rigour in the traditional quantitative understanding to qualitative research, applying these measures to

qualitative research requires redefinition. Nonetheless, many qualitative researchers do believe that situations and experiences that occur in people's lives should be reflected accurately in qualitative research.[209 210] Denzin[211] describes a rigorous qualitative study as one which addresses questions such as 'does the data appear to accurately capturing the phenomena?'

There are several strategies suggested in the literature to enhance the rigour of qualitative research of which I aimed to follow. These include researcher reflexivity, purposeful sampling and triangulation. Barbour[212] suggests that the use of these strategies does not in itself confer rigour. To be effective, these techniques need to be rooted within the underlying principles and beliefs behind the research. Rigour is less about sticking religiously to the rules and procedures and more about loyalty to the essence of qualitative work.[139]

3.6.1 Reflexivity

Reflexivity is a term used to describe the practice of critically reflecting not only the research but your role and influence as the researcher.[144 213] In order to understand the impact the researcher's beliefs and ideals have on the research, Self reflection or reflexivity is increasingly seen as a valid means of adding credibility to qualitative research.[214] Reflexivity suggests an understanding by the researcher, that they are a part of the social world under investigation and that their presence has contributed to the data collected in some way.[122 144 147] Who you are and where you are as a researcher will inevitably shape the kind of data generated.[144]

My own background is within Nursing, of which it is standard practice to double check all injectable drugs administered to a patient with a colleague. This conflicts with the anaesthetist's standard practice, where no confirmation of the drug with a second person, prior to administration, is typical. Trying to follow the advice of numerous research books I had read, I aimed to maintain a friendly distance from the participants within both of my studies and not be drawn into expressing my personal views.

At the first focus group (Chapter 4) I started with pre-conceived ideas of how I would conduct it, conscious of the fact that my voice should not be overly present and with the intention that my role was to prompt, probe and facilitate. However, when I came to transcribe this focus group I was shocked at how audible my voice was and to discover that I had slipped effortlessly and unconsciously into a clinical nursing perspective. I became extremely mindful of this during all the subsequent focus groups discussions, but accepted that my background and experience was something which would inevitably influence the data I collected.

I did however discover that my concerns of not 'doing the job properly' and 'colouring the data' were common concerns among qualitative researchers within the literature, but that it is considered beneficial due to the insight and richness gained in the data collected.[214]

Being reflexive has allowed me the opportunity to reflect on the role conflict I felt during the study, and to have an appreciation of how my views contributed to the research.

3.6.2 Triangulation

In my thesis, I have also used triangulation. Triangulation involves utilising more than one method or source of data,[132] and within both of my studies I used a combination of qualitative methods; observations, focus groups, reflective diaries and semi-structured interviews, and quantitative methods; questionnaires and workload scores.

Combining multiple sources of data allowed me to evaluate the data I had collected over time as well as enabling me to reflect and compare different types of data within my research.[122] Triangulation can be used to develop a broader, intricate representation of the issues or phenomenon being studied, rather than as a way of cross checking.[122] Triangulation can be seen as a way of providing a balanced view, increasing the perspective of qualitative research.[122 212 215]

3.7 Ethical Issues

My research did not involve vulnerable groups or a particularly sensitive topic, but this did not eliminate the need to address ethical issues within both of my studies. The principle role of ethics within health service research is to protect research participants from harm.[122] Gauging possible 'harm' is not easy, especially as the kind of 'harm' caused by qualitative research is invariably associated with hurt feelings, or invasions of privacy.[144]

The foundations laid down in codes of conduct and research guidelines should be followed by all research professions to ensure that no harm comes to those who participate in their studies. Researchers have a responsibility to produce good quality research. The *Research Governance Framework for Health and Social Care*[216] from the Department of Health sets out principles for all those involved in the conduct of research and makes it clear that it is the researcher's duty 'to protect the dignity, rights, safety and well being of participants'.[208 217] As well as the standards set out in this document, a central principle within qualitative research should be to endeavour to treat people as individuals, rather than a means to an end. Coercing someone to participate in an interview, or misleading them about the purpose of the research, would be hard to justify ethically even if confidentiality was respected and no harm ensued.[144]

Both of my studies involved NHS staff and in the second of my studies there was a particular issue in relation to confidentiality. A number of colleagues within the same anaesthetic department attended the same focus group and it was important

for me to stress that all discussions, as part of the focus group, remained confidential.

It has been recommended that ethical implications should be addressed at every stage in the research process. This should include protecting participants and researchers from harm, using voluntary participation, anonymity and confidentiality, as well as informed consent.[218]

The following discussion will consider these ethical issues, and how they were dealt with in my research.

3.7.1 Harm to Participants

As previously mentioned, the principle aim within research should be to prevent harm. Harm resulting from badly conducted research ranges from actual bodily injury and emotional trauma to the threat of law suits for scandal or slander in relation to the divulgence of personal information. The primary cause of harm often described in relation to qualitative research is emotional distress of participants.[219] However, this threat can generally be surmounted by perceptive and considerate researchers and by providing the opportunity for counselling should it be required.[124]

Research has a great potential to take advantage of those who participate.[125] The close contact and the likely personal nature of the information shared by the participants, makes qualitative research potentially susceptible to the exploitation

of individuals.[122] Sometimes the consequences can impact on the both the participants and the researcher in far-reaching and unexpected ways, because of this the researcher needs to take all reasonable precautions to consider the likely consequences and repercussions their research may inflict.[122 125 220]

I was mindful in both the focus groups and the interviews that there was the potential for the participants, who were all health professionals, to hold differing views to mine over acceptable standards of clinical practice. It was therefore extremely important to allow their beliefs and values, in relation to my research topic, to emerge naturally from the conversation, and not be extracted through cross examination.[221] Adverse comments and judgement could leads to demoralisation and defensiveness and would be extremely unhelpful in the research process.[221] It was therefore important to reassure participants that the focus of my research was the system and not the individuals.

3.7.2 Informed consent

In order to respect the research participant's autonomy, they must be permitted to make a 'free, independent and informed choice without coercion'.[217] It is important that the information provided is comprehensive and at an appropriate level to ensure consent is informed and given voluntarily.[144] Informed consent has been a cornerstone of most sets of ethical guidelines since the Nuremburg Code,[222] which have been endorsed through the Declaration of Helsinki.[223] Participants should appreciate fully what their involvement will involve, the reason for the study and what will happen to their confidential information.[122]

The participant information sheet, for both studies, fully explained the purpose of the research, the researcher's responsibilities and the likely risks and benefits incurred by the researcher and participants, clearly stating that the participant had the right to withdraw from the study at any time, without giving any reason [Appendix X, XI and XII].

Within the participant information sheet for my second study (Chapter 5) there was a specific section on what the procedure would be if practice was observed that could potentially cause serious patient harm. If during the standard debriefing, following the simulated scenario, the participant failed to acknowledge insight into potentially harmful practice, the matter would be discussed further with the Chief Investigator and the Director of the Trent Simulation & Clinical Skills Centre (TSCSC). In the unlikely event following this discussion it was felt the issue in question raised potential concerns about future clinical practice it would be discussed with the head of service (for Consultant Anaesthetists), or Educational Supervisor / Training Programme Director (for Anaesthetic Trainees). This would have been done with the full awareness and involvement of the participant.

All potential participants had the necessary information to make an informed decision about their involvement in the research study. Prior to the participating, the participants were provided with the opportunity to ask any questions, then each participant completed and signed the specific study consent form [Appendix XIII, XIV]. In accordance with the Research Governance Framework for Health and Social Care in England,[216] ethical approval for both studies was granted by a

Regional Ethics Committee and research governance permission was gained from all the participating sites.

3.7.3 Anonymity and Confidentiality

Ethical principles integrate the defence of privacy and the avoidance of deception. The right to privacy is a principle that many of us value, and contraventions of that right 'in the name of research' are deemed unacceptable.[132] Promises of confidentiality in research largely relate to who will have access to the data and how the data will be used.[224]

The Declaration of Helsinki[223] states that 'every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimise the impact of the study on their physical, mental and social integrity'. In order to achieve this, the true identity of the participants should only be known to the research team.[218] This becomes complicated when the research methods involve focus groups. Participants may find it hard to conceal the identity of other participants, despite agreeing to do so at the time of the focus group.[122]

The participant information sheet clearly stated that the names would always be confidential, and views would always be anonymised. However, it did also state that others might access the data to ensure the study had been carried out correctly, but all would have a duty of confidentiality and nothing that could reveal their identity would be disclosed. The process of protecting the participant's names

entailed removing their names from all transcripts and audio files and ascribing a code to them. This meant the data could not be traced back to particular individuals. The coding of respondents on audio files and transcripts were known only to the researcher and all audio files, transcripts and observation schedules were stored and archived securely.

There has been significant debate about the extent to which it is appropriate to modify data in the interests of anonymity, there is the potential that the more the data is anonymised, the further away it is from its original meaning and the less useful it becomes.[224]

In both of my studies I did want to be able to acknowledge the people who had contributed to the study when the study was published. With six focus groups, 29 observations and 101 participants, across both studies, it was felt that the numbers were sufficiently high enough to make individual identifications from the list of who had said what difficult. However, I am aware that this approach does of course threaten anonymity.

3.7.4 Researching Peers

Both of my studies involved either colleagues, who I work closely with on a regular basis, or professionals within the area that I work.

When researching the feasibility of a situation or commodity designed to impact on clinical practice, it can be extremely valuable to seek the views of those who are affected, to understand the experiences encountered during such changes. In this

research, the individuals whose experiences I sort to gain were my colleagues and peers.

There are distinct advantages in using one's peers; one benefit is that a more mutual relationship is often found, one that most qualitative researchers aspire to.[217] Another advantage is that the researcher, who is already involved in the culture of the participants, understands more readily the inherent cultural concepts. The drawback of this however, may mean the researcher has a superfluous identification with colleagues. Being too loyal to the profession may mean the researcher simply accepts what they observe without asking decisive questions or makes unjustifiable assumptions, there is also the issue of cultural blindness when observing a familiar field.[217 225] To overcome this, I appreciated the insight from members of the research team who were naïve to the area under study; this enabled me to look at the themes emerging from a fresh point of view.

Confidentiality perhaps becomes more of an issue when colleagues are involved in the research process. It was important to ensure that colleagues were not able to recognise or identify each other from the data presented and that all quotes were anonymised. Conducting research within your own professional community means you often have knowledge concerning individuals outside the remit of the research context. It is without doubt difficult, if not impossible, to isolate all prior knowledge of those colleagues when analysing the data generated by them.[173 224] It was therefore vital for me to distinguish what was actually knowledge gained through

the research process and what was gained through my personal contact with an individual and not to be shared.

3.8 Summary and conclusion

The aim of this chapter has been to define the methodology and methods of my research.

Qualitative data analysis is an intricate and innovative process which is continuous, reciprocative, inductive and instinctive. The data analysis within my research continued throughout, from the start of data collection to the final publication. I employed several strategies to ensure rigour, these included triangulation, purposive sampling and reflexivity. Finally, methods of analysis using grounded theory, ethical issues and considerations of including my peers in the research have been discussed.

The following two chapters set out the findings that emerged from both of my studies.

CHAPTER 4: CONFIRMING THE DRUGS ADMINISTERED DURING ANAESTHESIA: A FEASIBILITY STUDY IN THE PILOT NATIONAL HEALTH SERVICE SITES

4.1 Introduction

Previous research (Chapter 1) identified the use of a double checking methodology as a possible way of reducing drug errors in anaesthesia. This chapter therefore focuses on ascertaining whether it is feasible to introduce such a method into anaesthetic clinical practice within the NHS.

Drug errors within anaesthesia remain a serious cause of iatrogenic harm.[80 88] The reported incidence of the errors range from 1: 133 to 1: 5475 anaesthetics.[28 78 79 86 89] Despite the wide range of reported incidence, and perceived lack of consensus regarding the magnitude of the problem, it is unacceptable that any patients are harmed, no matter how minor, while undergoing anaesthesia.[226]

In September 2007, in the UK, the RCoA, AAGBI, and the NPSA set up a multidisciplinary Expert Consultative Group to provide strategic direction to a project called 'improvement through partnership'. Based on the reported incidents to the NPSA showing the majority of drug errors occurred during administration, and the suggestion that these could be prevented had a double-checking measure been in place,[100] the group decided that the feasibility of introducing a double-check of drugs given during anaesthesia should be explored. It was noted that confirmation of the drugs administered during anaesthesia, either using a second person check or a technology based system, is not routinely practiced in the UK or elsewhere in the world.

This chapter, therefore, aims to explore the feasibility of introducing a practice of confirmation of drugs given during anaesthesia in seven NHS Hospital Trusts within England and Wales over a three month period during 2008.

4.2 Methods

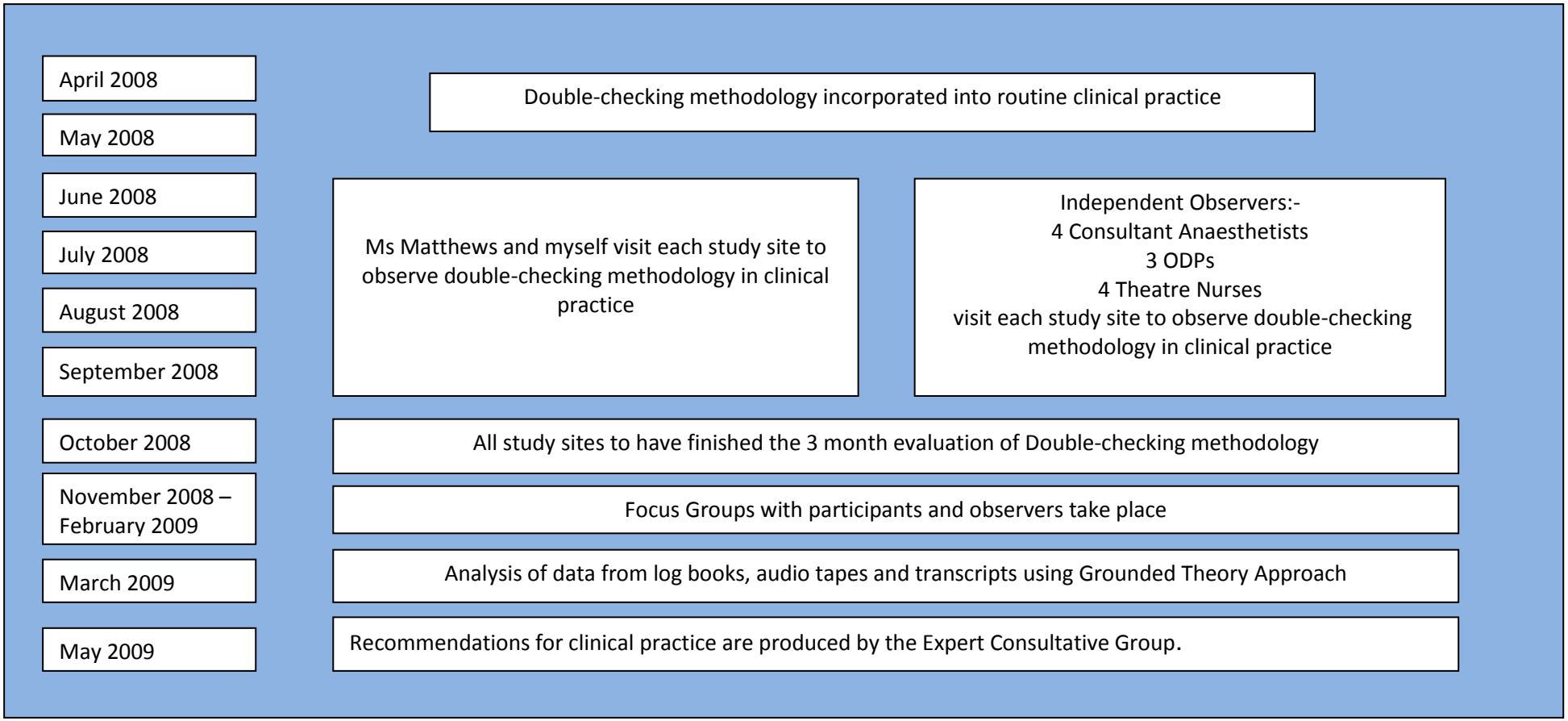
4.2.1 Study design and participants

This was a qualitative study using observation, reflective diaries and focus group interviews. In patient safety meetings, held at the Royal College of Anaesthetists, delegates were invited to participate. Purposive sampling was used to ensure a representative sample of NHS secondary and tertiary referral centre hospitals, geographically spread across England and Wales from amongst the anaesthetists who had volunteered. Anaesthetists from seven NHS Trusts were selected. Two of these Trusts were identified to have the SAFERsleep™ system (integrated drug administration and automated anaesthesia record system which utilises bar-code technology) installed, and five Trusts were identified to use the two person confirmation protocol.

The study was approved by the West Glasgow Ethics Committee 1 and local NHS research governance was gained at all sites. It was left up to the lead participant at each site to identify other anaesthetists who were willing to participate. A total of 36 consultant anaesthetists and three trainee anaesthetists, 15 ODPs, and seven anaesthetic nurses participated. Each participant was sent a letter of invitation and information sheet. Written informed consent to take part in the study was obtained from all participants who were informed that the data from the observations, focus

groups and reflective diaries were confidential and that they could withdraw from the study at any point without penalty.

Table 2: Diagram to show Double Checking Study pathway



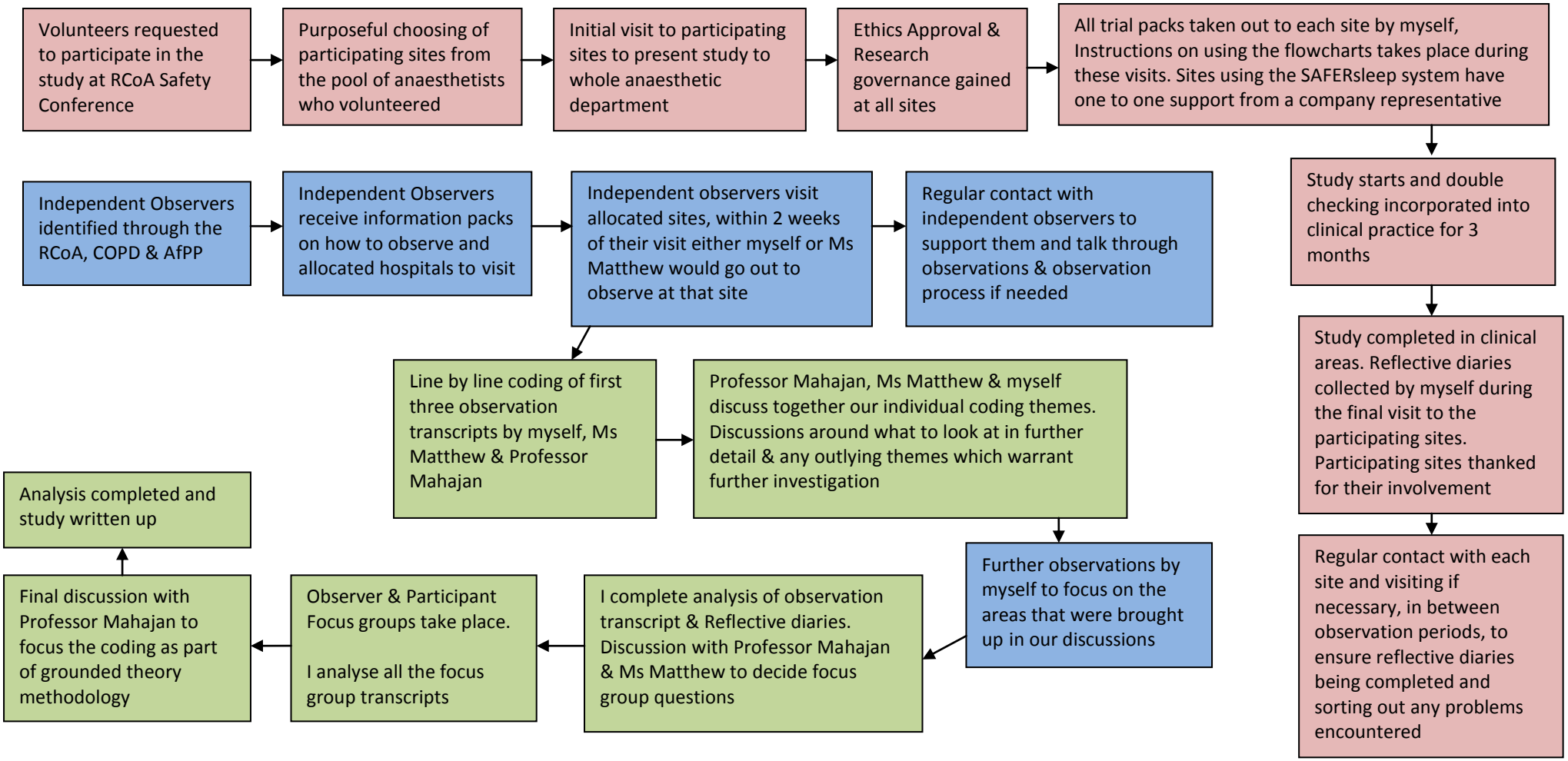


Figure 10: Study Process Flowchart

4.2.2 Primary Outcomes

The overall aim of the study was to perform a work-place evaluation of the practice of double-checking using second-person checks and/or electronic checks (SAFERsleep™ system), to determine the feasibility and barriers to the introduction of a double-check methodology.

4.2.3 Drug Confirmation

The two methods of confirmation of drugs were integrated into clinical practice for a period of three months. At all the participating sites the process of confirming the drug to be drawn up into the syringe was standardised through the use of a flowchart [Appendix XV]. At the five sites, which participated in two-person confirmation, there was the addition of a flowchart for drug administration [Appendix XVI]. The flow charts were designed by the human factors team within the NPSA, and piloted at an independent NHS Trust prior to the study.

I went out, prior to the start of the study, to go through these flowcharts with the lead anaesthetist at all of the study sites to ensure they understood the process. The task of disseminating this information further to the rest of the participating anaesthetists at each site was then delegated to these lead anaesthetists.

At the two sites that had the SAFERsleep™ system installed, a representative from the company spent several days with the participating anaesthetists to ensure they were familiar with the correct use of the system and to try to mitigate any problems.

At the two sites assigned to use the SAFERsleep™ system, a specific label that contained a bar-code identifying the drug was used (Chapter 2). The label was

placed onto the syringe after drawing up the drug, and the computer assisted bar-code reader was used to 'confirm' the drug prior to administration. Hence, the first flow chart was used to draw up the drug, and the electronic system was used during administration. The SAFERsleep™ system has been designed specifically for use within anaesthesia with the aim of reducing errors in drug administration and record keeping,[90] by scanning the bar-coded syringe under the scanner it produces audible and visual drug confirmation, at the same time the name of the drug and the dose administered are entered into an electronic anaesthetic record. The SAFERsleep™ system also utilises barcodes to enter anaesthetic events on the record, such as the start of surgery or the size and placement of the intravenous cannula. The SAFERsleep™ system gathers physiological data directly from the patient monitor via a serial connector. A real time anaesthetic record is produced from these data, and any further information that is entered via the bar-code reader.

4.2.4 Reflective Diaries

All the participants at the pilot sites were asked to keep reflective, also known as solicited, diaries. The reflective diaries were provided by the study team and were standard across all sites. Each diary entry was divided into five areas for the participant to reflect on; Setting, Drug Preparation, Time, Feasibility and Other [Appendix VI]. The prompts provided within these five areas were only a guide and were by no means prescriptive, but rather were there to help focus the participant's thoughts around the areas we were interested in. Participants were asked to complete these diaries after every surgical session for the first two to

three weeks of the study. Jacelon and Imperio [155] have previously found that the optimum length of time for completing reflective diaries is between 1 and 2 weeks. Less than a week the diaries do not provide enough depth of data; more than 2 weeks and the participants are tired of making regular entries. Reflective diaries provide participants with a means to respond to researcher-requested topics, as well as to record reflections that provide an account of their working day.[155]

4.2.5 Independent Observations

A number of anaesthetists (n=4), theatre nurses (n=4) and ODPs (n=3), working in NHS Hospital Trusts not participating in the pilot, were approached for independent observation of the study. The independent observers were recruited through RCoA, the College of Operating Department Practitioners (CODP) and the Association for Perioperative Practice (AfPP). I allocated the observers to observe the two-person confirmation and the electronic bar-code confirmation during the three month study period at a hospital that was not located in the same NHS region as their current place of work. Each person visited two pilot sites and observed both methodologies. In addition, myself and Ms Matthews made independent observations, at all of the sites, as soon as possible after an observation visit by an independent observer. This allowed for comparisons and internal validity checks on the data collected. All observers were provided with instructions and a schedule to record observations in order to promote consistency (Chapter 2) [Appendix VII, VIII]. The observers were asked to transcribe the detailed notes taken during the observation period immediately afterwards.

4.2.6 Focus Groups

At the end of the three month study period, a total of four focus groups were held. Invitations were sent out to all the sites for two participants to take part in the focus groups. Following on from this two focus groups were held, consisting of consultant anaesthetists (n=5), ODPs (n=3) and anaesthetic nurses (n=3) from the participating pilot sites were conducted within two weeks of the end of the study, unfortunately no trainee anaesthetists were able to attend, despite participating in the study. The other two focus groups, each with three independent observers, were conducted within two weeks of the completion of all observations. I moderated both of the observer focus groups with Ms Matthew taking notes for one of them. At the two participant focus groups Professor Mahajan moderated while I took notes.

Before the start of the focus groups a brief outline was given of the format of questions, we utilised the SWOT format to focus on Strengths, Weaknesses, Opportunities and Threats of both methods of confirming drug administration in relation to patient safety. All participants were assured of confidentiality and anonymity. A digital recorder was used to tape all discussions. Pre-defined questions and prompts were used to ensure continuity across all focus groups. The discussions were continuously taped and transcribed by one of the researchers within seven to ten days of completing each focus group. The finished transcripts were read through and checked against the original recordings by myself and Professor Mahajan for accuracy and integrity; any further comments were added at this stage.

4.3 Data Analysis

4.3.1 Data handling and analysis

The data from the reflective diaries were used to check outliers emerging from the observation data to enhance validity and provide triangulation.[122 227] Outlying themes were also explored further within the Focus Groups, allowing for a more comprehensive picture of the issues surrounding the introduction of the drug confirmation into clinical practice. I also kept a research diary during the study period; this was the means by which I wrote memos about the themes emerging and to highlight any areas or questions that needed further exploration. The main emphasis of analysis was on determining meaning and understanding rather than counting events or proving hypotheses.[228] Qualitative methodology was adopted to generate detailed descriptions and categories, as guided by the data[229] to explain the phenomenon under investigation.[122] The analysis of the data utilised the constant comparative method and so was iterative rather than sequential (Chapter 2).[228] Grounded theory methodology was used (Chapter 2). I performed the initial analysis and then both Ms Matthew and Professor Mahajan read through the transcripts and coded them (Chapter 2). We then met to discuss the coding and to concur or revise the thematic categories.

The line by line coding generated over 150 codes, these were then synthesised using focussed coding into theoretical categories of which two categories were further broken down into three sub-categories. Throughout the analysis the transcripts were repeatedly revisited to compare categories, to look for 'negative' or contradictory themes, and triangulation of data from reflective diaries and observations. These themes could then be explored further during the study period

through collecting additional purposive data in order to reach the point where no new themes were emerging known as data saturation. After finalizing the categories, the memos about each thematic category were written to define them and ensure consistency between researchers. Memo-writing allowed me to elaborate on a category, specify its properties, define any relationships found between categories or identify gaps in the data collected.[133]

4.4 Results

Table 3: Details of the Focus Group Participants - Double Checking Study

Participant Number	Occupation	Which method of Confirmation observed or used?
Focus Group 1- Observers		
1	Consultant Anaesthetist	Both
2	ODP	Both
3	Nurse	Both
Focus Group 2- Observers		
1	Nurse	Both
2	Consultant Anaesthetist	Both
3	Consultant Anaesthetist	Both
Focus Group 3- Participants		
1	ODP	Electronic
2	Consultant Anaesthetist	Two person
3	Consultant Anaesthetist	Two Person
4	Nurse	Two Person
5	Consultant Anaesthetist	Electronic
6	ODP	Two Person
7	ODP	Two Person
Focus Group 4- Participants		
1	Consultant Anaesthetist	Two Person
2	Nurse	Two Person
3	Consultant Anaesthetist	Electronic
4	Nurse	Electronic

The two main categories that emerged from the data were two-person confirmation and electronic bar-coding system, their subcategories being benefits, disadvantages, and practicalities. Other categories that emerged were perception of drug errors and wider cultural issues related to patient safety.

4.4.1 Second person Confirmation

4.4.1.1 Benefits

Participants felt that the second person confirmation had the potential to enhance patient safety, but it had to be carried out properly, with allocated time and without distraction. As one participating anaesthetist stated *"As a concept I have no doubt that it is a robust and if rigorously applied fairly fail safe methods of getting the right drug into the right syringe"* [Anaesthetist 2, FG3]. This was further supported by the comments from both an anaesthetist *"Providing it is done properly, it's ensuring what is in the syringe and the label match so it does confirm the content of the syringe"* [Anaesthetist 4, FG4] and nurse *"If it was adhered to rigidly and you were allowed the time taken to do it properly then it was just a matter of two minds confirming to each other the chosen drug is the one intended"* [Nurse 2, FG3] at separate study sites.

An additional benefit that emerged was that its introduction into clinical practice appeared to have increased awareness of drug errors and other safety issues, pointed out by two of the observers after visiting the study sites *"I think it has heightened awareness amongst users, they felt they were much more aware and spending time just checking ampoules, expiry dates"* [Anaesthetist 1, FG1], *"The double checking project has raised awareness and is being used for other procedures"* [Nurse 1, FG1].

Finally there was the consensus that one of the main benefits of two person confirmation was that there was no need to buy expensive equipment to be able to start; *"You don't need any expensive electronic equipment; all we need are the two people"* [Anaesthetist 2, FG3].

4.4.1.2 Disadvantages

One of the major barriers to the use of second person confirmation was the fact that during an emergency, when the drugs were needed in hurry, and when the potential for drawing up the wrong drug or misadministration could be heightened, the confirmation was often abandoned. One participating ODP commented that "*In an emergency situation it goes straight out of the window to be honest"* [ODP 2, FG3]. One of the anaesthetist observers made the observation that *"errors happen when the system is stressed, whatever the system is, and if there's an emergency that's when you want a system that can work and because the system is ignored when the emergency was happening it makes it worthless in a lot of ways" [*Anaesthetist 2, FG2]. Another observer went on to comment that *"I think the thing to do in an emergency is not to compromise the double checking but to call for more help"* [Anaesthetist 1, FG1].

Having to stop and wait for somebody to be available to confirm the drug was not intuitive, and it started to impact on the way the anaesthetist worked. *"I found it really didn't work when you are giving a drug in the middle of an operation, maybe a repeat dose of muscle relaxant and the ODP was not around"* [Anaesthetist 1, FG3]. Another anaesthetist commented *"I was giving my drugs when my ODA was there rather than when I wanted to give the drugs"* [Anaesthetist 1, FG4]

This impact on clinical practice was seen in the form of anaesthetists checking more than one drug at a time, *"If someone's busy reading out what's on the label, you're busy getting an ampoule out and likewise your nurse is not watching you drawing it up into a syringe, you could be drawing something else up"* [Anaesthetist 2, FG4].

On another occasion an inhalational agent was administered because no one was

available to confirm the IV drug. *"I felt that additional propofol was indicated in a patient but the perceived hassle of double checking was a disincentive and the patient was bagged with an inhalation agent"* [Anaesthetist 1, FG1].

Several participants described how they had started to modify the confirmation flowcharts in order to prevent any perceived delays to the running of the theatre list; this had led to the drug confirmation becoming no more than lip service. "*My experience of the process was not just that it was time consuming, but that it also became menial and frustrating and in any process like that I try to make it as efficient as possible. I found I was speeding up the process, so instead of checking one drug to its completion and finishing that, I would be checking more than one drug at once*" [Anaesthetist 2, FG3].

4.4.1.3 Practicalities

The main practical issues related to two-person confirmation were continued availability of a second person, one anaesthetist observer commented that the double check was *"perceived as a nuisance and an imposition on the ODP"* [Anaesthetist 1, FG1], while another observer commented that "*within the same patient there were other people checking the drugs as the procedure went on, so they started off with the ODP and they would latch onto whoever they could find*" [Anaesthetist 1, FG2]. This same anaesthetist observer also commented that at one site they had visited *"Some members of staff were refusing to be involved"* [Anaesthetist 1, FG2].

In addition, the observers noted that whilst the anaesthetists drew up the drugs in most instances, in some NHS sites, ODPs often drew up the drugs for induction of

anaesthesia to speed up the theatre lists; in these instances, availability of second person for confirmation was a major issue. Overall, the introduction of the confirmation protocol, generally, was not seen as too much of an infringement on their clinical practice by nurses and ODPs. In support of this one participant nurse commented that "*As a nurse it is routine, we always double check whatever we are giving*" [Nurse 2, FG4]. It was also recognised by one of the observers that *'If the sequence of events starts at the non anaesthetic end it is easier to do the double checking'* [Anaesthetist 1, FG1] suggesting the process of double checking is more acceptable and routine for nursing and ODP professionals. However, there were occasions when the confirmation was perceived as a nuisance, and was not carried out. Also, some participants were reluctant to perform confirmation in front of the patient. *"I don't think double checking takes that long to do it properly….I would just like the patient to not be there, for us to say we are ready now to focus on the patient"* [Anaesthetist 2, FG4], this may be in part due to the increased potential for distractions when a patient is present in the anaesthetic room; "*The patient hadn't arrived and it was easier to concentrate and double check without the patients*" [Nurse 2, FG4]

The perception among some clinicians was that double checking a drug would cause delays to the administration of that drug or to the running of the theatre list. However, others felt that it could be performed without causing too much of a delay, *"I think there is a misconception about the time it adds on, because how often do we go into theatre and we are waiting for the surgeon*" [Anaesthetist 2, FG4], while one of the observers commented that *"If you can double check (blood)*

in a bleeding aneurysm, why can't you double check drugs in other situations?" [Anaesthetist 1, FG1].

4.4.2 Electronic bar-coding system

4.4.2.1 Benefits

One of the main benefits was the ability to check the drug without a second person being present. On anaesthetist who used the system described it as an *"unblinking, untiring eye' on the drug, you never need to find someone else to do it (double check)"* [Anaesthetist 2, FG3]. One ODP observer commented that "*if your ODPs disappeared you don't need to have to keep calling them back to check the drugs"* [ODP 3, FG3], while another ODP observer suggested that "*the electronic [system] would make it easier in theatre during the case because you didn't have to have your second person, you'd have your machine with you"* [ODP 2, FG3].

The system itself was found to be easy to use and effective. Both observers and participants commented on the ease of use *"The scanning system was simple and effective to use and a good clear tool, both audibly and visually"* [Nurse 1, FG1], while another observer commented *"You could go through various individual safety features that you use, different labels, different syringes, different trays, but the ultimate one has to be bar-coding"* [Anaesthetist 1, FG1]. Even those anaesthetists' that had not used the electronic system directly outlined potential benefits of the system, *"I can see if you were scanning prior to administration it will reduce the potential for giving the wrong drug undoubtedly"* [Anaesthetist 2, FG4].

Another perceived benefit noted by many of the participants was the automated electronic record that the SAFERsleep™ system produced. One nurse observer

commented that *"There was a more complete record of the patient journey through theatre"* [Nurse 2, FG2]. This ability to follow the 'patient journey' and view the anaesthetic record in advance in areas such as the recovery unit was perceived to be immensely important, *"The nurses had looked at the chart and they had the whole picture of what had happened with that patient before they had even entered there and I thought that was really good and if I was in recovery I would love that"* [Nurse 2, FG2], Some elements of patient safety were perceived to be essentially a by-product of the electronic anaesthetic record, one anaesthetist suggested that *"the bait of good record keeping is an important key to changing the culture"* [Anaesthetist 1, FG1]. They illustrated this by suggesting that a consultant who was supervising trainee anaesthetists working within different theatres could monitor more accurately what had been happening with the patient's condition while they had been away; *"The ability for the consultant to keep track of what has happened when they are away from theatre; I think that is a great incentive…."* [Anaesthetist 1, FG1]. I found that the quality of the anaesthetic record produced by the system was seen, by both participants and observers, as a great incentive to use the system one participant commented that the subsequent anaesthetic record produced was *"an accurate record of what's going on and it's my record"* [Anaesthetist 2, FG4]. The electronic system was also seen to allow the participants more time to concentrate on the patient rather than having to concentrate on recording the physiological variables of the patient on a paper anaesthetic record.

4.4.2.2 Disadvantages

It was noted by observers and participants that there is the potential for the electronic bar-coding system to become a distraction while working through the learning curve. One anaesthetist commented that they found when initially using the electronic system that *"you're concentrating more on the system than on you patient"* [Anaesthetist 2, FG4]. A couple of the observers also noted that during their observations they found that the anaesthetists focus, on occasions, was directed at the system rather than the patient; *"so much attention was being paid to getting the electronic record started and that people were focusing more on that than on the patient"* [Anaesthetist 2, FG2], while another anaesthetist commented that *"there is potential for the system to be a distraction from other matters of patient/anaesthetic care*" [Anaesthetist 1, FG1].

Another disadvantage that consistently emerged from the data was the permissive design of the system, this was acknowledged by one of the participant anaesthetists, *"the system is permissive in that it allows you to do anything you like; some people might view this as a weakness in that it doesn't prohibit you from doing the wrong thing"* [Anaesthetist 3, FG3], they went onto to say that *"If you had bar-coded a drug that said cyanide for example, it would say cyanide and you could carry on"* [Anaesthetist 3, FG3]. A nurse observer, when visiting one of the sites, had heard a comment made by an anaesthetist that they thought the system was too permissive; *"if there was an [medical] alert and the anaesthetist wanted to scan penicillin, it would still allow him to do it"* [Nurse 1, FG2]. The drugs could also be given without having to swipe them through the bar-code reader, or multiple drugs could be scanned prior to administration *"There are ways round the system,*

because you can scan all the drugs for induction and have them sitting on the side, so there's still a potential for picking up the wrong syringe" [anaesthetist2, FG4], thus defeating the object of confirmation at the time of administration. Locating the scanner close to the IV drug administration port could potentially overcome this problem. But as one ODP observer pointed out *"The accuracy of the resulting documentation is totally dependent on the syringe being scanned and the dose that has been administered being entered correctly by hand. There is still room for user error"* [ODP 1, FG1].

4.4.2.3 Practicalities

The induction of anaesthesia in an anaesthetic room has been a traditional feature of anaesthetic practice in the UK since 1860.[21] Before transferring the patient from the anaesthetic room to the operating theatre the 'system' was 'parked', once in the operating theatre the second system was initiated and the patient data retrieved. The unexpected consequence of utilising the system in this way, however, was the ability to retrieve multiple patient records; "*Another theatre can retrieve your anaesthetic record if they are moving their patient from the anaesthetic room to the theatre at the same time as you and they chose the wrong patient*" Consultant Anaesthetist [study team observer 1].

The other practical issues related to initial teething problems that were encountered at both sites related to the physical placement of the system, during one of my observation visits an anaesthetist commented that if the arm holding the system had been sited on the opposite side of the anaesthetic machine it would have made it less of an obstacle, in its present position it was sited too close to the

patient. One of the anaesthetist observers also commented that there were problems with the siting of the bar code scanner; *"One of the issues that I saw was the remoteness of the scanner from the cannula, if it was right by the cannula then you are likely to scan it, but if it's a few feet away you may scan it, you might put it [syringe] down and pick up something else"* [Anaesthetist 2, FG2].

The integration of hospital monitoring devices and IT facilities with the system was also initially problematic. One anaesthetist, who had used the electronic system, commented that *"Occasionally we'll lose data from the monitoring that's going into the servers and it will just stop collecting data"* [Anaesthetist 2, FG4]. On a more practical issue it was necessary to ensure that the bar-code label, when attached to the syringe, was positioned carefully. One of the participating nurses commented that *"Sometimes the scanning of the drugs are a bit tricky or there's a crease in the label….it just takes a few attempts of the scanning so that can be a bit time consuming"* [Nurse 2, FG4].

During another observation visit, problems with the scanner reading the bar-code label were still being reported; *"In this pressured situation, the scanner would not accept the drug; however the consultant anaesthetist did persist and it was accepted. This took an additional 15 seconds"* [Nurse 3 - observations].

An oversight in the set-up meant that some commonly used drugs at one site were not in the database of the system. This meant that these drugs could not be entered into the anaesthetic record and had to be added on by hand once the record had been printed. A lot of the issues, except the system database, were part of the learning curve and became fewer the more familiar the participants became with the system.

4.4.3 Perception of Drug Errors and Cultural Issues

Many participants and observers agreed that drug errors happened in clinical practice, but felt that these errors were not a big problem. There was a perception that anaesthesia is safe, drugs errors are rare and of not much significance, and most of the times one could '*get out of trouble*'. This was the view of all professional groups, not just confined to the anaesthetists. The general consensus appeared to be that drug errors, when they occurred, were '*sanitized.*' As one anaesthetist commented *"we sanitise it [error] and accept it and it really doesn't matter, it happens but it really doesn't matter, and we're all guilty of that and it's overcoming that"* [Anaesthetist 2, FG4]

However, the attitudes to double-checking varied among professionals. In general, nurses thought it was a good idea to confirm drug administration but there were mixed feelings among ODPs over confirmation. The majority of ODPs thought that it was a good idea. One ODP commented that, at the beginning, anaesthetists and ODPs reacted differently to second-person confirmation; anaesthetists *'didn't want to do it'* and there were comments from participants that they'd heard other colleagues referring to double checking as *"Just another hassle for us to take on board"* [Anaesthetist 2, FG4] *or "What are you bothering doing that for? It's just a waste of time"* [ODP 3, FG3]. One of the participants also commented that they felt the second person confirmation made them feel as if their capability was being questioned. The ODPs on the other hand were of the opinion they already checked drugs, therefore there was no difference to their current practice. Several nurses commented that double checking was just a routine part of their job; "*We're all used to double checking anyway. As a nurse its routine, we always double check*

whatever we are giving" [Nurse 2, FG4] and because of this it really was not a problem are far as they were concerned, "*It's not really an issue to double check"* [Nurse 1, FG4]. One ODP observer commented that they felt double checking drugs was very important and felt that *"double checking of drugs should always take place"* [ODP 1, FG1].

Among participants, the views on the practice of second person confirmation ranged from *'it must done'* to *'complete waste of time'*. Some anaesthetists thought there was not enough evidence that drug errors are a problem to warrant this intervention *"There is just one pointless initiative after another – it can distort clinical priorities"* [ODP 1, FG1], while others felt measures to prevent errors should be supported *"Double checking is known to work, so why can't we have a directive to say this is the way it should be done?"* [Study team observer 1], further supported by *"Does everybody have to make a mistake before being convinced?"* [Anaesthetist 1, FG1].

It was highlighted that, in the current climate, theatre efficiency took priority making it difficult to introduce new initiatives that may be perceived to slow down the running of the theatre lists. This was believed to be at the detriment of patient safety by one of the anaesthetists.

It was a clearly emerging theme that the introduction of the confirmation of drug administration during anaesthesia will require cultural change in thinking and practice. This is however will not be straightforward and as one anaesthetist commented *"How do you change a culture though, I'm really not sure, you'd have to prove I think that there really is a reduction in error in some way"* [Anaesthetist 2, FG4].

In order to facilitate it, it will be important to raise awareness regarding drug errors among anaesthetists, ODPs and nurses, and prove that confirmation of drug administration reduces error.

Overall, anaesthetists showed a preference for the electronic system, this seemed to be due to several reasons; it made lesser demands on the change in current anaesthetic practice, it did not rely on the presence of a second person, and it did not break the *'rhythm of the work'*.

4.5 Discussion

This study was designed to explore the feasibility of introducing a method of confirming anaesthetic drug administration, within the existing environment of NHS hospitals, along with the attitudes, experiences and behaviours of the participants. Hence, a qualitative methodology was chosen for the study. Both methods i.e. two-person and the electronic confirmation, were perceived to have the potential to minimise drug errors and enhance patient safety. However, the second-person confirmation was not always feasible due to the availability of the second person at the time of drug administration. In addition, it was perceived to be time-consuming, prone to human manipulations, and met with some resistance from the staff.

Halbesleben and colleagues have suggested that systems designed to reduce error operate by instituting factors that may be seen as 'inefficient, unnecessary, or inconvenient' by the front line workers performing those duties.[230 231] Halbesleben and colleagues go onto to say that in order to precipitate their work and lessen disruptions, healthcare professionals may repeatedly circumvent these functions by

substituting alternative, informally designed, and inconsistently applied work processes, known as workarounds.[230] These workarounds, however, may result in reduced patient care quality and safety. Morath and Turnball [05] describe health care professionals as masters at work-arounds. They suggest the reason is due to so many procedures and processes in the health care delivery system being broken which leads to doctors, nurses and pharmacists seeing work-arounds as the only way to get the job done.[232]

The two person confirmation was more prone to work-arounds than the SAFERsleep™ system; however it was possible for the anaesthetist to administer the drug prior to scanning the barcode and achieving the double check. This violation of the 'rules' of the system would be deemed a work-around.

The electronic confirmation was also independent of the presence of a second person, and was found to be reliable and easy to use. However, it required a period of training for the staff, and overcoming the problems of introducing and installing new technology into the anaesthetic room and operating theatre environment.

Toft[64] has strongly recommended the use of an explicit appropriately configured verbal double checking safety protocol; the expectation is that if one person misses an error the other will detect it. In the present study, two distinct protocols and flow charts for the two-person confirmation were developed. The protocol design, developed by experts in human factors, ensured active engagement of the second person in the process. However, the participants found it difficult to adhere to

these protocols, in particular, in emergencies, and when there was a perceived shortage of time. There was also some reluctance among anaesthetists, which could have been the result of cultural change, as two-person confirmation was more acceptable to nurses and ODPs, who already double check any injectable drug they prepare or give.

Verbal double checking does not always prevent drug errors. This may be due to diffused responsibility, where two people are supposed to be responsible for the same task but in reality neither person is truly responsible, both relying on the other to be rigorous resulting in neither giving the task their full attention.[64 111-113] O'Connell[110] believes the benefits of double checking as opposed to single checking remain undetermined. It is important that some of our participants felt that drug confirmation would prevent errors, but they stressed the need for it to be performed correctly.

The observers noted that due to resource pressures at some sites ODPs often drew up the drugs for induction of anaesthesia all by themselves, which were subsequently administered by the anaesthetists. This is clearly in contradiction to the existing norm of good practice that, in normal circumstances, the anaesthetist should draw up all the drugs that he/she administers or intends to administer during anaesthesia. In addition, the circumstances described by one participant of trying to speed up the process, by simultaneously confirming more than one drug at once, defeats the whole purpose of drug confirmation. This in turn creates a situation where the confirmation becomes futile and involuntary automaticity can

take hold. Toft[5] describes the process of involuntary automaticity as the repeated use of identical checking procedures unintentionally leading to a ritualistic chant of the checklist items. This can then lead to 'the literal meaning of the message being ignored'.[115] It is important to note that this behaviour is not calculated but unconscious. Although the task actually demands careful attention, once under the influence of involuntary automaticity, the check becomes only cursory and the risk of overlooking any errors present is increased.[5] Our data suggests that, in practice, the two-person confirmation will not be achievable unless resource issues such as time and availability of a second person, and the culture in which anaesthetists work, are adequately addressed.

Merry and colleagues[100] designed the SAFERsleep™ system for double checking the drug prior to administration. They suggested the anaesthetists' attention would be regained through listening to the information articulated when the syringe is passed over the bar code reader immediately prior to administering the drug, thus providing a "computerised two person check" which is prompt, definitive and not prone to human susceptibility. In this study, the SAFERsleep™ system was accepted into clinical practice readily at one site, and after few organisational teething problems in the other. The benefit of the anaesthetic record was seen as one of the driving factors in this swift adoption. Compared to the two-person confirmation, the SAFERsleep™ system appeared to be more feasible and less challenging culturally.

Merry and Colleagues[100] found that increased familiarity with the SAFERsleep™ system resulted in greater efficiency of use, particularly during emergencies. From our data, training and education of all members of staff in the use and purpose of the SAFERsleep™ system was of paramount importance in its adoption. Reducing cognitive load is helpful to decision making, and so is the clear display of accurate physiological data; the automated record achieves both of these.[100]

One of the perceived disadvantages of the SAFERsleep™ system was that the anaesthetist could bypass many of its safety features by scanning multiple drugs at the same time. The risk of this could be reduced by locating the scanner close to the IV port. Other technical issues were also raised which included integration with existing technologies and IT within the operating theatre, possibility of technological failure, space utilization and the location of the scanner. These are more logistical issues of integrating new technology into an existing environment rather than the limitations of the system. Of the two methods, all observers preferred the SAFERsleep™ system over two-person confirmation and the participants using the SAFERsleep™ system were positive about its potential to reduce error. However, I would suggest that any system used to confirm drug administration, during anaesthesia, should be capable of overcoming the logistical and technical issues raised in this study for its appropriate utilization in enhancing patient safety.

The introduction of any new technology may have its own hazards which may not have become immediately obvious in this study. A further detailed expert technical

hazard assessment exercise should be conducted with a view to developing recommendations for introducing such a system in the NHS environment.

This data suggests that clinical staff differ in their perception of the significance of drug errors and their attitude towards measures to prevent them. It is therefore important that the introduction of any method of preventing drug errors should be accompanied by a drive towards awareness of drug errors. This may be achieved by active engagement of professionals in reporting, analysis and dissemination of learning from critical incident reporting at local and national level. For any measure of patient safety to be successful, an acceptance by the professionals is essential. This study has uncovered a number of factors, barriers and facilitators, which can determine successful uptake of safety interventions in clinical practice within or even outside anaesthesia. Further studies for in-depth exploration of the cultural issues, some of which are uncovered by the present study, are required for successful implementation and long lasting uptake of safety initiatives in health care systems.

4.6 Limitations

There were a number of limitations with this study. Prior to starting out in assessing the feasibility of introducing a double check methodology into clinical practice, it would have been ideal to have evidence that double checking, whether by second person confirmation or through the use of technology, does actually reduce error. The Expert Consultative Group was aware, however, of an ongoing multi-million dollar study already taking place in New Zealand. They took the decision that it

would not be cost effective to carry out a similar investigation, into the effectiveness of a double checking intervention, in the UK. The Expert Consultative Group were also of the opinion that double checking would reduce drug error and therefore, one of the main limitations of this study was that it was based on opinion and not data.

Another potential limitation of this study was that the sample was one of convenience. Following a safety conference at the RCoA where the call for volunteers was announced, there were several anaesthetists who contacted the RCoA and volunteered to participate in the study. We were lucky enough to have more contacts than we needed and were able to choose the sites to represent a broad spectrum of teaching and district general hospitals across the country. There is the potential for these to represent more safety conscious departments and the results may be limited to the anaesthetists who are motivated in the area of patient safety. However, the findings of the participants were triangulated by using independent multi-professional observers and the reflective diaries. In addition, we included the nursing staff and ODPs from the participating sites in the study to build a more complete picture.

There was a possible limitation with the observation schedule. It probably would have been better termed ‘observation field notes’ as it was an unstructured form of collecting data. I did find, however, that the observations from the independent observers were very similar to my own observations at the same sites, and so I was satisfied that there was consistency in their observations.

The relationship between the researcher and the participants has been recognised as a source of potential bias. In this study this relationship was recognised. To a large extent these influences are unavoidable, however, the researchers tried to minimise these by having a heightened level of awareness, adhering to basic rules of interviewer's behaviour and having more than one methods of collecting data.

This study has produced a considerable amount of data from multiple sources. The issue of the observers causing a Hawthorne effect has been discussed previously (Chapter 2).[208] The introduction of observers did not appear to change the behaviour of any of the anaesthetists or assistants during the process, as the phenomenon of observation is not new in the NHS environment. The risk of different observers placing importance onto different aspects of the process was limited through the use of the observation schedule [Appendix VII], the observers were also encouraged to reflect on what they had observed at the end of the session in order to capture any prejudices or preconceptions they may have that could impact on the data collected. I also aimed to limit the bias through using two independent study team members, one unfamiliar with the anaesthetic environment, to cross check the observations of those more familiar with the setting under observation and these produced correlative accounts. I believe that the data collected were an accurate account of the experiences of the participants, and this was confirmed at the focus groups for those who had participated, and through the reflective diaries. The findings were also similar across all seven sites which support the generalisability of the study. These findings may be transferable

on international scale but this study does have idiosyncrasies that are only typical in the NHS.

4.7 Conclusion

In summary, the introduction of the two person drug confirmation was found to be difficult to achieve at times, due to staff availability and its reliance on time being allocated for the process to take place unhindered. If this check was to be introduced in the NHS a significant impact on the existing working practices of the anaesthetist and issues related to resource and cultural change will need to be addressed for it to be successful. The electronic confirmation, on the other hand, was more feasible as it is not reliant on a second person to be available and is more intuitive to the anaesthetist's current working practice. It allows the anaesthetist to remain as an independent practitioner being able to give the drug when they want to give it and not when a colleague is available to check. For it to be effective, technological aspects of making its integration into the operating theatre environment will require further attention.

This Chapter has presented a feasibility study which was not designed to explore cultural issues. However it soon became apparent that one method was more readily accepted than the other. Despite the SAFERsleep™ system being the more expensive option it seemed to 'culturally fit' with anaesthetist's clinical practice.

There were several remarks during the focus groups that related to cultural issues, but unfortunately I was unable to go into greater detail at that point as that would detract from the main aims of the study. However, the themes were so strong that I felt I needed the opportunity to explore these in greater detail.

This opportunity presented itself through the VASER study. Although it was a simulation based study and not strictly clinical, it did provide me the opportunity to use the SAFERsleep™ system again but with a totally different staff group.

The following study (Chapter 5) explores in greater depth the anaesthetist's and ODP's attitudes and beliefs to the introduction of technology designed to reduce drug error, and the potential impact on the anaesthetist's workload.

CHAPTER 5: VALIDATING ANAESTHESIA SIMULATION-BASED ERROR RESEARCH (THE VASER STUDY).

5.1 Introduction

For a safety measure to be successful, its acceptance by the professionals is essential. This can be achieved by deep understanding of the cultural issues, active engagement of the professionals, and taking into consideration any resource issues that may have positive or negative impact on the implementation. Previous research (Chapter 4) identified that the perception of the significance of drug errors varied amongst anaesthetists, and this may determine their attitude towards measures to prevent them.

Due to the remit of my first study (Chapter 4), I did not have the opportunity to explore deeper the cultural issues and attitudes of anaesthetists and other professional groups towards drug errors and methods of preventing them. However, through integrating my research aims into a larger international study seeking to validate anaesthesia simulation-based error research (VASER), it was possible to explore these cultural issues in more depth.

During 2008 a substantial clinical randomised controlled trial (RCT) of SAFERsleep™ in comparison with conventional methods of drug administration and record keeping in anaesthesia was undertaken at Auckland City Hospital, New Zealand. This provided the opportunity to validate simulation based research in patient safety by repeating the study, with the same hypotheses and outcome measures, in a simulated environment at the simulation centres based in Auckland, Nottingham and Cambridge. A simulation-based research design has been developed by Professor Merry's research team to allow safety initiatives to be tested during reproducible clinical scenarios of standardised complexity.[226] This 'research design' allows an increase in the frequency of error through ensuring that each anaesthetic

scenario is complex. It is also possible to have every anaesthetist care for exactly the same two "patients", and to use the intervention of interest with one and not the other.

The objective of the VASER study was to assess the validity of simulation as a research tool for investigating initiatives to improve anaesthesia safety. In order to achieve this objective the aim was to evaluate the SAFERsleep™ system and the individual principles which underlie it in comparison with conventional methods of anaesthesia in a simulated operating theatre setting.

Over the last decade innovations have been designed to address errors in drug administration and record keeping in anaesthesia. These innovations have been incorporated into a novel system called SAFERsleep™[100] based on lessons from empirical incident reporting, the psychology of human error, and the principles of safe-system design and human factors widely used in other industries. The SAFERsleep™ system is commercially available and is now in regular clinical use within one Trust in the United Kingdom, and has also been used in well over 250,000 anaesthetics worldwide. In addition, the SAFERsleep™ system has been approved by the Food and Drug Administration for use in the United States.[233]

5.2 Aims and Objectives

The aim of my research within this study was to explore the beliefs and attitudes of anaesthetists' and ODPs' taking part in error research, and their views on the introduction of technology designed to reduce errors. Also, as part of the VASER

study I assessed the workload of the participating anaesthetists in order to evaluate whether the SAFERsleep™ system added further workload to the simulated clinical scenarios.

In addition I explored the beliefs and attitudes of anaesthetists' and ODPs' that did not participate in the VASER study in order to further evaluate the cultural effects of drug error within anaesthesia and their subsequent reporting.

5.3 Methods

VASER was a multi-centre, mixed methods study. The study was approved by the Leicestershire, Northamptonshire and Rutland Ethics Committee 2, and had research governance approval from Nottingham University Hospitals NHS Trust. No patients participated in the study; it was purely based within the simulation suite using Hi-fidelity manikins.

Recruitment was through a purposive sample of convenience on the basis of availability; all eligible Consultant anaesthetists, anaesthetic trainees and qualified ODPs within the Specialist Support Directorate of the Nottingham University Hospitals NHS Trust, were invited by letter and/or verbally by one of the researchers to participate.

Written informed consent to take part in the study was obtained from all participants prior to participating. As discussed previously (Chapter 2), participants were informed that all information collected during the course of the research would be kept strictly confidential and that they could withdraw from the study at any point.

5.3.1 Study Design

Study participants participated in the study for one morning (08.00-12.45) or one afternoon (12.15 – 17.00) at the TSCSC during which time both simulated study scenarios were completed. For each simulation there were two possible states: Intervention (in which the SAFERsleep™ system was used) and Control (using conventional methods). These states were allocated randomly between the two scenarios with stratification for time of day (morning or afternoon). The randomisation for the whole study was performed by the University of Auckland research team from which the randomisation sequence for the participants to be recruited in Nottingham was derived. This trial was open label as blinding was impossible in this context.

All participants were provided with pre-reading material and were orientated to the equipment and the environment. Briefing was used to reinforce-specified key points related to the use of the SAFERsleep™ system, simulation, details of the study, format of the study day and the tests used.

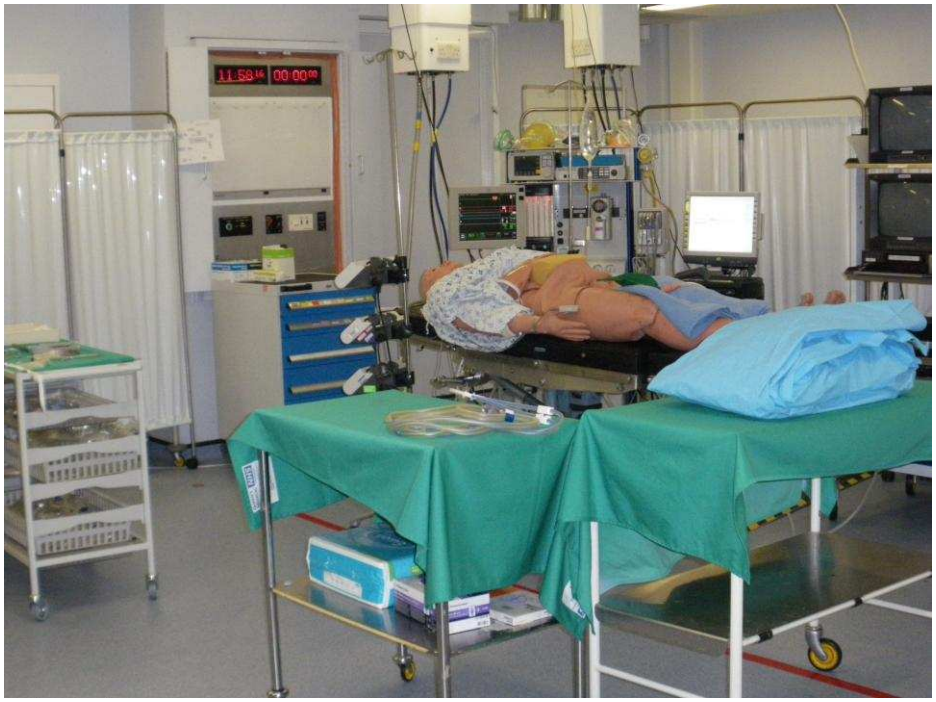


Figure 11 Simulated theatre set up for the introductory VASER scenario

An introductory simulation scenario was initially completed by both the participating anaesthetist and ODP together allowing familiarisation to the simulation environment. An educational debrief with the participating anaesthetist and ODP followed this scenario, which allowed for individual reflection and feedback on practice and behaviours observed during the simulation and on the optimal use of the SAFERsleep™ system.

Scenario 1 (Orientation Scenario)	Scenario 2	Scenario 3
70 year old, male, generally well patient for elective Laparoscopic +/open anterior mesh rectopexy. First case on elective list, routine elective ASA 2 **Assessment:** Generally well, history of depression on citalopram, occasional 'missed beat', never caused a problem, no allergies, no reflux, no previous anaesthetics. **Scenario Summary:** Induction: brief post-induction hypotension with BP down to 80/35, pulse 45. Followed by period of stability with BP around 120/80, period of stability Minor event: Hypertension OR hypotension ➢ Hypertension following trocar insertion to 210/110, pulse 70. Resolves after 5 minutes (with or without treatment. **OR** ➢ Hypotension following trocar insertion. Falls progressively to 80/50 over 5 minutes, stays there (unless treated) for 5 more minutes. Resolution and Blood pressure, second period of stability, handover to another anaesthetist who doesn't know patient. Participant told about the acute case and they need to go and see them.	76year old male, admitted to the medical ward yesterday with abdominal pain and has deteriorated significantly in the past 6 hours. **Assessment:** Has had previous abdominal surgery and is thought to have adhesions. He has a history of mild dementia, COPD, ex-smoker, and possible previous MI 3 years ago. He is normally on a beta blocker and aspirin, he is slightly confused and there is some suggestion of heavy alcohol intake. **Scenario Summary:** Acute case for laparotomy with query small bowel obstruction and dead gut **Induction**: brief post-induction hypotension which stabilizes with appropriate treatment – any reasonable treatment **Incision**: period of hypertension, followed by reperfusion hypotension and atrial fibrillation. Intra-op ABG will have glucose of 13, becomes acidotic, K rises to 4.1. Will need significant inotropic support. Initially questionable bowel, but looks viable so rapid progression to closure. **Emergence and Extubation**: no ventilated bed available.	49 year old male, acute vascular case following complications from abdominal surgery the previous day. **Assessment:** Usually well, history of recurrent terratoma treated with chemotherapy and surgery. Usually normal renal function, now rising creatinine. Now has compartment syndrome in his right leg. **Scenario Summary:** This patient is hyperkalaemic, recently transfused (K^+ 5.9 mmol, Hb 12.3 on ABG). Arterial line and central line *in situ*. Heparin infusion running at 10.6ml/hr via Central line. Will run out in 30 min after briefing. **Induction**: Post-induction hypotension stabilizes with any reasonable treatment. At incision there is hypertension, followed by reperfusion hypotension requiring further vasopressor support. ABG and ECG will show hyperkalaemia and acidosis and there is myoglobinuria with risk of acute renal failure. Oliguria. Surgeon requests mannitol. Surgery is rapid **Emergence and Extubation:** extubation with transfer to PACU and HDU is planned.

Table 4: Scenarios Script for Study

Time Line	VASER Study	VASER Simulation Scenarios	Interviews	Error Questionnaires	Analysis
Sept 2009	VASER pre-study briefing for 4 anaesthetists	8 Participants completed scenarios		6 Error Questionnaires completed	
Nov 2009					Finalisation of interview questions
Dec 2009	VASER pre-study briefing for 6 anaesthetists		1 Interview completed		
Jan 2010		12 Participants completed scenarios	2 Interviews completed	11 Error Questionnaires completed	Interviews transcribed
Feb 2010			1 Interview completed 1st Focus Group completed		Interview transcribed Analysis of Interview transcripts Finalisation of focus group questions
March-April 2010					Focus Group transcribed. Analysis of Focus Group data highlighting need for 2nd focus group
June 2010					Analysis of Borg Workload Scores Analysis of Error Questionnaires highlighting need for more questionnaires to be completed
July-Aug 2010				20 Error Questionnaires completed	
Sept 2010			2nd Focus Group completed		2nd Focus Group Transcribed
Oct 2010					Analysis of Focus Group data

Table 5: Study Time Line VASER Study

5.3.2 Data Collection

During the simulated anaesthetics I observed and recorded key times in the anaesthetics, as well as an inventory of all relevant disposable items (including drugs) used during the anaesthetics, directly into a laptop computer using specialist task analysis software developed for the original clinical study. Purpose designed sharps containers and video-recording was also utilised.

As part of the VASER study objectives, errors were recorded using a predefined list, identical to the clinical study in Auckland, New Zealand. Drug related errors included (but not be limited to) omissions, swaps, wrong doses, wrong routes double administrations, errors in the technique of drug drawing-up and administration. Errors in drug administration recording were also included. The anaesthetists completed a form to record self-reported errors at the end of each anaesthetic, before the debriefing.

Established measurement tools, which have been previously validated in clinical anaesthetic practice as well as in the clinical study in Auckland, New Zealand, were also utilised. The Vigilance Latency Task (VLT), the Borg Workload Scale (BWS) and the NASA Task Load Index (NASA-TLX) were all utilised in the main VASER study. I used only the Borg Workload Scale within my study and this is described in greater detail in Chapter 2.

The VLT and BWS are minimally invasive measures. The VLT involved acknowledging the illumination of a small, bright light on the anaesthetic machine at 9 to 14 minute random intervals; this was devised to provide an index of an anaesthetist's vigilance and spare work capacity. In this study a Personal Digital Assistant (PDA)

with a touch screen was used, and the response involved touching the device's screen.

At 7 to 15 minute random intervals, I measured the psychological workload of the anaesthetist with the BWS and the anaesthetists then self-reported their workload score. This involved me asking the anaesthetist to verbally rate their BWS at that particular time point, I also scored what I believed the BWS of the anaesthetist to be at that time. Only the Participating anaesthetist, and not the ODP, was asked to complete these tasks.

At the end of the procedure, as part of the main VASER study, both the anaesthetist and the ODP completed the NASA-TLX, and used visual analogue scales (VAS) to rate the physical and mental demands of the previous anaesthetic and specific components of the new system and comparable conventional alternatives. Methods of identifying drug administration error developed and refined in previous research by the Auckland team were also used. A modified sharps container allowed positive identification of all used ampoules; this method was supplemented with techniques of inventory reconciliation of drugs in the drug drawer before and after the procedures.

As part of my research aim participants were also invited to complete an error questionnaire and participate in a semi-structured interview or a focus group.

5.3.2.1 Error Questionnaire

The error questionnaire [Appendix XVII, XVIII] was designed to allow me to gain a baseline understanding of both anaesthetists' and ODPs' views on the occurrence of drug error in anaesthesia and their subsequent reporting as well as previous use of technology in drug error prevention and record keeping. A five point Likert scale was used in order to measure intensity of feelings about these points. Each respondent was asked to indicate his or her level of agreement with the statement, one on the scale corresponded to 'strongly disagree' and five corresponded to 'strongly agree'. The replies for each item were collated and grouped into 3 categories; strongly agree and agree was termed a positive response, strongly disagree and disagree was termed as a negative response and finally neither agree or disagree was termed a neutral response. The results are presented grouped as anaesthetists and ODPs.

Prior to being used within my study I piloted the questionnaire on a small group of anaesthetists and ODPs to ensure it would function effectively. There are a number of reasons why I chose to pilot the questionnaire; to test how long it would take to complete, to check that the questions were not ambiguous and to check that the instructions were clear.

5.3.3 Semi-structured Interviews

At least four weeks after the completion of the scenarios participants were invited to participate in semi-structured interviews (Chapter 2). A digital audio recorder was used to continuously tape all the discussions. All interview tapes were transcribed within 5-7 days of the interviews. The completeness of each transcript

was checked against the original audio file and the transcripts amended where possible. All transcripts were imported into NVivo 8, a qualitative data analysis package (QSR International Ltd, Melbourne, Australia), these were then analysed using the grounded theory approach (Chapter 2). The emerging themes were then used to construct the focus group questions.

5.3.4 Focus Group

At the end of the study period participants were invited to take part in a focus group (Chapter 2). Both focus groups were conducted within the University Division of Anaesthesia and lasted approximately one hour. I ran the focus Groups with the help of another member of the research team; one of us acted as moderator, while the other took written notes. A digital audio recorder was used to tape all the discussions.

A focus group schedule was utilised to start the discussions. The questions within the schedule for the first focus group [Appendix IV] were generated by the initial analysis of the transcripts from the semi-structured interviews; the questions for the second focus group [Appendix V] were generated from the themes that emerged within the first focus group.

The audio tapes were transcribed within 5-7 days of holding each focus group. The typed transcripts were read, and checked against the audio recordings for completeness and accuracy. Again the transcripts were analysed using a grounded theory approach (Chapter 2).

The findings are illustrated with appropriate, anonymised quotations in the subsequent results section

5.4 Analysis

5.4.1 Qualitative Analysis

The main categories that emerged from the interview and focus group data were *Drug error in anaesthesia* with sub-categories: the occurrence and causes of error, vigilance of the individual involved and the level of risk at an individual level and within the environment; the *SAFERsleep™ system* with sub categories being advantages and disadvantages; *Reporting of drug error* with sub-categories being reluctance to report, recriminations of reporting and feedback; and finally C*ulture* with subcategories of culture and system. Following analysis of the initial focus group using a grounded theory approach it was deemed necessary to further explore the emerging themes to achieve theoretical saturation. In order to achieve this, a further three anaesthetists and one ODP participated in a second focus group.

5.4.2 Error Questionnaire Analysis

The error questionnaires were analysed question by question. The 'strongly agree' and 'agree' responses were termed positive and grouped together under this title, as were the 'strongly disagree' and 'disagree' responses termed negative responses, the 'neither disagree or agree' response was termed neutral. For every question percentages were calculated for each composite and presented in bar graphs.

5.4.3 Borg Workload Analysis

The subjective workload data of the anaesthetists were divided into two groups; either using conventional methods during the simulation or using the SAFERsleep™

system during the simulation. The highest, mean & lowest workload scores were calculated, and these were subsequently compared using Wilcoxon signed rank test.

5.5 Results

Ten Anaesthetists paired with ten qualified ODPs completed two standardised highly scripted simulated anaesthetic scenarios. One scenario was with the SAFERsleep™ system and one using methods currently used in clinical practice within the Trust.

The length of the scenarios ranged from 45 minutes to 1hr and 25 minutes depending how the anaesthetist reacted to the different challenges within the scenarios. From this an average of 10 Borg workload scores were recorded from each anaesthetist across both scenarios.

20 anaesthetists and 17 ODPs completed the error questionnaire. Four anaesthetists and one ODP participated in a semi-structured interview, two anaesthetists and three ODPs participated in the first focus group and three anaesthetists and one ODP participated in the second focus group.

The results for the Error questionnaire, Qualitative analysis and the Borg Workload scores are presented separately.

5.5.1 Error Questionnaire

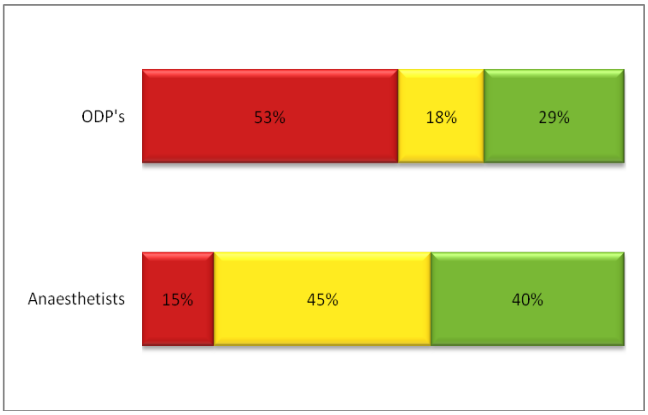
20 anaesthetists and 17 ODPs completed the error questionnaire [Appendix XVII, XVIII]. The questionnaire comprised of a total of 12 questions focusing on incidence of error in anaesthesia, reporting error and the use of technology in error prevention. The results were split into professional groups and then further subdivided into those anaesthetists and ODPs that had participated in the VASER study and those who had not. The graphs are presented below.

Key to Charts

Negative response Neutral response Positive response

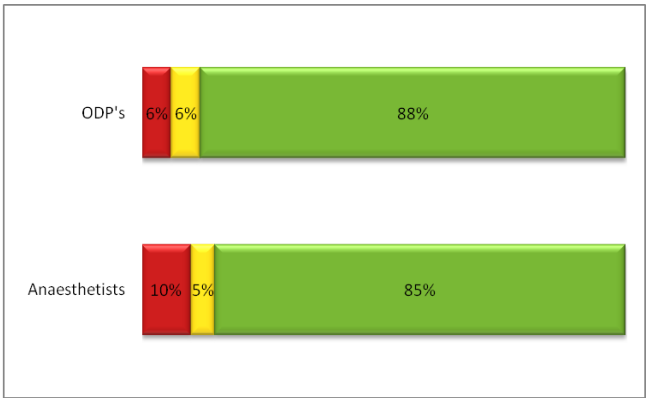
5.5.1.1 Error in anaesthesia

Question 1: Drug errors are common in anaesthesia



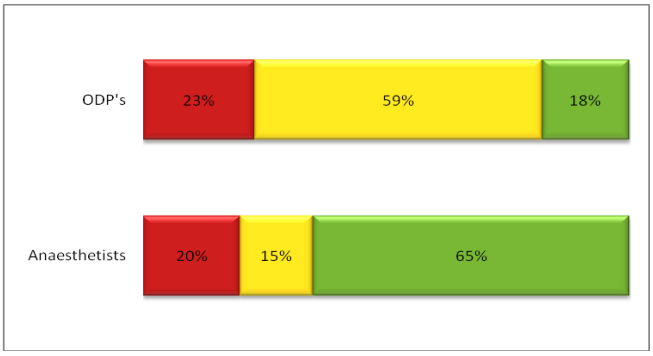
53% of ODPs thought that drug errors were not a problem in anaesthesia compared to only 15% of anaesthetists. These views conflict with those of the focus group and interview participants [see later] who believed drug errors were a problem within anaesthesia, suggesting the anonymity of the questionnaire may present a more accurate view of the beliefs around drugs errors within anaesthesia.

Question 2: Drug errors can cause significant harm in anaesthesia



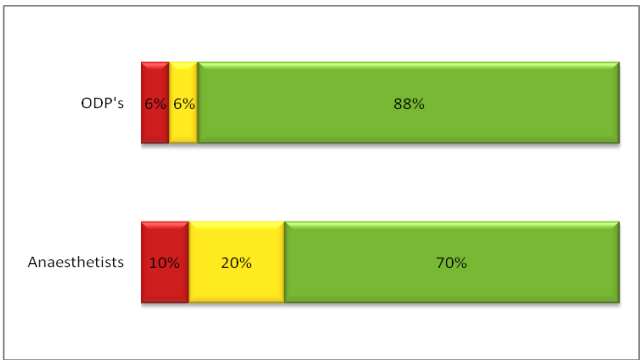
The majority of anaesthetists and ODPs believed that drug errors do cause significant harm in anaesthesia, on further analysis of the data I found that the anaesthetists and ODPs that disagreed with this statement were those who had participated in the VASER study.

Question 5: My thoughts or actions are commonly influenced by the risk of medication error during my anaesthetic practice



The majority of anaesthetist that agreed with this statement had not participated in the VASER study. The neutral response from the OPD's might be due to the wording of the question rather than a general indifference towards drug error, due to it specifically stating anaesthetic practice.

Question 11: Whenever feasible, all drugs for parental administration should be supplied in pre-labelled and pre-filled syringes

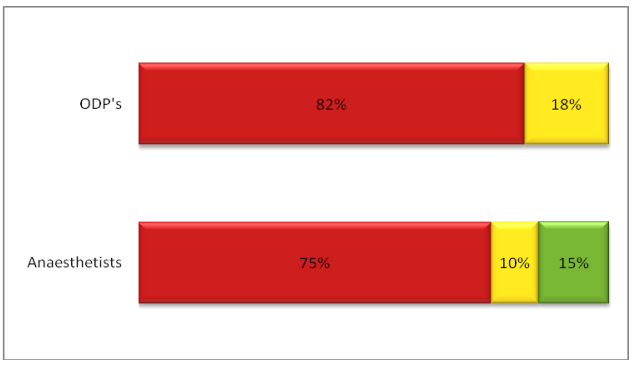


There was a high level agreement across both professional groups with this statement. On closer examination of the data the anaesthetists that had not participated in the VASER study, which utilised pre-filled syringes as part of the SAFERsleep™ system, were less in favour of using pre-filled syringes than those who had participated.

Professional Group	Negative response	Neutral response	Positive response
ODPs who didn't participate in VASER	10%	0%	90%
ODPs who did participate in VASER	0%	14%	86%
Anaesthetists who didn't participate in VASER	20%	20%	60%
Anaesthetists who did participate in VASER	0%	20%	80%

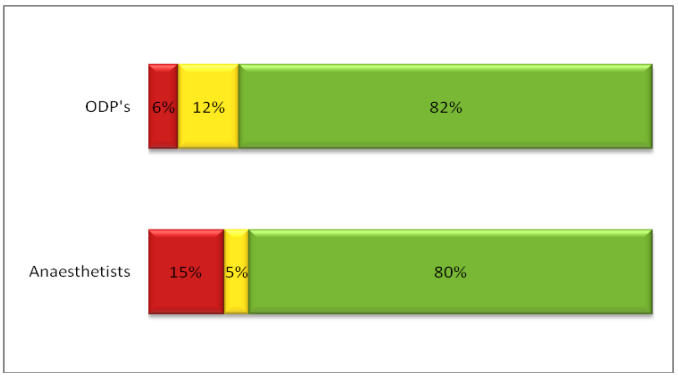
5.5.1.2 Reporting error in anaesthesia

Question 3: Drug errors that are caught and corrected do not need to be reported



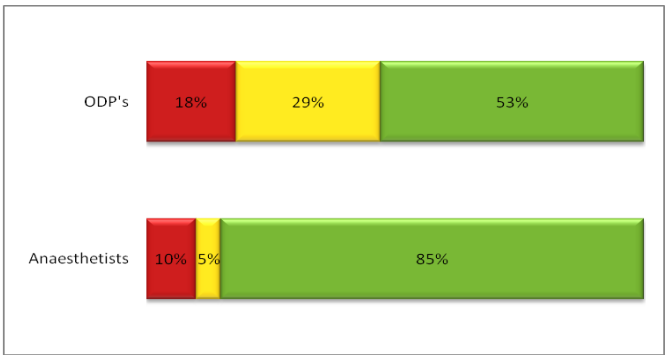
There was a high level of disagreement with this statement across both groups, the level of agreement within the anaesthetist group was similar for those that had and had not participated in the VASER study.

Question 4: Failing to record a drug given during an anaesthetic is a medication error



The level of agreement to this statement again does not match the data emerging from the interviews or focus groups.

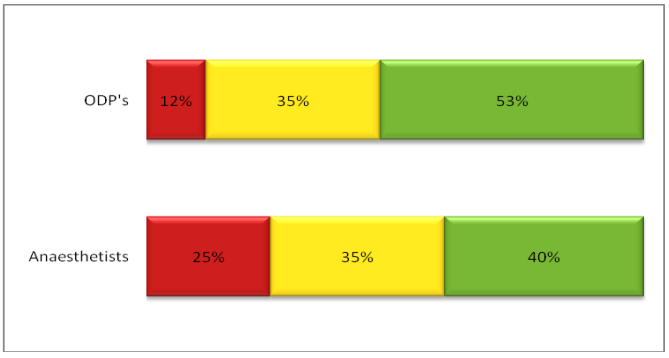
Question 6: Inadvertent administration or failure to administer medication, that has no immediate potential to harm the patient, should be recorded as an error



There was 100% agreement to this statement by the anaesthetists that had participated in the VASER study compared to 42% of anaesthetist that did not participate.

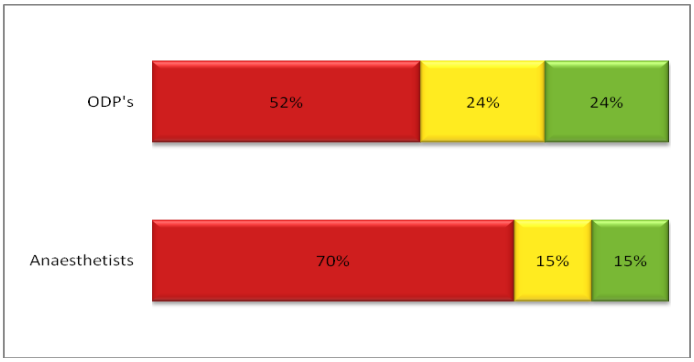
5.5.1.3 Technology

Question 7: Anaesthetic records should be computerised



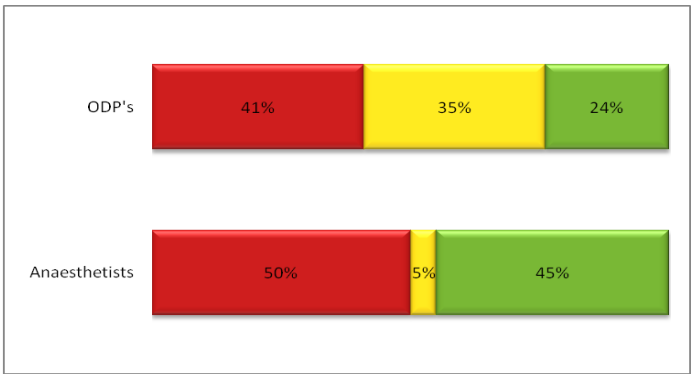
Overall there was not an overwhelming support for computerising anaesthetic records across either profession. On closer examination of the data the agreement between those that had participated in the VASER study, in both professional groups, compared to those who did not was also very similar.

Question 8: New technology will prevent drug errors in anaesthetic practice



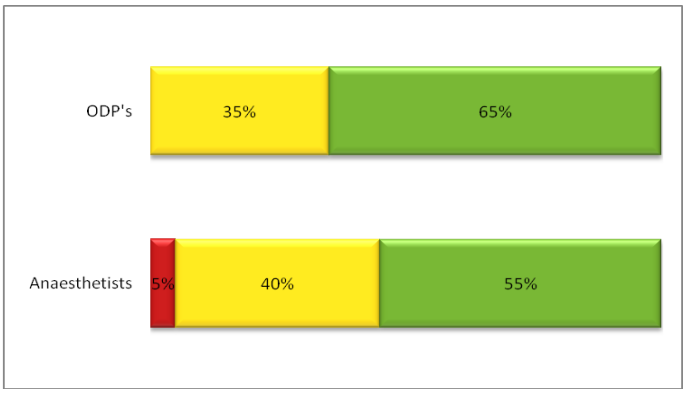
Within the VASER study there was always the potential for the more technology minded anaesthetists and ODPs to volunteer to participate rather than those who were not. However the level of disagreement to this statement would suggest that this was not the case. On closer breakdown of the data, although more of the anaesthetists that did not participate in the VASER study disagreed with this statement, there were still over half of the anaesthetists who had participated in the study who believed new technology would not prevent drug errors.

Question 9: I have previously used computerised record keeping in anaesthesia



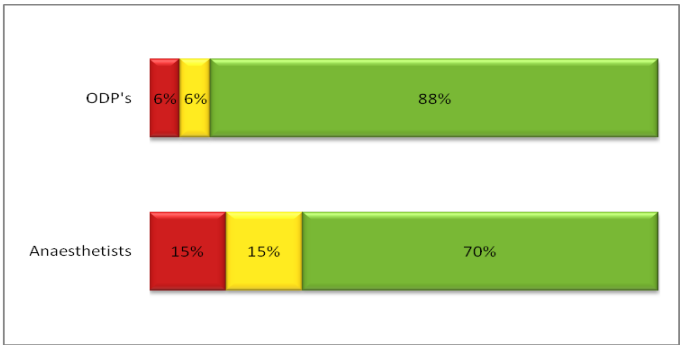
There was a similar distribution across both professional groups for previously using technology and this was also reflected in the participants and non participants of the VASER study.

Question 10: The introduction of new technology will have a positive impact on my future anaesthetic practice



Slightly more ODPs agreed with this statement than anaesthetists, with 86% of ODPs that had participated in the VASER study agreeing compared to 50% of ODPs that did not participate.

Question 12: I would welcome the addition of new technology in anaesthetic practice which is designed to reduce the chance of medication errors



While all of the anaesthetists that did not participate in the VASER study agreed with this statement only 40% of those participated in the study did. The level of agreement within the ODP groups were comparable, however the level of disagreement was confined to those ODPs who had participated in the VASER study.

5.5.2 Qualitative Results

5.5.2.1 Drug Error in Anaesthesia

Occurrence of Drug Error

There was general consensus among both professional groups that drug errors do happen within anaesthesia, "*I think without a doubt drug errors do happen, we know that right the way across hospitals, as anaesthetists we are going to be no different*" [Anaesthetist 5, Interview], this theme was consistent with the perception of error theme found in my previous research (Chapter 4).

There was the overall perception that errors were quite common, one of the anaesthetists suggested that anaesthetists were probably more prone to making errors due to the relatively high number of injectable drugs given in a short space of time. There was also, however, the perception that drug errors were also under recognised and under reported, *"I think they're quite common and they're probably under recognised as well as under reported"* [Anaesthetist 10, Interview], *"Errors that go unnoticed or without incident I'm sure they're not reported"* [Anaesthetist 03, Interview].

Emerging from the data was a very powerful theme that I have termed 'error proximity'. To explain this in more detail, the closer the wrong drug came to being administered to the patient the more serious the error was deemed to be by the participants. If the error was picked up when the drug was not in immediate danger of being administered it was not considered an 'error' or even a 'near miss' "*If you notice the mistake and throw the syringe away before it gets anywhere near a patient then that is not a near miss*" [Anaesthetist 2, FG1]. However the closer to the patient, in actual distance, the incorrect drug came to being administered the

more likely it was seen as a near miss or an actual error and subsequently reported *"It comes down to how close you are to committing the error as to whether it should be reported"* [Anaesthetist 2, FG1].

Within the focus groups and the interviews we had no one that believed drug errors did not occur within anaesthesia, however as previously shown this is contrary to the error questionnaire results.

Causes of Drug Error

There was a general consensus amongst the participants that they believed time pressure was a significant cause of error in anaesthetic practice. The pressure to keep the theatre lists running was a significant cause of concern; one participant described one theatre list where they were left little or no preparation time, *"I was thinking of time pressure such as a busy elective list, rushing to keep up, you've got patients coming in when you're just getting the other patient out, you know you're going to overrun and they're still being sent for"* [Anaesthetist 2, FG1]. The strains currently being put on teams was also put forward as a cause for error *"time pressures, such as a stretched team not able to unwind mentally in between cases"* [Anaesthetist 1, FG1].

Another potential cause of error emerging from the discussions was lack of familiarity or experience. Drawing up infusions that were not commonly used within theatre was highlighted as a potential source of error, *"Lack of familiarity isn't it because you don't do it very often"* [Anaesthetist 1, FG2].

Error were perceived as more preventable the more experienced the anaesthetist or ODP was, one anaesthetist suggested that *"a lot of people prevent near misses from becoming incidents, it's just actually experience"* [Anaesthetist 1, FG2] while another anaesthetist commented that with greater experience the anaesthetist would be more likely to have the *"necessary skills to deal with or mitigate the effects of that error"* [Anaesthetist 2, FG2].

Finally, the point was put forward that similarity of drug packaging or ampoules could be a further source for error, *"boxes look very similar don't they, one box of something looks very similar to another box of something or the ampoules change and look very similar"* [Anaesthetist 1, FG2], *"we have confusions that drugs look the same, boxes look the same"* [Anaesthetist 2, FG2].

5.5.2.2 The SAFERsleep™ system

Advantages

One of the main benefits of the SAFERsleep™ system was the design of the whole package. Participants remarked on the advantages of using the specifically designed drug trays, the pre-filled drugs and their storage in purposely designed drawer units; *"the plastic trays were brilliant, kept everything very tidy"* [ODP2, FG1]

The belief was that pre-filled drugs removed the possibility of drawing up the wrong drug in the first place, *"I think the more pre-filled syringes we can have the better, cause that will stop me making those errors beforehand…that's an error that's quite likely to happen, particularly in emergencies or with high turnover"* [Anaesthetist 10, Interview]; one of the main causes of drug error sited in the literature. The use

of prefilled syringes was also perceived as time saving, *"I don't hide the fact that I'm a very big fan of pre-filled, um pre-prepared syringes because it's very likely to reduce errors and it certainly does save time"* [Anaesthetist 2, FG1]. In fact the whole system was seen as allowing more time to be spent with the patient, this seemed in part to be related to the automation of the anaesthetic record, *"I thought the electronic one was very accurate, timely and um it took us off to do other things rather than focus on putting down different parameters, so I thought it was a very useful from that point of view"* [Anaesthetist 2, FG1].

Several ODPs commented that they liked the audible feature of the SAFERsleep™ system; the name of the drug was articulated as the drug was passed over the bar-code scanner. From their point of view it improved their working relationship with the anaesthetist *"If you can hear things being given then it brings you closer to the anaesthetist"* [ODP 3, FG1]. One ODP illustrated this by describing a situation where an anaesthetist had been giving lots of drugs in quick succession, but not telling the ODP what was going on. They said they had felt like a spectator, however with the SAFERsleep™ system they felt it was possible to gain a greater insight into the patient's condition by the type of drugs being scanned.

There were a couple of themes from my first study (Chapter 4) that were also evident in this analysis. Firstly that the anaesthetists found it more acceptable to use SAFERsleep™ system when double checking drugs than having to find a second person to check "*I think it's a better system than having everything double checked"* [Anaesthetist 2, FG1]. Secondly, although the anaesthetists believed the SAFERsleep™ system would not eliminate drug errors completely, it would go some

way to reducing the incidence of drug error in anaesthesia; *"Using a system like VASER would reduce the possibility for drug error but it wouldn't altogether disappear"* [Anaesthetist 1, FG1] another anaesthetist commented that *"It's not that that system gets you out of that problem, because it doesn't. But I think it's more accurate*" [Anaesthetist 10, Interview].

Disadvantages

Due to the nature of the study, there was a steep learning curve for both the anaesthetists and ODPs to master in a short space of time. The nature of the hi-fidelity scenarios and the introduction of the SAFERsleep™ system were at times described as demanding *"I'd like to see it work in a less stressful environment, so it's assisting me rather than distracting me"* [Anaesthetist 3, Interview]. This led the SAFERsleep™ system to be described as more of a distraction than a help at times. One anaesthetist commented "*I was feeling quite overloaded just mentally"* [Anaesthetist 5, Interview], due to having to take in a lot of new information quickly.

Another barrier discussed was that in order for the system to act as a double check of the drugs it is necessary to scan the syringe prior to administration. Several anaesthetists commented that this felt unnatural but was something they believed would change over time with familiarity of use. The interface of the system also caused concerns. The SAFERsleep™ system did on several occasions double swipe the drug; this meant that two entries for one drug administration were inputted onto the anaesthetic record *"Having to scan the events and use codes for*

everything else was a nightmare as it kept scanning the same thing over and over again for lines" [Anaesthetist 2, FG1]. This subsequently meant the anaesthetic record had to be edited to show accurate drug administration. It was an obvious source of frustration; several anaesthetists' commented that because it happened so frequently, it was becoming an irritating distraction, *"I'm sure the sort of user interface would improve; again that was the main source of my frustration"* [Anaesthetist 3, Interview], moving on from this there were comments made about the accuracy of the subsequent anaesthetic record within both focus groups. One participating anaesthetist commented that "*I Found it sometimes did double swipe and I wasn't sure if it picked up the drug every time*" [Anaesthetist 1, FG1], whereas a concern raised in the second focus group was the potential requirement to continuously annotate the chart *"So it would potentially create more work for us in that we would perhaps annotate the electronic record to explain the fact that being artefact"* [Anaesthetist 2, FG2], as well as the belief that the electronic record would not be a truthful reflection of the patients physiological monitoring *"I would still want to make sure that what was happening in reality was being reflected truthfully on the anaesthetic chart"* [Anaesthetist 1, FG2].

5.5.2.3 Reporting of Drug Errors in Anaesthesia

One of the major overarching themes emerging from my analysis was the reluctance to report drug errors using the national critical incident reporting system. I was actually quite surprised by the underlying strength of feeling. I have sub divided this theme into the following categories; reluctance to report, recriminations of reporting and feedback.

Reluctance to report

There was a palpable reluctance to use the current reporting system within both professional groups. This reluctance however was not apparent in the error questionnaire results, where there was a strong belief that drug errors should be reported, even when those errors are caught and corrected, or presented no immediate harm to the patient.

The general consensus for this reluctance, within the focus group discussions, was due to the distinct lack of feedback when incidents are reported and the lost opportunity to learn.

Several participants thought that people should be allowed to make one mistake before being reported *"everyone should be allowed to make one mistake"* [Anaesthetist 1, FG1], *"If it's the first time it is a mistake, if it's a second mistake it's probably a pattern"* [ODP2, FG1] but the subsequent debate on how anyone would know when or whether this was a first mistake did not produce any concrete resolutions.

Several participants also believed that if a mistake was noticed before reaching the patient it did not need to be reported, again coming back to the theme 'error proximity', *"if it was a near miss then no, it doesn't need to be reported"* [ODP2, FG1], however there did seem to be a feeling of slight confusion over what was a reportable incident, as one anaesthetist commented *"it's difficult to know when to report"* [Anaesthetist 1, FG2].

There was also strong support for a more informal approach to error management; one ODP stated *"I think if I felt something could be discussed and dealt with, with the individual concerned then it doesn't need to be reported further"* [ODP2, FG1], while another ODP said *"if I saw one I would flag it up with the anaesthetist but I wouldn't report it"* [ODP1, FG1]. Only if the individual showed no sign of recognition or remorse would they go on to report it *"it's down to the reaction of the individual, how they respond to it"* [ODP2, FG1].

In a similar finding to my previous study (Chapter 4), several participants thought that drug errors within anaesthesia did not cause significant patient harm; *"a lot of the times there will be no adverse effect to the patient"* [Anaesthetist 5, Interview], *"I've had drug errors that I thought were insignificant and I didn't report them*" [Anaesthetist 2, Interview]; this could possibly be one explanation for the reluctance in incident reporting.

The perception of the severity of the error, in the view of the anaesthetist or ODP, appeared to be the deciding factor as to whether the error was reportable or not. There was a general consensus that every little error did not need to be reported and if an untoward event was justifiable as part of the anaesthetic this also would not be reported.

Several participants thought that it was appropriate to report an incident if there was a lack of insight shown by the person making the error. If, though the error was

acknowledged or there was remorse shown by the individual, this was a significant response and the error was seen as being adequately dealt with.

Another participant did believe that they thought reporting at a local level was more acceptable than to an outside department; *"at a departmental or local level would be ok rather than sending it off to an office far away to be told off"* [Anaesthetist 1, FG1].

Recriminations

The perceived punitive response to error seems to be deep seated and quite evident in all of the discussions. Several participants thought that the reporting process was not constructive but was used as tool to punish those who made mistakes. One anaesthetist commented that the lack of reporting might be down to *"not wanting to be suspended or hauled in front of the clinical director or you know, have your practice challenged and that sort of thing so…self preservation perhaps"* [Anaesthetist 3, FG2] , *"they are tarnished with the error if incident reports are used"* [ODP2, FG1] while an ODP suggested that they were *"slightly dubious about reporting as feels like being taken into a box and beaten and it's not a constructive process"* [ODP3, FG1]. Another ODP discussed the negative experience they had been subjected to when they had previously reported errors, "*I have been twice interrogated over why I have reported someone"* [ODP 3, FG1]. This was also evident when the system was the cause of the fault.

The impression was that reporting would improve if there was a more discernable electronic method of recording and reporting the information *"there have been a few changes in the last three or four years, people have lost track of where and*

when to report but once that becomes filtered into one recognisable electronic method of recording I think it will improve" [Anaesthetist 5, Interview].

Feedback

The widely held view seemed to be that once incidents were reported the information was not utilised any further and there was little feedback, one anaesthetist commented that *"I think it's quite lacking, we don't get enough feedback about what's happened"* [Anaesthetist 3, FG2].

There were several comments from participants that they had not received feedback following the submission of a critical incident form; one anaesthetist commented that they've *"filled out a form and nothing's happened"* [Anaesthetist 2, FG2] while another stated that *"You send it off and it disappears"* [Anaesthetist 3, FG2], this appeared to be a consistent theme across both professional groups as an ODP also commented *"I've not had any feedback from any forms I've put in"* [ODP1, FG2]. One anaesthetist went as far as to say that "*if you used the critical incident system then the individual concerned wouldn't get any feedback"* [Anaesthetist 1, FG1].

One anaesthetist suggested that the lack of feedback impacted on the use of the reporting system *"I think things are underreported because people see limited feedback from the reports"* [Anaesthetist 10, Interview]. There was also the belief that this led to a lost opportunity for teaching and learning *"Is it going to be used to debrief the individual and be used for teaching or is it just going to be reported and*

not used further?" [ODP2, FG1] as one anaesthetist pointed out a reporting system should be used for *"Prevention and education, the idea is that someone else doesn't make the same mistake and protect future patients"* [Anaesthetist 2, FG2].

5.5.2.4 Culture

The theme of 'safety culture' was evident within my previous study (Chapter 4) and this was explored further here. Despite the increased attention on safety culture over the last decade, and the need to recognise the part the system plays in the origin of error, there still seems to be a person-centred approach to why the error occurred. Several participants believed they worked within a strong blame culture and one anaesthetist's comment in response to this was *"I don't know maybe a bit of cultural change of please"* [Anaesthetist 3, FG2]. Another prominent theme was that the organisation should take more responsibility to prevent errors occurring, one anaesthetist suggested that *"In any high risk organisation you design the system to protect"* [Anaesthetist 2, FG2] they went onto say that this wasn't happening and that one of the failures of the organisation in preventing errors was that it was *"relying on individuals to maintain vigilance"* [Anaesthetist 2, FG2].

There was a concern raised by a couple of the participants that the reporting system was used inappropriately due to the intrinsic blame culture of the organisation. One anaesthetist suggested that *"we have to be cautious though that we don't turn people into vigilantes reporting every possible error or near miss as it becomes a pointless exercise"* [Anaesthetist 1, FG1] while another suggested this already happened to some extent *"there's an awful lot of incidents or reporting that*

probably isn't actually true near misses or incidences, more of a way for staff to highlight other concerns or grievances against individuals" [Anaesthetist 2, FG2] the worry of this was that it had the effect of diluting the important messages that could be learnt from the true incidents or errors.

5.5.3 Borg Workload Scores

Workload scores were measured for 10 anaesthetists. An average of five workload scores were collected per scenario. Table 4 shows the highest, mean and lowest Borg workload scores recorded. The anaesthetists' self rated scores were compared against the observer scores. Apart from the highest score results (*P* - 0.005), we could find no difference between the anaesthetist and the observer ratings.

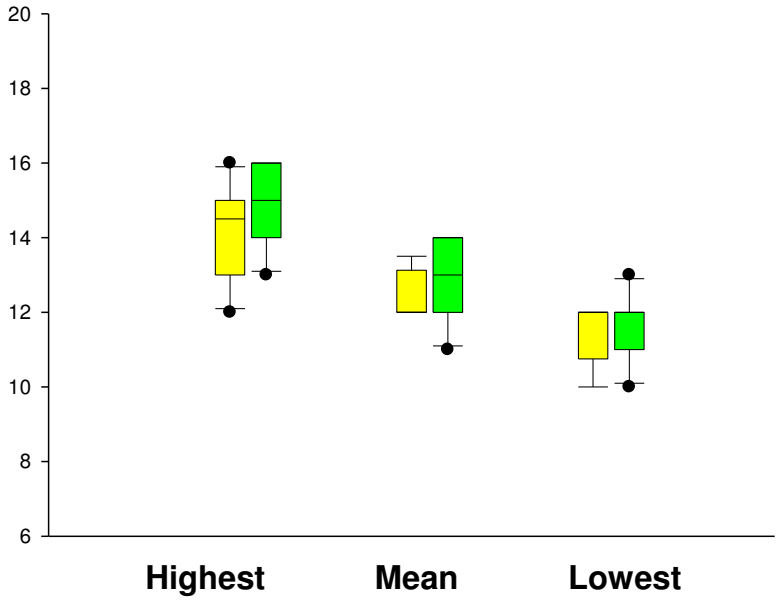
Table 6: Borg Workload Scores

Data are presented as Median [IQR] *P - 0.005

Borg Workload Scores	Using SAFERsleep™ System		Using Conventional Methods	
	Anaesthetist self reported	Observers Evaluation	Anaesthetist self reported	Observers Evaluation
Highest	16 [15,17]	15* [14,16]	15 [14,16]	14.5 [13,15]
Mean	13 [12,15]	13 [12,14]	12 [12,14]	12 [12,13]
Lowest	12 [11,13]	12 [11,12]	12 [10,12]	12 [11,12]

The box plot shown in Graph 1 represents the highest, mean and lowest scores recorded by the observer, the yellow boxes showing the scores recorded during the conventional method, while the green boxes represent those recorded during the SAFERsleep™ system scenarios, on analysis we could again find no difference in scores between the two methods.

Figure 12: Highest, Mean and Lowest Borg Workload scores of the anaesthetist as rated by the observer



Key

Borg Workload Scores during the scenarios using conventional methods

Borg Workload Scores during the scenario using the SAFERsleep™ system

5.6 Discussion

This study was designed to explore, in greater depth, cultural issues surrounding drug error in anaesthesia and the barriers, benefits and potential impact of introducing technology into clinical practice, such as increased workload for the anaesthetist.

I found that although there was the general perception that errors do occur within anaesthesia, there was still the perception that these do not cause significant harm and the majority do not need to be reported. I found many similarities to my first study (Chapter 4); however the main difference was the reluctance to report drug errors when they did occur.

Anaesthetists disagreed, more than the ODPs, that technology would prevent drug errors in anaesthetic practice, however over half of the anaesthetists and ODPs questioned said they would welcome new technology that was designed to reduce drug error. Several anaesthetists commented that the SAFERsleep™ system was a distraction; however I found no difference between the Borg Workload scores during the scenario using SAFERsleep™ compared to the scenario using conventional methods of anaesthesia.

5.6.1 Errors

There was consensus among both professional groups that drug errors do occur within anaesthesia. ODPs' believed drug errors were more common than anaesthetists however both groups did agree that drug errors, when they did occur, caused significant harm. As previously discussed (Chapter 1) the incidence of error within anaesthesia has been reported as high as 1:133 anaesthetics.[88]

In answer to the statement that 'my thoughts and actions are commonly influenced by the risk of medication error' there was a greater positive response from the anaesthetists compared to the ODPs. The ODPs remained neutral on this subject; this may in part be due to the wording of the question. The responsibility of the ODP is not to prepare or administer drugs during an anaesthetic as this is the role of the anaesthetist.

There was a high level of agreement, from both professional groups, with the statement that failing to record a drug given during an anaesthetic constituted an error. Errors of omission have previously been implicated in twice as many medication errors compared to errors of commission,[234] so it was encouraging to find that both professional groups believed them to be reportable events.

There have been many ways described in the literature to prevent drug errors.[28 88 90 235] One of the questions put to the participants was whether the use of pre-labelled, pre-filled syringes for parental administration should be adopted. The majority of participants agreed with this statement, with the ODPs slightly more in favour. Within the review by Jensen and colleagues[90] utilising prefilled syringes within anaesthesia was listed as ninth on the list of recommendations to prevent drug errors. Other authors suggested that through using prefilled syringes it would virtually guarantee the accuracy of labelling and would facilitate the use of highly legible, printed labels, reducing the risk of medication error.[90 100 236]

Time pressure was put forward as one of the major causes of drug error within anaesthesia; this has previously been cited within the literature (Chapter 1). Abeysekera and Colleagues[28] suggested that the 'pressure to proceed' may lead to short-cutting of usual checking routines, while Hintong and Colleagues[79] found that

haste was one of the most common contributing factors to error in anaesthesia.[28 79] The main issue I found emerging from the theme 'time pressure', was the anaesthetists' need to keep the theatre list running smoothly and efficiently. One participant described the next patient being sent for while they were still taking the previous patient round to the recovery unit, they stated that this had put increased pressure on them while they were preparing the drugs that would be needed for the next patient. They went on to comment that they had had no time to collect their thoughts and prepare a 'plan' for the next case.

The proximity of the drug error to the patient seemed to be the deciding factor in whether an error was reportable or not. If the error was noticed while the drug was being drawn up, the general consensus was this was not a reportable incident. Webster and Colleagues[88] commented that picking up the wrong syringe might be thought so common place as not to merit reporting. However, I found that if the drug was very close to being given to a patient, especially if the syringe was attached to the patient's cannula before the error was detected, this became either a near miss or an actual incident. If the 'near miss' was witnessed then this also influenced whether the incident was reported or not.

5.6.2 Reporting

Since the introduction of the NRLS, generic for all specialities in the NHS, by the NPSA in 2001 over 4 million incidents have been reported.[52] One of the fundamental beliefs for reporting incidents is that safety can be improved through learning from incidents and near misses, rather than denying their occurrence.[48]

The importance of incident reporting has been acknowledged previously, however several authors have found under-reporting to be a common problem.[57 237 238] Underreporting was a theme that emerged from my analysis; however I found contradictory evidence between the focus group and interview data and the error questionnaire data. Although there was a high level of agreement within the questionnaire data that drug errors which are caught and corrected need to be reported, this was not evident in the analysis of the interview or focus group transcripts. There was a similar finding for failing to record a medication on the anaesthetic chart. Within the focus group data, several anaesthetists suggested that drugs were not recorded on the anaesthetic chart due to the chart being a dual speciality document. One anaesthetist gave the example of where a surgeon had taken the record to write up the surgical notes and this had meant that any drugs given in the last ten minutes of the operation were unintentionally missed off the chart. Another anaesthetist commented that a nurse from the recovery unit had come round to the theatre to find out if a patient had been given a particular drug that had not been documented on the chart. This omission was not reported, and from the discussions this appeared to be a common occurrence. Omissions of recording drugs on the anaesthetic chart were only reported when they had led to an actual error, for example the patient had received the same drug twice in too short a time period.

One of the deciding factors in whether an error or near miss should be reported appeared to be the perceived seriousness of the mistake. Smith and colleagues [228] reasoned that the hallmark of expert anaesthetic practice is having the skill to

ascertain whether a response or condition during anaesthesia is 'normal' or 'abnormal', and therefore this in turn defines the boundary of seriousness. In a later publication Smith and colleagues [237] terms this ability to 'set' or impose a definition on the situation as routine or critical as 'definitional power', a notion that expertise in anaesthesia brings with it the authority to define the boundaries between routine and critical but also between acceptable and unacceptable. Another reason put forward that influenced the enthusiasm to report was the lack of feedback received by participants. This issue has previously been reported in the literature by Evans and colleagues; [239] who found that two thirds of respondents, to a survey of 186 doctors and 587 nurses, cited lack of feedback as the greatest deterrent to reporting. In this study several of the participants noted that they had received no feedback to any of the incident forms they had submitted. One anaesthetist commented that if you did report an incident, following the correct procedure, the individual concerned would have no feedback and no opportunity to learn from it. While another commented that despite a drug error occurring on the Intensive Care Unit, within the same hospital, very few anaesthetists had heard about it. The same error reoccurred within the anaesthetic department, which they suggested could have been prevented if there had been feedback within the Trust to all departments, rather than only to the department involved. Benn and colleagues[240] suggested that a vital aspect to promote future reporting is to ensure ongoing feedback. However, as seen within the results of this study, the relationship between reporting an incident and receiving any sort of response or follow-up is often lengthy and questionable.[52]

The potential for recriminations following the reporting of an incident was put forward as a barrier to reporting. One participant suggested that errors may not be reported because the anaesthetist does not want to appear stupid, especially if it could be deemed a silly mistake. This corresponds to the notion that only bad doctors make mistakes.[52] In this study in line with previous literature,[241-244] there was the perception within both professional groups that reporting was punitive, not constructive, and that their career would be tarnished if they reported an error. One participant described the process as being taken into a box and beaten. A Previous study found that the potential for blame influenced the level of reporting. This idea was more dominant if the reports were to be reviewed by someone outside anaesthetic practice. This may go some way to explain the under-utilisation of the NPSA's NRLS, the perception being 'loss of control' over the incident.[237]
In response to underreporting within anaesthesia, the RCoA, AAGBI and the NPSA have developed a speciality-specific critical incident reporting system. Reported incidents through this system will be reviewed by professionals and independent experts, and acted upon promptly. The intention of the group is to disseminate summary reports of the analysis regularly to all clinicians, thus providing the much needed feedback directly to those who report the incidents.[63]

5.6.3 Technology

Within healthcare, information technology has been described as a revolutionary force bringing about drastic changes in patient care.[245] However, one of the recommendations made from my previous study was to further investigate the impact of introducing technology, designed to reduce drug errors, on the

anaesthetist's clinical practice. Within this study I found a mixed response to the questions related to technology within the error questionnaire, this was also reflected in the focus group discussions. There was a strong distrust of technology within the focus group of anaesthetists and ODPs who had not participated in the VASER study. It was difficult though to say whether this was due to lack of familiarity or more to do with a perceived loss of control over the subsequent anaesthetic record. The response within the interviews however was positive and all of the participants thought that the introduction of technology would have a constructive impact on their clinical practice.

5.6.3.1 Computerised anaesthetic records

Less than half the anaesthetist thought that anaesthetic records should be computerised, there was a similar response from the ODPs. There was also more reluctance to adopt a computerised anaesthetic record by the anaesthetist that had not previously used it. This may suggest that they had pre-conceived ideas about how the system collected and collated the data rather than how it actually worked in practice.

The main concern was that electronic version would not be an accurate record and would need annotating to ensure that the chart reflected what had truly happened in clinical practice. Discrepancies between what gets recorded retrospectively and what actually happened are well known in anaesthesia.[235] Previous studies have shown that the hand written anaesthetic record can, and often is, subject to the 'phenomenon of smoothing'.[246-249] Smoothing has been described as due to three possible causes; firstly averaging the physiological monitor readings of a given

variable when a single reading is unexpectedly out of range; secondly ignoring an aberrant reading or thirdly recording a high pressure a bit lower and lower pressures a bit higher.[246] The resulting anaesthetic chart has previously been described as showing what the anaesthetist wishes it to show rather than what the monitor recorded.[246] Other studies have demonstrated discrepancies between handwritten records and automatically generated records, with the times of induction and emergence being the most commonly occurring errors in accurate recording.[245 248] Reich and colleagues[248] went as far as suggesting that some of the physiological data in the handwritten records were inaccurate. The main concern of the anaesthetists appeared to be related to how they were judged as practitioners should the charts be reviewed by someone outside of the anaesthetic community. The perception was that an 'outsider' would not understand why they did not respond to every minor change in the patient's condition and therefore they would be seen as failing to look after the patient adequately.

5.6.3.2 Prevention of Drug errors

Two thirds of the anaesthetists and half of the ODPs thought that new technology would not prevent drug errors in anaesthetic practice. However in a recent study by Webster and colleagues[250] they suggested that the multiple checking techniques of the SAFERsleep™ system may make undetected events less likely to occur than with conventional methods.

The main obstacle described by the participants was remembering to scan the drug prior to administration, enabling the system to double check the drug. This was

recounted as feeling unnatural, although the general consensus was that it would improve over time. The potential for professionals using work-arounds with technology has been previously reported in the literature and briefly discussed in Chapter 4. Work-arounds mostly occur when the member of staff feels there is a block in the system that is hampering their ability to do their job. Work-arounds can also potentially create more holes in the system. Each workaround represents a latent violation of a safety procedure and this can in turn lead to 'all the slices of the Swiss cheese aligning'. Halbesleben and colleagues also suggest that when one work-around occurs it may lead the health care professional to engage in other unsafe practices.[230] Webster and colleagues[250] found a similar problem, the only drug errors reported were when the principle of scanning prior to administration was violated. They concluded that it was possible to assume that if the anaesthetist had complied with the requirement of the system to scan before administration, all or most of the 19 reported incidents related to clearly documented violations might have been avoided.[250]

5.6.3.3 Distractions

Several anaesthetists commented that data entry into the SAFERsleep™ system was distracting and became a source of frustration. One anaesthetist commented because it was a new task, any slight distraction had a much bigger impact. Distractions have been implicated as a cause of medication error previously in the literature. More recently distraction was cited as the cause of a fatal drug error on a neo-natal ward in July 2010, in Nottingham.[251] Returning a narrative verdict, the Coroner said: "There's no doubt that a dreadful mistake took place but drug errors

are more common than we know, in this case there were two people that made a drug error because of distraction by others"[252]

Westbrook and colleagues[253] found that the more interruptions nurses received during medication administration, the greater the number of errors. Additionally, they found that the greater the number of interruptions, within a single drug administration, the more severe the error.[253] Previous studies utilising the SAFERsleep™ system have found a similar problem relating to distraction, around the use of the barcode scanner. Houliston[254] suggested this might be due to inconvenience of having to pass the syringe over the bar code scanner and wait for it to be read, as well as the requirement for exact positioning of the label in order for it to be 'seen' by the scanner.

Previous studies have shown that when technology has been integrated into anaesthetic practice the anaesthetic process is not necessarily faster, but the workflow and time constraints are altered. Also discussed was the worry that the entry of data into the electronic system may distract from the core principle of continually focusing on the patient. The concern then is that the anaesthetist spends more time interfacing with the computer than the patient.[245]

5.6.4 Workload

Workload has been described by Leedal and Smith as "a dynamic balance between the challenge of a task and an individual's response to that task".[172] Due to the complexity and multiple dimensions, workload is affected by external

circumstances both within the environment and from existing perceptions, organisational dynamics and emotional factors.[255] Weinger and colleagues[255] describes the environment in which the anaesthetist works as "a complex, high-technology, high workload, high-risk task environment", they go onto say that this can result in even the smallest of equipment or human failings having a disastrous consequence.

A further definition of mental workload has been provided by Byrne and colleagues,[256] they describe mental workload as the "amount of mental effort involved in performing any given task". They go onto say that there is a limit to an individual's mental workload, which they described as mental capacity. The proportion of the mental capacity in use at any given time is dependent on the task being performed.[256]

The importance of measuring mental workload is a high priority within many high risk industries due to the impact on safety. Increased mental workload can have a direct influence on the occurrence of error and poor performance.[177] Weinger and Englund[188] suggested that, as the workload increased for the anaesthetist, high priority would be given to primary functions compared to secondary functions, termed 'load shedding'. They also suggested that individual tasks (especially those involved in gathering information) would tend to be performed for longer periods (i.e. longer than average dwell times). In a survey of 279 anaesthetists, carried out by Gaba and colleagues,[257] 63% of respondents suggested that they had made errors because of workload.

It has been suggested that the more experienced the individual anaesthetist is, the greater their ability to deal with increased workload. Weinger and colleagues[181] proposed that this is due to experienced anaesthetists having better resource allocation and therefore are less strongly influenced by workload, while Leedal & Smith[172] found that experienced staff appeared to show 'spare capacity' in performance during routine cases, which they suggested allows an attentional 'safety margin' to handle any adverse events should they arise.[172 181] The anaesthetists that participated in the scenarios were Consultant Anaesthetists and Senior Trainee Anaesthetists. Both scenarios had scripted challenges throughout, designed to increase both mental and physical workload. Each scenario continued until surgery had finished and the anaesthetist had decided a post operative management plan. The length of the scenarios ranged from 45 minutes to 1 hour and 25 minutes depending upon how the anaesthetist responded to the different challenges within the scenarios. In order to assess workload the anaesthetists were asked to keep accurate anaesthetic records as well as reacting to a 'vigilance light' placed on the anaesthetic machine, designed to illuminate intermittently. The anaesthetic record completion and the vigilance light were designed as secondary tasks, but the participants were not made aware of this.

Leedal & Smith[172] described the benefits of introducing a performance based measurement as giving a measure of capability for the main task of interest, and where a secondary task is introduced, as within this study, a measure of spare capacity. A disadvantage of this measure is the ability to determine the increases or decreases in workload if the individual compensates with increased or decreased

effort respectively.[172] Another possible limitation is that the secondary task may actually interfere with the primary task.[258] Therefore the measurement of performance on the main task will give an indication of the anaesthetist's workload, but it is not possible to assume that as workload increases performance deteriorates.

5.6.4.1 Borg Workload Scale

The Borg workload scale was used to rate workload within this study. The scale has been used previously to rate anaesthetist's workload by Weinger and colleagues.[181] [186] [255] The scale ranges from 6 to 20 and has been found to correlate to a heart rate of 60-200 beats min^{-1},[182] [259] a score of 12 was roughly equal to the workload an anaesthetist would undergo at the time of a routine oral intubation.

The advantages of using the Borg scale include the ease at which it can be implemented and its non-invasiveness. In light of results from previous research, the scale was used during the scenarios and not retrospectively, this ensured that any potential bias due to memory loss or superseding activities was removed.[178] [187] The Borg workload scale [Appendix VIX] is asymmetrical to minimise the respondents grouping their replies at the centre or extremes of the scale, reducing bias that can be a blight of symmetrical numerical scales. In a similar finding to Weinger and colleagues,[255] we found that real time subjective workload assessment was practical and minimally invasive during the scenarios.

A suggested disadvantage of the scale is that the more experienced the anaesthetist the more likely they are to underestimate workload in demanding experimental tasks.[259] Weinger and colleagues[255] found higher subjective workload scores from novices as opposed to experienced anaesthetists. Within our results we did not find any outstanding differences in Borg workload scores between the Consultants and the trainees, however all the trainee anaesthetists who participated were nearing completion of their training. The inclusion criteria of the study prevented novice anaesthetists taking part and so the results may have been similar to Weinger and colleagues[255] findings if this group had participated.

My observation Borg workload score ratings corresponded to the anaesthetist's self ratings for all but the highest scores. I found that I tended to underestimate the workload scores, which may suggest that workload for the anaesthetist at that point was more cognitive in value and so not obvious to me as an onlooker. I also found no difference in recorded workload between the SAFERsleep™ scenario compared to the conventional methods scenario, either for my ratings or the participant anaesthetists. This would suggest that despite the steep learning curve experienced by some of the anaesthetists in first using the SAFERsleep™ system it did not have a noticeable impact on their workload during the scenarios.

I have also found that we are able to create scenarios that effectively constitute times of high and low workload; however the lowest workload scores were found to be higher than those recorded in previous studies observed during clinical practice. This may suggest that that within the simulation environment,

anaesthetists are waiting and preparing themselves for a critical event. This may be due to previous experiences of participating in simulation training exercises as all the anaesthetists who took part had been on at least one course within the simulation centre. Several anaesthetists commented that they were “waiting for something bad to happen”, in an attempt to address this, during the debriefing for both scenarios the anaesthetists were informed that the scenarios did not involve catastrophic events.

5.7 Limitations

There were a number of limitations within this study. Firstly it was a single centre study and so this could be seen as a limitation. Secondly, as with the previous study it was a sample of convenience. Anaesthetists within the anaesthetic department where I work volunteered to part of the study, and there is always the possibility that these may have been the more safety conscious individuals within the department. The anaesthetists also only had a short space of time to come to terms with the SAFERsleep™ system. I tried to mitigate this to some extent by providing training in how to use the system prior to the actual study day.

Although cultural issues did come through within the focus groups nicely, the attitudes and beliefs of the participants were slightly different to those expressed in the questionnaire data. This leads me to believe that because the questionnaire was on such a small sample of people it may have been better omitted.

5.8 Conclusion

In conclusion, drug errors within anaesthesia are recognized as a problem; however within this study there was an underlying belief that most do not cause serious patient harm. Working from the understanding that preventing error in medicine requires more than simply telling clinicians not to make mistakes, Merry and colleagues[100] designed the SAFERsleep™ system as a package to prevent drug administration errors in anaesthesia. The SAFERsleep™ system has been designed to view errors and failures as evidence of faulty work systems that need to be re-designed rather than due to weaknesses of the individual clinician. My previous research evaluating the feasibility of introducing a double check into anaesthetic clinical practice (Chapter 4) found that using the SAFERsleep™ system was more readily accepted by anaesthetists than utilising a two person check.[260] The potential for unintentional consequences on the anaesthetist's workload and clinical practice when this technology is introduced however was not explored in that study.

The results from this study have shown that, within the simulated environment, there was no difference in the workload scores of the anaesthetist when using the SAFERsleep™ system compared to standard conventional methods of anaesthesia. The simulated environment may however have unexpectedly and unintentionally raised the lowest Borg workload scores of the anaesthetists and the observer had the tendency to underestimate anaesthetist's workload at more stressful times.

The prominent theme emerging from this study was the reluctance to report errors when they occurred. This reluctance, alongside other factors such as lack of feedback and a perceived culture of blame may be one explanation for the apparent unwillingness to utilise critical incident reporting. The level of reporting in

an organisation has been correlated with the existing safety culture. Hutchinson and colleagues[261] have suggested that higher reporting rates may be related to a more supportive and positive culture of safety, rather than a marker of less safe care.

Future studies need to explore further the organisations role is developing and promoting a more positive safety culture, whether through education, anonymous speciality specific reporting or timely feedback to enable learning from those errors which are reported.[52 63]

CHAPTER 6: SUMMARY AND CONCLUSION

6.1 Summary and Conclusion

The overall aim of this thesis was to explore the attitudes and beliefs of anaesthetists in relation to drug errors in anaesthesia, the technology and systems designed to reduce such errors and the inherent culture that impacts on and influences the subsequent compliance with these proposals.

Currently there has been little work carried out in the UK in relation to the use of double checking protocols, and despite Toft recommending the use of double checking protocols in preventing drug error, this recommendation appears to be based on opinion rather than fact. On closer inspection of the literature there is little concrete evidence to suggest the process of double checking actually reduces drug error. However there remains a need for a robust check that can be implemented within the NHS. As previously discussed (Chapter 1) manual double checking presently takes place on an ad hoc basis and technology specifically designed for use within anaesthesia has been developed, but is currently only installed within a very few NHS hospital Trusts.

The first study detailed in this thesis (Chapter 4) was to explore the feasibility of introducing a double check methodology, either second-person confirmation or electronic confirmation into clinical practice within the NHS.

Investigating two methods of double checking anaesthetic drugs given by injection was a priority area agreed by the NPSA and the RCoA for the 'improvement through

partnership' collaborative project aimed at improving patient safety through working directly with clinicians.

This qualitative study involved seven NHS Trusts across the UK and evaluated the feasibility of introducing a manual second-person double check or an electronic bar-code double check into clinical practice. This was the first study of this nature within the NHS and explored the attitudes, barriers and benefits of each method. Previous literature (Chapter 1) has recommended double checking as a way of preventing drug errors; however this study was the first to look at the feasibility of introducing a double check methodology into anaesthetic clinical practice within the NHS in the UK.

The findings presented in Chapter 4 suggested that while many participants acknowledged that the checking of injectable medications by one of their colleagues was an important factor to minimise the opportunity of any unsafe medication administration, the process of second person confirmation could be prone to human manipulation. The findings also showed that the process of double checking could alter the behaviour and practice of the anaesthetist, resulting in a reluctance to adopt it. The electronic confirmation method, on the other hand, was more feasible as it did not rely on the presence of a second person at the time of drug administration. I found that it was more readily adopted by the anaesthetists, mainly due to the process seemingly being more intuitive to their current working practice.

The recommendations made from this study are that anaesthetists, and other professional groups, should give serious consideration to implementing methods of confirming the drugs administered during anaesthesia. However, if second person confirmation is being considered as the method for implementation then adequate resources in terms of time and personnel should be ensured. I found that despite both of the methods being perceived as being effective in preventing drug errors, the introduction of the two person drug confirmation in anaesthesia practice was at times difficult to achieve due to resource issues such as staffing and time allocation.

For the second person confirmation to have any chance of success, it is critical that there should be active engagement with the clinicians who will be using it; this is to ensure that the impact on the existing working practices of the anaesthetist is determined and enables any anxieties to be resolved.

A further recommendation, in relation to the electronic confirmation method, is to ensure careful planning at the outset to enable a smooth integration with the current technology utilised within the theatre environment and the Hospitals' own IT system. It is essential that adequate training is provided for staff, no matter which method is chosen to be introduced.

The final recommendation for this study was that the implementation of confirming drug administration during anaesthesia should be accompanied by constant drive to improve the patient safety culture within the operating theatres. Kizer[262] defined a

safety culture as 'an integrated pattern of individual and organisational behaviour, based on a system of shared beliefs and values that continuously seeks to minimise patient harm that may result from the process of care delivery'.[262] This is also in line with the first step of the 'seven key steps to patient safety' set out by the NPSA, where they suggest safety culture is "creating a culture that is open and fair".[263] Education in methods to improve patient safety, training in human factors, team working, reporting and learning from incidents, and participation in safety improvement initiatives are also essential elements in order to achieve a 'safety culture'.

Since Chapter 4 found that the use of an electronic confirmation method of checking injectable drugs in anaesthesia was more acceptable, and as previously discussed technology is increasingly seen as the way forward in providing the means to improve patient safety,[100, 116] the study proposed in Chapter 5 was designed to investigate the impact of introducing the electronic confirmation on the anaesthetist's workload as well as explore in greater depth the culture issues raised in this first study (Chapter 4). This was achieved through integrating my research aims into a larger international study - VASER.

The aim of this research (Chapter 5) was to explore the beliefs and attitudes of anaesthetists and ODPs taking part in error research, and their views on the introduction of technology designed to reduce errors. Also, as part of the VASER study I assessed the workload of the participating anaesthetists in order to evaluate

whether the SAFERsleep™ system added further workload to the simulated clinical scenarios.

In addition I explored the beliefs and attitudes of anaesthetists' and ODPs' that did not participate in the VASER study in order to further judge the cultural effects of drug error within anaesthesia and their subsequent reporting.
The findings presented in Chapter 4 suggested that the introduction of the electronic confirmation did not impact on the anaesthetist workload, however as previously suggested, there is a definitive need for adequate training to ensure that the learning curve of using new equipment was minimised.

Another finding from this study was that while the majority of participants were positive that drug errors should be reported, there was a palpable reluctance to report them in practice. A 'culture of blame' and the 'lack of feedback' if an error was reported were the two main themes that stood out from the analysis; there was also the issue of lack of awareness of the actual causes of error.

The Quality Interagency Coordination Task Force (QuIC)[264] suggested that the lack of success in reducing drug errors could be attributed to a general lack of awareness or alarm about errors. Leape supported this view stating that low error rates lead to complacency,[265] while Dean and colleagues[266] suggested that prescribing errors made by junior doctors were due to a lack of knowledge and self-awareness related to error.

Finally, I found that the anaesthetists and ODPs that did not participate in the VASER study had similar views on drug error incidence, incident reporting and the use of technology to those who had participated.

Recommendations from this study (Chapter 5) to address these issues are focussing future work on the acknowledgment of errors, undergraduate and lifelong education in relation to safety culture, and interventions to improve the safety culture already inherent within the organisation.

This thesis has shown that technology was more readily accepted and seen as more feasible to use by anaesthetists within their clinical practice. However, it has also demonstrated that the culture and beliefs of the organisation and individuals, of one of 'blame and shame', has such a strong influence that it continues to prevent a true safety culture developing into an open culture of reporting incidents.

The palpable reluctance to report, a major theme encountered within chapter 5, however contradicts the overall picture painted within the literature and how I perceived the anaesthetic profession to be prior to starting my thesis. Anaesthesia is depicted as a profession that drives safety initiatives and promotes patient safety far more than any other professional body. The anaesthetic profession has set up the Safe Anaesthesia Liaison Group (SALG) and is the first profession to have speciality specific incident reporting, however if anaesthetists don't feel they can report errors or near misses, whether due to fear of retribution or lack of

understanding how can this then feed into learning and improving practice and subsequently patient safety. The Aviation industry operates a just or "no blame" reporting culture which they believe to be essential if a complete picture of the causal factors behind an event is to be identified. The European Regions Airline Association [ERAA][267] support the 'Just Culture' ideal and promote the provision of such an ideal in incident reporting. The ERAA state that "this process ensures the pilot is free from threats of legal action and career inhibition risks, unless, such actions result from wilful misconduct, non adherence to Standard Operating Procedures (SOPs) or under the undue influence of alcohol or any other form of substance abuse" in such cases the ERAA states that they support any legal action that may be brought.

Unfortunately within the NHS there still remains a perceived 'blame culture' (Chapter 5) and until this alters I don't believe the anaesthetic profession can compare their safety record to that of the aviation industry.

Given the opposing priorities between safety, performance level and resource constraints, the message that can be drawn from the literature, as well as the evidence from the participant's views presented within this thesis, is that in order to ensure and maintain drug safety within the anaesthetic environment there needs to be a fine balance between the demands of production and maintaining safety principles. Wilson[268] stated that "most public organisations cannot afford to prioritise safety over all other values; they must serve multiple, mutually contradicting values". There are many unavoidable tensions between various

priorities within the organisation. The need for safety within anaesthetic practice, reducing associated costs of drug error including extended hospital stay, the drive to improve the Trust's performance, or the targets set by government, all of these issues impact and put increasing pressure on theatre departments to run extremely tight, inflexible operating lists.

The Francis report[32] provides a disturbing picture of how one Trust's pre-occupation with targets can impact severely on patient care and safety. It was recognised that within that Trust there were health care workers with questionable standards of practice, however the acceptance of poor professional conduct and insufficient attention on the maintenance of professional standards highlights that a failing safety culture is a mixture of both person and system based violations and errors.

It is important to focus on how best to realistically improve and maintain safety in anaesthetic drug practice, alongside these competing and potentially detrimental priorities. I feel it is important to think in terms of 'responsibility' rather than 'Blame'. Within each error or incident the role of the individual health care professional or layer of the system, such as the targets set by management or the protocols defining practice, needs to be acknowledged and the responsibility distributed accordingly. Rather than what seems to be the current practice of pointing the finger and blaming the last link in the process, which unfortunately is usually the health care professional.

6.2 What this thesis did not explore

This thesis did not explore in greater detail the impact that error awareness, individual and organisational learning and team culture has on safety within anaesthetic practice.

There was the suggestion within this thesis that awareness of error was lacking and that this had a direct impact on the levels of incident reporting taking place. Leape[265] suggests that the reluctance by doctors to accept that errors do happen is due to the high rates of injury and death not being consistent with their personal experience. Speciality specific reporting is a potential solution to this problem of error awareness as long as feedback to clinicians is timely and consistent. As previously discussed, the AAGBI, RCoA and the NPSA have developed a speciality-specific critical incident reporting system for anaesthesia. It will be interesting to see if this system raises awareness of error and impacts on the levels of reporting and learning within anaesthesia.

Education has also been suggested as a critical part of changing the culture within an organisation, Fukuda and colleagues[269] found that hospitals which implemented an education programme around incident reporting significantly increased the rate of reporting by doctors.

Training alone, however, is not enough; improving patient safety requires a multifaceted approach, one which involves the whole team. Espin and colleagues[20] found that team collaboration was centrally important to the study of safety and

medical error. They suggest that errors often occur in team settings in which many health care providers work together. Within the theatre environment in which anaesthetists work there are many different professional groups, therefore, understanding the similarities and differences of each profession's perceptions is critical to preventing drug errors.

Working effectively as a team can support individuals in avoiding mistakes, intercepting errors, and reduce psychological precursors.[1 20 265] Previous work has looked at the role of team building and training within the theatre environment.[270-273] The concern I encountered within this thesis was that individuals were more willing to report incidents that involved colleagues from their own profession rather than those involving a member of a different professional group (Chapter 5). The problem with this approach to reporting incidents means that many team based errors go unreported and unsafe practices continue to persist with no prospect of organisational learning.[20] Future work needs to explore how best to foster a shared outlook of responsibility in order to achieve changes and improvements to the culture of safety.

6.3 Concluding remarks

I started out with the Department of Health recommendations that double checking should be utilised and introduced to prevent drug error. Due to the peculiarity of anaesthetic practice where many injectable drugs are given in a short space of time, I chose to look at the feasibility of introducing such a check into clinical practice.

I found that the second person confirmation method was not taken up as it was perceived to be time consuming, there was a perceived lack of availability of the second person to check the drug, as well as the process being seen as open to manipulation. The SAFERsleep™ system was preferred due to the lesser impact on the anaesthetist; however there were barriers to its adoption. These barriers included culture, attitudes and beliefs, stemming from a fear of retribution.

My studies have shown that the introduction of any safety intervention is only possible if efforts are made to improve the safety culture within the organisation. Accordingly, I would like my future work to focus on the implications of introducing the SAFERsleep™ system into clinical practice within theatres, and the impact this may have on culture and safety within the Trust. I specifically want to explore whether there is a reduction in medication errors with the introduction of the SAFERsleep™ system and also whether it reduces other errors. I also want to explore whether the use of the SAFERsleep™ system streamlines the process of information transfer in the pre-operative, peri-operative and post-operative periods, and whether there is also a reduction in medication errors in the pre-operative and post-operative periods.

This thesis has highlighted that education, experience, environmental and technological matters all play a part in creating latent conditions, latent conditions that are capable of generating situations where medication administration is not ideal and potentially unsafe. However, it has also become apparent to me that the inherent culture within the anaesthetist's working environment also plays a

significant role in the safety of medication administration and the adoption of any safety initiative.

It is important to continue exploring the processes that influence and impact on patient safety. However, different interpretations of the same participants' views may come up with different latent factors, contributing factors, solutions or intrinsic factors of the system. It is clear that there are many different ways in which drug errors in anaesthesia may occur, however technology is seen as the way forward in addressing some of these issues.

I have come to the conclusion that a major paradigm shift at organisational level is required to embed any safety measure, such as SAFERsleep™, in order to realise its full potential and to change the culture from one of 'blame' to one of 'responsibility'. This would involve methods of improving culture such as team building, team training, education and error awareness.

Further research is now needed in order to determine the best strategies to ensure compliance with any safety initiative that is introduced, and the development of an evaluation programme to ensure that such initiatives reach their full potential.

APPENDICES

APPENDIX I: Interview Schedule – VASER (Chapter 5)

Question 1

What are your views about the quality of the anaesthetic record produced during the scenarios?

- Accuracy
- time
- missing data
- usefulness
- usability
- potential

Question 2

Thinking back to the scenarios can you tell me about the preparation of drugs & the differences between VASER & Conventional methods?

- Time taken to prepare drugs
- difference between pre-filled or not
- acceptability
- cost
- Distractions – while prep drugs, should patient be in the room or should time be allowed to do this

Question 3

What are you views on the occurrence of drug errors within anaesthesia and their subsequent reporting?

- Drug Errors – reporting - harm v no harm
- Can Technology help in preventing them - benefits, problems, distractions, ideal kit requirements

APPENDIX II: Focus Group Schedule - Participants (Chapter 4)

Question 1

What is your perception of drug errors within anaesthesia?

Question 2

In relation to the system you used: What were the strengths?

Question 3

In relation to the system you used: What were the weaknesses?

Question 4

In relation to the system you used: What were the opportunities?

Question 5

In relation to the system you used: What were the threats?

Question 6

In relation to the system you used: What cultural issues arose when it was introduced?

Question 7

If you could design the perfect system to prevent drug errors in anaesthesia, what would it be like?

APPENDIX III: Focus Group Schedule – Observers (Chapter 4)

Question 1

What is your perception of drug errors within anaesthesia?

Question 2

What were the strengths of the systems you observed?

Question 3

What were the weaknesses of the systems you observed?

Question 4

Do you think either of the systems will improve patient safety?

APPENDIX IV: Focus Group Schedule - Participants (Chapter 5)

Question 1

The first area we want to explore is the reporting near misses in particular those where there is no direct or immediate lasting consequence to the patient.

- What are the benefits
- What are the barriers
- Give some examples of medication errors that you would report
- Errors of omission/documentation omission and the potential impact in the post op period rather than during the immediate/intra-op period
- DVT prophylaxis and the responsibility of individuals to prescribe
- Pre-op medication given/not given, recorded or not?

Question 2

What aspects of conventional practice predispose the occurrence of medication errors?

- Time pressure
- Distractions during preparation or administration
- Accuracy/standardisation of documentation to check the administration pre and post anaesthesia
- Preparation of less common infusions/drugs
- Equipment/method of delivery
- Use of standardised protocols – which drugs, theatre staffs role?

Question 3

Thinking back to some of the features of the SAFERsleep™ system what were the positive aspects and where do you think differences/inaccuracies would be compared to the conventional record

- Time saver
- Welcomed advance?

APPENDIX V: Focus Group Schedule - Non-Participants (Chapter 5)

Question 1

The first area we want to explore is what constitutes a near miss?

- When does it become an incident or a non event
- Give some examples of medication errors that you would report
- Errors of omission/documentation omission and the potential impact in the post op period rather than during the immediate/intra-op period
- DVT prophylaxis and the responsibility of individuals to prescribe
- Pre-op medication given/not given, recorded or not?

Question 2

What aspects of conventional practice predispose the occurrence of medication errors?

- Time pressure
- Distractions during preparation or administration
- Accuracy/standardisation of documentation to check the administration pre and post anaesthesia
- Preparation of less common infusions/drugs
- Equipment/method of delivery
- Use of standardised protocols – which drugs, theatre staffs role?

Question 3

What do you think the barriers to reporting are?

Question 4

How do you think practice should or could change to influence the risk of medication errors occurring?

- Awareness of Technology available to benefit practice

APPENDIX VI: Reflective Diary (Chapter 4)

Trust Headed Paper

REFELECTIVE DIARY

Try and complete the diary as close to finishing the list as possible while the main issues of using the double checking methodology, whether positive or negative are still fresh in your mind. The prompts within each box are there to give you an idea of the some of the areas you may want to reflect on but are not exhaustive.

If you have any problems with using the double check methodology or need further clarification please contact a member of the study team as follows:

Chief Investigator	Professor Ravi Mahajan	RCoA	0115 823 1009
Research Associate	Mrs Rachel Evley	RCoA	0115 823 1004
Co-Investigator	Ms Beverley Norris	NPSA	0207 927 9559

Description of Today's List

Number of patients on list	
Start and end time of list	

Setting • Type of Theatre – including type and length of surgery, • Brief description of anaesthetic room - including drug storage, working space

Drug Preparation When were the drugs prepared – in advance for the whole pathway or just for the induction phase? • Were any drugs prepared for the next patient?

Time • Did the double check cause any delay in giving drugs? How and why? • Which part of the anaesthetic was delayed – induction, maintenance or reversal? • Were there any delays to the list due to the double-checking procedure? If yes, could they have been avoided with an amendment to the double-checking procedure?

Feasibility

- Were there any problems in using the double checking procedure? Please describe
- What parts of the double-checking protocol did you find most difficult to adhere to?
- Was a member of staff available to carry out the double check? If not describe what happened
- Feedback & Criticisms by staff – all grades
- Potential Impact on patient? Is the double checking effective in preventing errors or near misses?
- Can you think of any error or near miss you have experienced or witnessed where the double-checking protocol could have prevented it from occurring?
- If there were any emergencies, did you manage to use the double check?

Other Comments

APPENDIX VII: Observation Schedule (Chapter 4)

Observation Schedule

The observation schedule set out below is designed to help you focus your observations.

Please feel free to use as many pages as are necessary to record all data for an observational session, and number pages at the top. An observation session is defined as each time the pathway is followed, so each time a new patient enters the anaesthetic room.

Please record the start time in the left-hand column and any key time points within the session, such as the checking or administration of drugs etc.

Record as fully as possible all talk and all actions by Anaesthetists, Operating Department Practitioners, Theatre Nurses and other members of the theatre team in relation to the main themes set out below. If you feel something is important to the study and is not covered in the main themes please feel free to include this as well.

The following precautions will make this data fully usable:

- try to keep handwriting legible
- leave a lot of space so that annotations and corrections are easy to make
- keep a key to any abbreviations used at the bottom of the page

- **Setting**
  - Type of Theatre
  - Brief description of anaesthetic room
  - Grade of Anaesthetist observed
  - Level of support staff – type and number

- **Drug Preparation**
  - When are drugs prepared i.e. for whole pathway in advance or just induction phase
  - Which syringes are used for which drugs
  - Bolus or infusions – which drugs?

- **Time**
  - To prepare drugs following the pathway
  - Is there any delay in giving the drug?
  - Is induction delayed?
  - Is the list delayed?

- **Pathway / Electronic workstation**
  - Ease of use
  - Problems with use
  - Staff adherence to its use

- **Feasibility of use**
  - Staff availability to follow pathway
  - Criticisms by staff – all grades
  - Impact on patient
  - Is it effective in stopping errors occurring – near misses?

Observation Schedule

Name of Observer	
Date of Observation	
Duration of Observation	**Start time:** **Finish time:**
Type of Theatre	
Number of patients per list/day	
Type & length of surgery observed	

Un-Scrubbed Theatre Team Members	**Grade/Band**	**How long has the lead anaesthetist worked with each team member?**

How long have the team worked together?	
Do team work together regularly?	
Are there rotations through different theatres / shift patterns?	

TIME	OBSERVATIONS

Reflections

APPENDIX VIII: A Guide to being an Observer (Chapter 4)

A guide to being an observer

Please read this guide carefully. Observation for evaluation research is a skilled task that requires structure, focus and concentration. Preparation is important. Consider the principles outlines below and think how you will apply them before you start the observations.

> *'Observation begins the moment the observer enters the setting, where he or she will strive to set aside all preconceptions and take nothing for granted'* [Angrosino 2007].

In everyday life we know that several people witnessing an event will interpret the event differently. We all have filters which screen out a lot of information. Do not make assumptions about what is relevant information. Remember that the data collected in the observations must be comparable across sites and across observers.

When you record your observations think of them as 4 parts.

- Factual descriptions
- Talk of participants – record as close as word for word as possible,
- Your perceptions of what is happening and by the views of participants gathered while talking to them (such as during coffee break)
- Your reflections of what you have observed over the day.

When you write down any observations please make a note in the margin as to which of these 4 categories your observations fall into. This will help when we come to analyse and when you reflect at the end of the day. There is a page at the end of the observation sheet for you to elaborate on your views and reflections.

Some principles of observation

- There should not be interaction between the observer and staff during the observation; you are there to watch only. We know this will be difficult. But please try not to give your clinical view on either of the double checking systems to those participating at the sites.
- Don't be drawn into helping and don't interfere in what you are observing. If you see a drug error about to happen you can in your professional capacity stop this, but the incident must then be reported through the normal critical incident event reporting system within that Trust.
- Describe what you observe accurately, factually and thoroughly. Remember that absence of action or communication may be relevant
- Focus on the process under scrutiny (of double checking) and any factors that contribute to or affect its implementation. Do not get distracted by irrelevant detail. For example the activities of the surgeons are unlikely to be relevant except when this directly affects the anaesthetic team.
- Make sure that every page on the observation schedule has the date and page number on.
- When recording observations write the notes down, however brief, as quickly as possible after seeing or hearing something interesting such as little phrases, quotes, key words, etc.
- Record verbal exchanges in the participants own words when possible, putting these in inverted commas. Nothing conveys the sense of 'being there' more than the actual words of the participants.
- Go over your notes as soon as possible after the observation, to make sure they are clear, legible and readable. Note your abbreviation key as you go so that when you don't end up asking 'what did I mean by that?'
- When writing up the reflective sheet do this as promptly and as fully as possible, at the very latest at the end of the day. Expand on anything you have documented in the observation schedule that may be unclear to us and note your impressions and your views as a

clinician. Also record your views and feelings on the process of the observation.

- Don't worry if you take copious notes about relevant activities. If in doubt, write it down. But there may also be times when there is little to record.

References:

Angrosino M. *Doing Ethnographic and Observational Research*. London: Sage. 2007.

Patton, MQ (1987) *How to use qualitative methods in evaluation*

A guide to making observation notes for the double checking project

Please find below guidance about each section of the observation schedule to help you complete them.

Information to be collected before start of observation

Make time with the lead anaesthetist beforehand to ask for this information.

Setting

Describe what type of theatre list is taking place:

- The type and length of surgery
- The usual number of patients on the list per day.

Describe the anaesthetic room and theatre layout and their relationship to each other, giving some idea of size. It may be easier to draw a diagram. Include drug storage in the description.

Staff & Teams

For the purpose of this study we are looking at the interactions between the un-scrubbed members of the theatre team – anaesthetists, ODPs, & nurses.

1. Document each member of the team and grade[1] . Note if any are agency staff.

[It is a good idea to allocate abbreviations or shorthand, such as A1 for anaesthetist 1, ODP 1 etc and to use these throughout the observation.]

2. Ask if there will be changes of staff during the list and find out about the new members of staff, and how the handover will be conducted
3. Find out whether **lead anaesthetist** has worked together on a regular basis with each member of the team:
    - How long (weeks, months, years)?
    - How many days in the last 7 days*?*

[1] Training /grade of staff:
Anaesthetist: Consultant, Specialist trainees (include year of training); Foundation trainee (year 1 or 2)
ODP: record band
Nurse: record band

Also, whether the rest of the team work together regularly, or if there are regular rotations/shift patterns. What is the role of the ODP? How much autonomy do they have?
If a scrubbed member of the theatre team is involved in double checking activity this should be noted in the main section of the observation record.

Observation during anaesthesia and surgery

Communication
Make a note of when there is verbal and non-verbal communication between team members and who those members are. If the communication is "task oriented" (i.e. about the job being done) document as precisely as possible what is said (or done if it is non-verbal). Things to consider include:

- Are instructions/information specific?
- Is it addressed to a specific person?
- Is it timely?
- Are instructions/information acknowledged?
- Are instructions/information clearly audible to you? If not, do you think they were clearly audible to the staff member?
- What factors might affect audibility? E.g. clarity of speech, noise interference, face mask.
- Does the person receiving instructions/ information seek clarification?
- Is double checking discussed at the beginning, before any drugs are administered, or not, including assigning the double checker? If it is, try to document precisely how it is discussed.

Please also note when there is non-task communication, such as talking to the patient, general conversation with colleagues and non-verbal communication. It is not necessary, however, to record the content of this communication.

Also estimate the time spent on each type of communication - task oriented and non-task oriented.

Movement

Please try to document all movement in & out of the theatre/anaesthetic room by the un-scrubbed team members and any communication related to this movement. Document the purpose of the movement if this is clear; if it is not clear also make a note of this.

Environment

Document noise and activity that might affect the staff administering the drugs.

Drug Preparation/Administration

This section needs to be documented in as much detail as possible. Try to document what each individual says and does during the double check and any non-verbal actions that take place which are connected with the double check.

- Are staff following the flowcharts to the letter?
- If not, at which points are they deviating from them?
- Can you tell why?
- When and how do they label the syringes?
- How do they prepare the next patient's drugs?
- Are there any logistical problems with completing the double check
- Which staff are used as the second checker?
- Are scrubbed team members ever asked to double check?

It would be extremely useful for us to know in the greatest detail possible about the actual double check process so if in doubt record everything you see!

The most frequent drug error sited in the literature is 'syringe swap' this is where the wrong syringe is selected and the drug administered. It is therefore very important for us to know if there are any problems or barriers to using the double check prior to administration of the drug.

Do the anaesthetists have their own system to prevent drug errors? Such as:

- Do they use certain syringes for certain drugs?
- Do they place labels on the syringe differently for different drugs?
- Do they place certain drugs in separate trays?
- Do they keep them in different areas whilst in theatre?
- If so which drugs are separated off?

Anything they do themselves to try and prevent drug errors would be very useful to know

Time

Try to record length of time the double check takes. Note down any delays caused by using the double check, how and why they occur such as:

- No staff to check,
- Software problem
- Not being able to prepare in advance

Double Checking / Workstation

This is combined with the drug preparation section (see above). Record any comments the staff involved make about the use of double-checking/ electronic workstation. Is the double check used throughout all stages of the anaesthetic - induction, maintenance and reversal?

In your observation notes please make the distinction between the double check being used for preparation of the drug and when it is used to check prior to administration.

Feasibility of Use

Note down any problems encountered using the double-checking method or the electronic workstation. Try and record, word for word, the criticisms and praises of staff of the systems as accurately as possible.

- Did the use of the double-check/workstation impact at all on the patient?
- Did they comment at all about the process?
- If there were any emergencies did the double check take place in full?

- If not, which parts were missed out or changed and how?

If in doubt about what to record, write it down.

Reflections

We have included a reflective sheet at the end of the observation schedule to enable you to record your reflections from observing, and to give greater detail or explanation about any events you have seen or recorded.
Refer to your observation notes for supporting evidence for these reflections. Your perceptions are valuable, but try to differentiate these from the factual observations.

You may wish to reflect on the following.

- What were the team dynamics and the communication between the staff that might have had an impact on the double-check being performed?
- Did the team work well together; was communication effective within the team?
- Consider the role of leadership and the skill mix. Does being in charge vary by clinical activity?
- What contributed to the success of the double check - enthusiastic user, team work? What makes it unsuccessful – shortage of staff, user's perception, dynamics within the team?
- Did the double check prevent any drug errors during your observations? Please also reflect on how you think the double check could have taken place safely during an emergency.

I hope this has been useful, but please if you are unsure about any aspect of the observation let me know, my contact number is 0115 8231004, or if you prefer please let me have your contact number and I will happily contact you to go over anything.

Best Wishes
Rachel

APPENDIX IX: Borg Workload Scale

Borg Workload Scale

6	No exertion	←	(completely sedentary subject)
7	Extremely light		
8			
9	Very light		
10			
11	Light		
12		←	Workload level of a routine, oral, asleep, intubation of anaesthesia
13	Somewhat hard		
14			
15	Hard (heavy)		
16			
17	Very hard		
18			
19	Extremely hard		
20	Maximal exertion	←	(during a full blown OR resuscitation)

APPENDIX X: Participant Information Sheet (Chapter 4)

Participant Information Sheet

Hospital headed paper

Title: A multi-centre qualitative study to evaluate the process of double-checking of drugs administered during anaesthesia in order to reduce the risk of drug errors and improve patient safety.

Introduction

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

- Part 1 tells you the purpose of this study and what will happen if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Many published surveys from different parts of the world have suggested that most practicing anaesthetists have experienced at least one drug error. There is now growing awareness that the magnitude of drug errors during anaesthesia is more serious than previously thought. Using facilitated incident monitoring, and data collected from over 10,000 anaesthetics in New Zealand, approximately 1 drug error has been shown to occur for every 130 anaesthetics. Similar figures have been reported from Seattle, and many other studies also suggest similar magnitude of the problem.

In the UK, a national survey of lead obstetric anaesthetists in all consultant-led maternity units showed that 39% of the respondents knew of at least one drug error in their unit in the previous year. In another survey in the South West Region of England, 55% of the respondents indicated that they had made at least one drug error in the previous 12 month period; the majority of the respondents did not report the incidents. Of the reported incidents to the National Patient Safety

Agency (NPSA), 685 incidents were related to drug errors during anaesthesia in the time period between January 2007 and December 2007 (personal communication). It has been identified by an Expert Consultative Group made up from representatives of the National Patient Safety Agency (NPSA), the Royal College of Anaesthetists (RCOA), the Association of Anaesthetists of Great Britain and Ireland (AAGBI), the College of Operating
Department Practitioners, the Association for Perioperative Practice, independent experts and patient representatives that prevention of drug errors during anaesthesia is an area of priority for action to improve patient safety.
This group decided that, before making firm recommendations on how to prevent drug errors during anaesthesia, it will be necessary to conduct a work-place evaluation of two different methods that have been proposed to reduce drug errors. The two methods to be evaluated are second person double checking and electronic checking using an electronic anaesthetic workstation supplied by SAFERsleep™ (New Zealand).

Why have I been chosen?

You are being asked to participate in this study because you are an Anaesthetist, Operating Department Practitioner or a Theatre Nurse working within the theatre that has been chosen as one of the sites for this qualitative observational study.

Do I have to take part?

No, it is up to you whether or not you decide to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

A member of the research team will discuss with you what will happen if you take part. After reading all this information and you decide to take part in this study, you will be asked to sign a consent form.

You will be asked to follow a Pathway for the preparation and administration of all injectable drugs for 3 months. This will involve double checking all injectable drugs prepared using a designated pathway and double-checking all injectable drugs prior to administration using another pathway.

However, when it is not possible to double check the injectable drug, your participation in this study should **NOT** delay the administration of the drugs during anaesthesia and you should conduct the anaesthetic as routine practice.

During this time you will also be asked to keep a log book to document how often it was not possible to perform the double-check methodology, at what time points in the pathway they were unable to perform the double-check methodology and why? Anaesthetists will also be asked to record how many patients they anaesthetise during this period.

Over the 3 month period where the double-checking methodology is incorporated into clinical practice, you will be observed in the clinical environment at least once by an anaesthetist, ODP or theatre nurses from another NHS Trust. A member of the study team will also observe you during the 3 month period.

At the end of the 3 month period you may be asked to participate in a Focus group to be held at the Royal College of Anaesthetists in London.

The purpose of the focus group is to gain an insight into your experiences of the process of double-checking, the strengths and weaknesses of the process of double-checking drugs and what modifications you would suggest to make the method of double-checking widely acceptable.

All reasonable travel expenses will be paid to allow you to attend the focus groups.

What are the possible disadvantages of taking part?

There should be no disadvantages of taking part in this study. However, some time may be involved in completing the reflective diary. We do not anticipate that the study will impact on your routine practice, but the double checking of the preparation of drugs may cause a slight delay between the two anaesthetics.

What are the possible benefits of taking part?

This study is to perform a work-place evaluation of the practice of double-checking using second-person checks and/or electronic (bar-coding) checks, to determine feasibility and barriers in introducing double-check methodology.

There is an opportunity to have your experiences of the double-checking methodology known at the focus groups, and to ensure the recommendations made by the Expert Consultative Group reflect the practical feasibility of introducing double-checking into clinical practice.

What if there is a problem?

The occurrence of any problems as a result of participation within this study is not expected. If any errors in practice are detected or observed during this study then normal NHS procedures for critical incidence reporting will apply. However, if the observers were to see a drug error about to be made they can, in their professional capacity, alert the person involved to prevent such an error occurring.

Will my taking part in the study be kept confidential?

All the information about your participation in this study will be kept confidential. The details are included in part 2.

Contact details:

If you have any questions please do not hesitate to contact one of us on the following phone numbers.

Professor Ravi Mahajan	Chief Investigator	0115 823 1009
Ms Beverley Norris	Co-Investigator (NPSA)	020 7927 9559
Mrs Rachel Evley	Research Associate	0115 823 1004

This completes **Part 1** of the information sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. However all data collected in your log book and from any observations that have already taken place will still be used in the final analysis.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. The contact numbers are:

Professor Ravi Mahajan	Chief Investigator	0115 8231009
Ms Beverley Norris	Co-Investigator (NPSA)	020 7927 9559
Mrs Rachel Evley	Research Associate	0115 8231004

If you remain unhappy and wish to complain formally, you can so this through the NHS complaints procedure. You can complain orally or writing to the [*insert name*] Trust. In the event that you are harmed during participation in this study there are no special compensation arrangements, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this study be kept confidential?

If you chose to take part in the study, all information which is collected about you during the course of the research will be kept strictly confidential. Nothing you say will be read by anyone other than the research team. Names will not be written on the transcripts and you will be anonymous in any written or verbal reports on the research. All information generated by this study will be archived securely within the Division of Anaesthesia, University of Nottingham and destroyed 7 years after the study is completed.

Representatives of regulatory authorities and authorised people from the Trust may inspect the data to check that the study is being carried out correctly. All will have a

duty of confidentiality to you as a research participant and nothing that could reveal your identity will b disclosed.

What will happen to the results of the research study?

The findings will be used by the Expert Consultative Group to produce recommendations for future practice on the use of double-checking for preventing drug errors during anaesthesia. The findings of this study will also be presented to various national/meetings, along with publication(s) in medical journal(s).

Who is organising and funding the research?

The Chief Investigator for this study is Professor Ravi Mahajan and it is sponsored by the University of Nottingham. The study is funded by the Royal College of Anaesthetists in collaboration with the National Patient Safety Agency.

Who has reviewed the study?

This study has been approved by the West Glasgow Regional Ethics Committee 1. It has also been reviewed and approved by the Research & Development department at [Insert Trust R&D Department Here].

Thank you for taking the time to read this information sheet. If you decide to take part you will be given a copy of the information sheet and a signed consent form to keep.

APPENDIX XI: Participant Information Sheet - Anaesthetist (Chapter 5)

University of Nottingham
School of Clinical Sciences
Division of Anaesthesia and Intensive Care
Queen's Medical Centre
Derby Road
Nottingham
0115 8231009

Anaesthetist Participant Information Sheet
Validating Anaesthesia Simulation-based Error Research
(the VASER study).

Introduction

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Please take the time to decide whether or not you wish to take part.

What is the purpose of the study?

Iatrogenic harm, often due to error, is a major public health problem, expensive in human and financial terms. There have been international calls for initiatives to reduce it, but evidence is needed to justify investment in such initiatives. From the viewpoint of human cost, error in healthcare (including anaesthesia) is unacceptably frequent, but for the purpose of demonstrating the benefit of safety interventions it is relatively uncommon; the number of anaesthetics needed for a clinical randomised controlled trial (RCT) to evaluate any safety intervention in anaesthesia is therefore very large (even using surrogate endpoints such as errors rather than harm). A significant reduction of patient harm from any safety initiative

in anaesthesia (even pulse oximetry) has never been demonstrated in a clinical randomised controlled trial. There are also considerable ethical, legal and practical difficulties in investigating safety initiatives in the clinical setting. High fidelity simulation offers an alternative which circumvents many of these difficulties by avoiding the possibility of actual harm to patients. In addition, a statistically powerful paired study design (the Design) for simulation-based randomised controlled trials has been created and tested in which complex scenarios make high rates of error likely, thereby making it easier to show a difference between groups with relatively small numbers of participants. Simulation RCT evidence could potentially be as compelling as clinical RCT evidence (and much less expensive to obtain) provided it can be shown that the conclusions of these approaches are equivalent. Few studies have examined this important question. In the Validating Anaesthesia Simulation-based Error Research (VASER) Study we will compare the conclusions of a large clinical trial with those of a simulation study designed to answer the same questions.

The problem of error in drug administration is particularly pressing in anaesthesia because of the many potent agents given during the relatively short period of an anaesthetic. A record of these drugs forms part of the overall anaesthesia record, an important clinical tool, medico-legal document and resource for audit (the value of which depends on its completeness and accuracy. In response to this problem, a safety initiative (SAFERsleep™) has been developed, designed to reduce drug administration error, facilitate safe practice and improve the quality of record keeping in anaesthesia. It is multifaceted and includes purpose designed drug drawers and trays, prefilled syringes with colour coded and bar-coded labels, a computer that “speaks” the name of each drug when its barcode is swiped, and an integrated automated record keeper (ARK). The SAFERsleep™ system is commercially available and in regular clinical use in within one Trust in the United Kingdom, and has also been used in well over 250,000 anaesthetics worldwide.
As for any safety intervention, evidence of its value or lack thereof is needed. To this end a substantial clinical randomised controlled trial of the SAFERsleep™ system vs. conventional methods of delivering anaesthesia has recently been

completed at Auckland City Hospital, New Zealand. In the VASER Study we will compare the SAFERsleep™ system with conventional methods of anaesthesia using a specific research design to evaluate high-fidelity simulation as a research tool.

Why have I been chosen?

You are being asked to participate in this study because you are a Consultant Anaesthetist or a Trainee (post fellowship (FRCA)) working within the Specialist Support Directorate of Nottingham University Hospital's NHS Trust.

Do I have to take part?

No, it is up to you whether or not you decide to take part. In order to participate in the study, one of the requirements, in order to meet the inclusion criteria, is that you are willing to participate in a semi-structured interview and a focus group.
If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.
You are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

A member of the research team will discuss with you what will happen if you take part. After reading all this information and you decide to take part in this study, you will be asked to sign a consent form.
You will attend a morning or an afternoon at the Trent Simulation & Clinical Skills Centre, where you will complete, with a participating Operating Department Practitioner (ODP), three simulated study scenarios, one to allow you to familiarise yourself with the SAFERsleep™ system and two study scenarios. Prior to attending the VASER study day you will be provided with pre-reading material.
At the beginning of the VASER study day we will show you and the participating ODP how to operate the SAFERsleep™ system and the philosophy behind its design. This briefing will also reinforce specified key points related to the use of simulation, details of the study, format of the study day and the tests used.
An introductory simulation scenario will then follow which will allow you to familiarise yourself, and the participating ODP, with the simulation environment. An

educational debrief will follow this scenario, which will allow for additional feedback on simulation behaviours and on the optimal use of the SAFERsleep™ system.

You and the participating ODP will then be asked to complete together two standardised highly scripted simulated anaesthetic scenarios (Scenario A and Scenario B). For each simulation there are two possible states: Intervention (in which the SAFERsleep™ system will be used) and Control (using conventional methods). These states will be allocated randomly between the two scenarios with stratification for time of day (morning/afternoon).

Before beginning the first study scenario you will be asked to complete a NASA Task Load Index (TLI) questionnaire. During the study period you will be asked to complete a Vigilance Latency Task (VLT), this involves acknowledging the illumination of a small, bright light on the anaesthetic machine at 9 to 14 minute random intervals and yields an index of an anaesthetist's vigilance and spare work capacity. In this study a Personal Digital Assistant (PDA) with a touch screen will be used for this task, and the response will involve touching the device's screen. At 7 to 15 minute random intervals, psychological workload will be measured with the Borg Workload Scale both by the observing researcher and by yourself. This will involve the researcher asking you to verbally rate your work load scale at that particular time.

At the end of the procedure you will be asked to complete another NASA Task Load Index questionnaire and use visual analogue scales (VAS) to rate the physical and mental demands of the previous anaesthetic and specific components of the new system and comparable conventional alternatives.

All scenarios will be video recorded and will form part of the data collection for the study, the Video recordings will also be used during the educational feedback to allow reflection on practice and behaviours observed during the simulation. The educational debrief will be video recorded to highlight any themes that need further exploration within the semi-structured interviews and focus groups.

At the end of the study period you will be invited to take part in a semi-structured interview, to allow deeper understanding of the impact the introduction of technology can have on anaesthetists and ODPs working practice and the effect

(good and bad) on patient safety. You may also be invited to take part in a Focus group to be held in the University Department of Anaesthesia, Nottingham. Lunch and refreshments will be provided during the research scenarios study day and all reasonable travel expenses will be paid to allow you to attend the research scenario study day, interview and focus group.

What are the possible disadvantages of taking part?

There should be no disadvantages of taking part in this study. However, it will involve attending the Trent Simulation & Clinical Skills Centre for half a day, an interview for one hour and attending a focus group, which would be a maximum of one and a half hours.

What if some aspect of my practice is observed that causes concern?

Simulated scenarios are designed in a way that mistakes are likely to occur. The occurrence of such mistakes and the underlying predisposing factors form the basis of the subsequent debriefing session. Very occasionally practice may be observed that could potentially cause serious patient harm if this occurred in clinical practice. Once again such a witnessed occurrence would be discussed, as part of the debriefing process, following the scenarios (aided by the use of video). This will allow clarification of any issues highlighted and provide an opportunity for us and you to gain insight into your demonstrated practice.

If the debriefing fails to acknowledge insight into potentially harmful practice the matter would be discussed further with the Chief Investigator and the Director of the Trent Simulation & Clinical Skills Centre. In the unlikely event following this discussion it is felt the issue in question raises potential concerns about future clinical practice it will be discussed with the head of service (for Consultant Anaesthetists) or Educational Supervisor / Training Programme Director (for Anaesthetic Trainees). This would be done with your full awareness and involvement.

These measures follow the defined protocol of the Trent Simulation and Clinical Skills Centre for managing such situations, in the interest of patient care and safety.

What are the possible benefits of taking part?

There is no direct benefit of taking part in terms of material gain. However there is the possibility of indirect benefit through working in the hi-fidelity simulation environment of the Trent Simulation & Clinical Skills Centre, participating in feedback allowing the opportunity to verbalise and reflect on your experience of participating in the simulated scenarios, as well as the potential for an increased awareness of patient safety issues.

Will my taking part in this study be kept confidential?

If you chose to take part in the study, all information which is collected about you during the course of the research will be kept strictly confidential. Nothing you say will be read by anyone other than the research team. Names will not be written on the transcripts and you will be anonymous in any written or verbal reports on the research. All information generated by this study will be archived securely within the Division of Anaesthesia, University of Nottingham and destroyed 7 years after the study is completed.

Representatives of regulatory authorities and authorised people from the University of Nottingham and the Nottingham University Hospitals NHS Trust may inspect the data to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. However all data collected during the simulation, from the interview and the focus group will still be used in the final analysis.

What if there is a problem?

The occurrence of any problems as a result of participation within this study is not expected.

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. Any distress caused through participating in the study scenarios will be addressed using facilitated debriefing; this process is standard policy within the Trent Simulation and Clinical Skills Centre. If you still have concerns following this process we would encourage you to discuss the issues further with either your educational supervisor or a Consultant peer and a process of mentorship or counselling would be available should the need arise.

If you remain unhappy and wish to complain formally, you can so this through the NHS complaints procedure. You can complain orally or writing to the Nottingham University Hospitals NHS Trust. In the event that you are harmed during participation in this study there are no special compensation arrangements, the normal National Health Service complaints mechanisms will be available to you.

Contact details:

Please do not hesitate to contact one of us on the following phone numbers.

Professor Ravi Mahajan
Chief Investigator 0115 823 1009
(University Department of Anaesthesia)

Professor Bryn Baxendale
Co-Investigator 0115 9249924 Ext. 67095
(Director - Trent Simulation & Clinical skills Centre)

Mrs Rachel Evley
Trial Manager / Co-Investigator 0115 823 1004
(University Department of Anaesthesia)

What will happen to the results of the research study?

The findings of this study will also be presented to various national/meetings, along with publication(s) in medical journal(s).

Who is organising and funding the research?

The Chief Investigator for this study is Professor Ravi Mahajan and it is sponsored by the University of Nottingham. The study is funded by a grant from the Association of Anaesthetist of Great Britain and Ireland.

Who has reviewed the study?

This study has been approved by the Leicestershire, Northamptonshire and Rutland Ethics Committee 1. It has also been reviewed and approved by the Research & Development department at Nottingham University Hospitals NHS Trust.

Thank you for taking the time to read this information sheet. If you decide to take part you will be given a copy of the information sheet and a signed consent form to keep.

APPENDIX XII: Participant Information Sheet - ODP (Chapter 5)

University of Nottingham
School of Clinical Sciences
Division of Anaesthesia and Intensive Care
Queen's Medical Centre
Derby Road
Nottingham
0115 8231009

Operating Department Practitioner Participant Information Sheet

Validating Anaesthesia Simulation-based Error Research (the VASER study).

Introduction

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Please take the time to decide whether or not you wish to take part.

What is the purpose of the study?

Iatrogenic harm, often due to error, is a major public health problem, expensive in human and financial terms. There have been international calls for initiatives to reduce it, but evidence is needed to justify investment in such initiatives. From the viewpoint of human cost, error in healthcare (including anaesthesia) is unacceptably frequent, but for the purpose of demonstrating the benefit of safety interventions it is relatively uncommon; the number of anaesthetics needed for a clinical randomised controlled trial (RCT) to evaluate any safety intervention in

anaesthesia is therefore very large (even using surrogate endpoints such as errors rather than harm). A significant reduction of patient harm from any safety initiative in anaesthesia (even pulse oximetry) has never been demonstrated in a clinical randomised controlled trial. There are also considerable ethical, legal and practical difficulties in investigating safety initiatives in the clinical setting. High fidelity simulation offers an alternative which circumvents many of these difficulties by avoiding the possibility of actual harm to patients. In addition, a statistically powerful paired study design (the Design) for simulation-based randomised controlled trials has been created and tested in which complex scenarios make high rates of error likely, thereby making it easier to show a difference between groups with relatively small numbers of participants. Simulation RCT evidence could potentially be as compelling as clinical RCT evidence (and much less expensive to obtain) provided it can be shown that the conclusions of these approaches are equivalent. Few studies have examined this important question. In the Validating Anaesthesia Simulation-based Error Research (VASER) Study we will compare the conclusions of a large clinical trial with those of a simulation study designed to answer the same questions.

The problem of error in drug administration is particularly pressing in anaesthesia because of the many potent agents given during the relatively short period of an anaesthetic. A record of these drugs forms part of the overall anaesthesia record, an important clinical tool, medico-legal document and resource for audit (the value of which depends on its completeness and accuracy. In response to this problem, a safety initiative (SAFERsleep™) has been developed, designed to reduce drug administration error, facilitate safe practice and improve the quality of record keeping in anaesthesia. It is multifaceted and includes purpose designed drug drawers and trays, prefilled syringes with colour coded and bar-coded labels, a computer that “speaks” the name of each drug when its barcode is swiped, and an integrated automated record keeper (ARK). The SAFERsleep™ system is commercially available and in regular clinical use in within one Trust in the United Kingdom, and has also been used in well over 250,000 anaesthetics worldwide.

As for any safety intervention, evidence of its value or lack thereof is needed. To this end a substantial clinical randomised controlled trial of the SAFERsleep™ system vs. conventional methods of delivering anaesthesia has recently been completed at Auckland City Hospital, New Zealand. In the VASER Study we will compare the SAFERsleep™ system with conventional methods of anaesthesia using a specific research design to evaluate high-fidelity simulation as a research tool.

Why have I been chosen?

You are being asked to participate in this study because you are a qualified Operating Department Practitioner (ODP) working within the Specialist Support Directorate of Nottingham University Hospital's NHS Trust.

Do I have to take part?

No, it is up to you whether or not you decide to take part. In order to participate in the study, one of the requirements, in order to meet the inclusion criteria, is that you are willing to participate in a semi-structured interview and a focus group.
If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.
You are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

A member of the research team will discuss with you what will happen if you take part. After reading all this information and you decide to take part in this study, you will be asked to sign a consent form.

You will attend a morning or an afternoon at the Trent Simulation & Clinical Skills Centre, where you will complete, with a participating anaesthetist, three simulated study scenarios; one orientation scenario to allow familiarisation with the SAFERsleep™ system, and two study scenarios. Prior to attending the VASER study day you will be provided with pre-reading material.
At the beginning of the VASER study day we will show you and the participating anaesthetist how to operate the SAFERsleep™ system and the philosophy behind its

design. This briefing will also reinforce specified key points related to the use of simulation, details of the study, format of the study day and the tests used.
An introductory simulation scenario will then follow which will allow you to familiarise yourself, and the participating anaesthetist, with the simulation environment. An educational debrief will follow this scenario, which will allow for additional feedback on simulation behaviours and on the optimal use of the SAFERsleep™ system.

You, and the participating anaesthetist, will then be asked to complete together two standardised highly scripted simulated anaesthetic scenarios (Scenario A and Scenario B). For each simulation there are two possible states: Intervention (in which the SAFERsleep™ system will be used) and Control (using conventional methods). These states will be allocated randomly between the two scenarios with stratification for time of day (morning/afternoon).
Before beginning the first study scenario you will be asked to complete a NASA Task Load Index (TLI) questionnaire. At the end of the procedure you will be asked to complete another NASA Task Load Index questionnaire and use visual analogue scales (VAS) to rate the physical and mental demands of the previous anaesthetic and specific components of the new system and comparable conventional alternatives. Please be aware also, that during the study scenarios the anaesthetist you are working with will be interrupted by one of the researchers as part of the data collection.
All scenarios will be video recorded and will form part of the data collection for the study, the video recordings will also be used during the educational feedback to allow reflection on practice and behaviours observed during the simulation. The educational debrief will be video recorded to highlight any themes that need further exploration within the semi-structured interviews and focus groups.
At the end of the study period you will be invited to take part in a semi-structured interview, to allow deeper understanding of the impact the introduction of technology can have on anaesthetists and ODPs working practice and the effect (good and bad) on patient safety. You will also be invited to take part in a Focus group to be held in the University Department of Anaesthesia, Nottingham. Lunch

and refreshments will be provided during the research scenarios study day and all reasonable travel expenses will be paid to allow you to attend the research scenario study day, interview and focus group.

What are the possible disadvantages of taking part?

There should be no disadvantages of taking part in this study. However, it will involve attending the Trent simulation and clinical centre for half a day, the interview for one hour and the focus group, which would be a maximum of one and a half hours.

What if some aspect of my practice is observed that causes concern?

Simulated scenarios are designed in a way that mistakes are likely to occur. The occurrence of such mistakes and the underlying predisposing factors form the basis of the subsequent debriefing session. Very occasionally practice may be observed that could potentially cause serious patient harm if this occurred in clinical practice. Once again such a witnessed occurrence would be discussed, as part of the debriefing process, following the scenarios (aided by the use of video). This will allow clarification of any issues highlighted and provide an opportunity for us and you to gain insight into your demonstrated practice.

If the debriefing fails to acknowledge insight into potentially harmful practice the matter would be discussed further with the Chief Investigator and the Director of the Trent Simulation & Clinical Skills Centre. In the unlikely event following this discussion it is felt the issue in question raises potential concerns about future clinical practice it will be discussed with the Matron for Theatres Directorate. This would be done with your full awareness and involvement.

These measures follow the defined protocol of the Trent Simulation and Clinical Skills Centre for managing such situations, in the interest of patient care and safety.

What are the possible benefits of taking part?

There is no direct benefit of taking part in terms of material gain. However there is the possibility of indirect benefit through working in the hi-fidelity simulation environment of the Trent Simulation & Clinical Skills Centre, participating in feedback allowing the opportunity to verbalise and reflect on your experience of participating in the simulated scenarios, as well as the potential for an increased awareness of patient safety issues.

Will my taking part in this study be kept confidential?

If you chose to take part in the study, all information which is collected about you during the course of the research will be kept strictly confidential. Nothing you say will be read by anyone other than the research team. Names will not be written on the transcripts and you will be anonymous in any written or verbal reports on the research. All information generated by this study will be archived securely within the Division of Anaesthesia, University of Nottingham and destroyed 7 years after the study is completed.

Representatives of regulatory authorities and authorised people from the University of Nottingham and the Nottingham University Hospitals NHS Trust may inspect the data to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. However all data collected during the simulation, from the interview and the focus group will still be used in the final analysis.

What if there is a problem?

The occurrence of any problems as a result of participation within this study is not expected.

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions.

Any distress caused through participating in the study scenarios will be addressed using facilitated debriefing; this process is standard policy within the Trent Simulation and Clinical Skills Centre. If you still have concerns following this process we would encourage you to discuss the issues further with the Matron for Theatres Directorate, a process of mentorship or counselling would also be available should the need arise.

If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. You can complain orally or writing to the Nottingham University Hospitals NHS Trust. In the event that you are harmed during participation in this study there are no special compensation arrangements, the normal National Health Service complaints mechanisms will be available to you.

Contact details:

Please do not hesitate to contact one of us on the following phone numbers.

Professor Ravi Mahajan 0115 823 1009
Chief Investigator
(University Department of Anaesthesia)

Professor Bryn Baxendale 0115 9249924 Ext. 67095
Co-Investigator
(Director - Trent Simulation & Clinical skills Centre)

Mrs Rachel Evley 0115 823 1004
Trial Manager / Co-Investigator
(University Department of Anaesthesia)

What will happen to the results of the research study?

The findings of this study will also be presented to various national/meetings, along with publication(s) in medical journal(s).

Who is organising and funding the research?

The Chief Investigator for this study is Professor Ravi Mahajan and it is sponsored by the University of Nottingham. The study is funded by a grant from the Association of Anaesthetist of Great Britain and Ireland.

Who has reviewed the study?

This study has been approved by the Leicestershire, Northamptonshire and Rutland Ethics Committee 1. It has also been reviewed and approved by the Research & Development department at Nottingham University Hospitals NHS Trust.

Thank you for taking the time to read this information sheet. If you decide to take part you will be given a copy of the information sheet and a signed consent form to keep.

APPENDIX XIII: Participant Consent Form (Chapter 4)

Hospital Headed Note Paper

Study Number:

CONSENT FORM

A multi-centre qualitative study to evaluate the process of double-checking of drugs administered during anaesthesia in order to reduce the risk of drug errors and improve patient safety.

Researchers: Professor Ravi Mahajan
Ms Beverley Norris
Mrs Rachel Evley

Please write your **initials** in each box

1. I confirm that I have read and understand the information sheet (version **1** dated **21st February 2008**) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I understand that if I participate in the Focus Group it will be tape recorded but that I can refuse to answer a question if I wish and leave the focus groups at any time without having to give an explanation. ☐
4. I understand that all information will remain strictly confidential. ☐
5. I agree that all information collected about me as part of the study can be stored and analysed by the research team at the Division of Anaesthesia, University of Nottingham. ☐
6. I understand that small parts of what I say may be quoted anonymously when the results of the research are reported. ☐
7. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Researcher	Date	Signature

APPENDIX XIV: Participant Consent Form (Chapter 5)

CONSENT FORM

Validating Anaesthesia Simulation-based Error Research (the VASER study).

Researchers: Professor Ravi Mahajan
Professor Bryn Baxendale
Mrs Rachel Evley

Study Number: _____

Please write your **initials** in each box

8. I confirm that I have read and understand the information sheet (version **2** dated **3rd August 2009**) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

9. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that information may still be used in the project analysis. ☐

10. I understand that all data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to me taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

11. I understand that the simulation scenario will be video-recorded and used in the debriefing session for educational purposes and in the analysis of the study. ☐

12. I understand that if I participate in a semi-structured interview or the Focus Group they will be tape recorded, but that I can refuse to answer a question if I wish and leave the interview or focus group at any time without having to give an explanation. I understand that small parts of what I say during the interview or the focus group may be quoted anonymously when the results of the research are reported. ☐

13. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

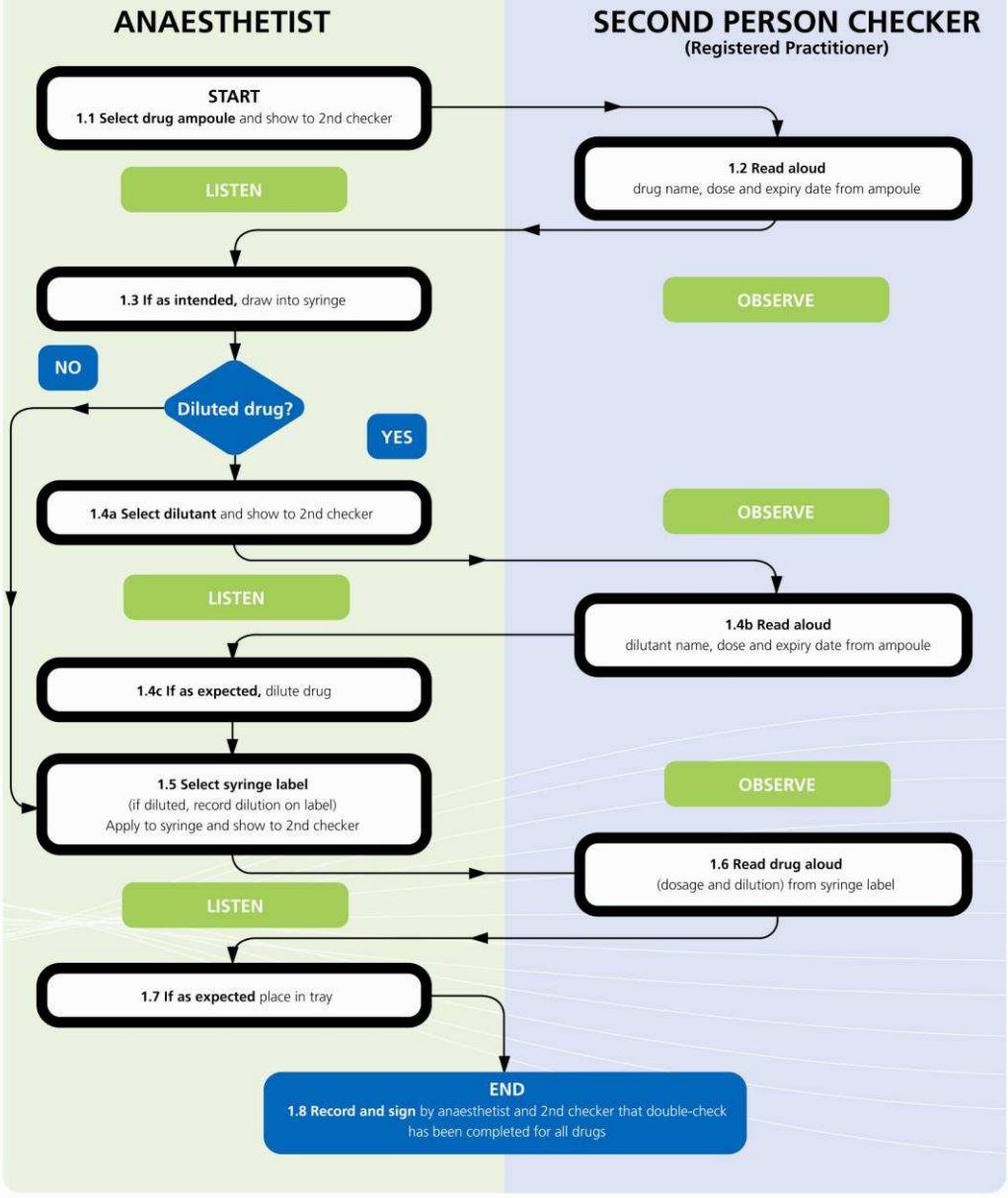
APPENDIX XV: Flow Chart – Double Checking Process for Drug Preparation (Chapter 4)

The Royal College of Anaesthetists

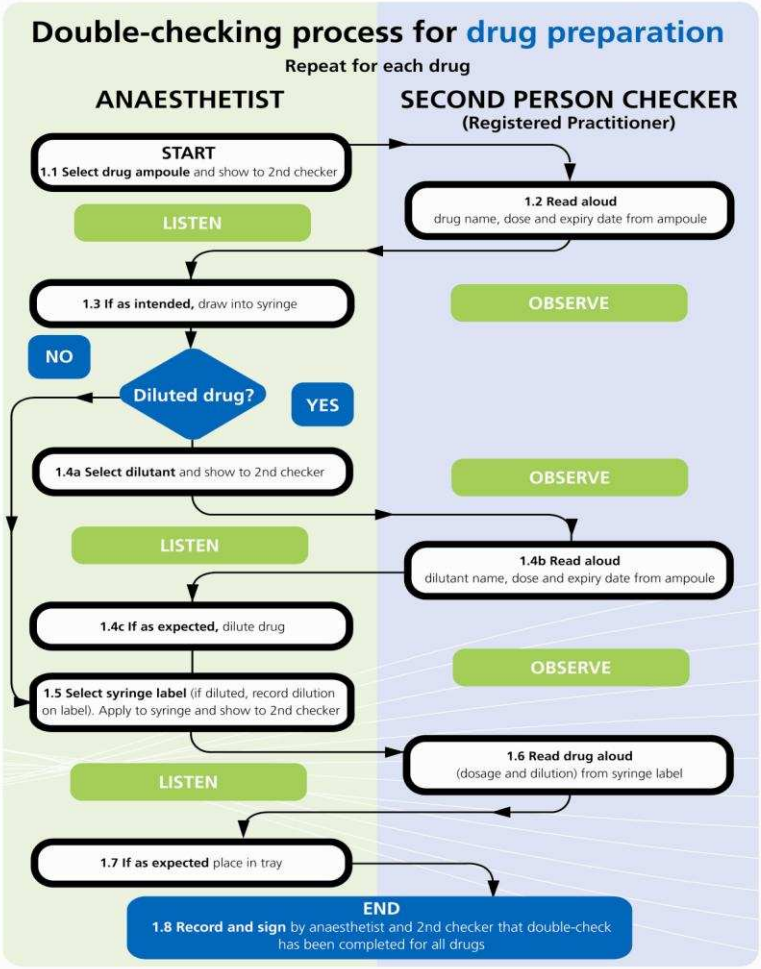
NHS National Patient Safety Agency
National Reporting and Learning Service

Double-checking process for drug preparation

Repeat for each drug

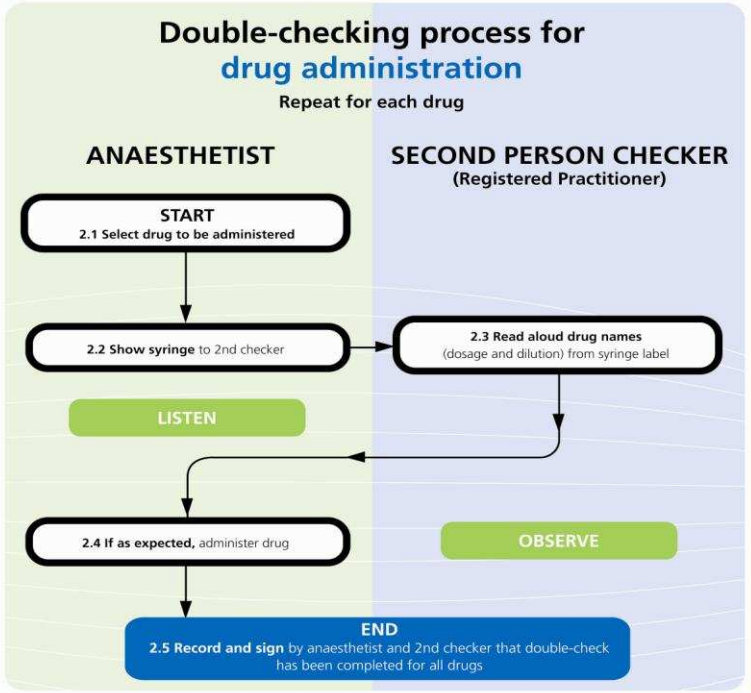


APPENDIX XVI: Flow Chart – Double Checking Process for Drug Preparation and Administration (Chapter 4)



The Royal College of Anaesthetists

NHS
National Patient Safety Agency
National Reporting and Learning Service



APPENDIX XVII: Error Questionnaire - Participants (Chapter 5)

VASER error questionnaire

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. Drug errors are common in anaesthesia	1	2	3	4	5
2. Drug errors can cause significant harm in anaesthesia	1	2	3	4	5
3. Drug errors that are caught and corrected do not need to be reported	1	2	3	4	5
4. Failing to record a drug given during an anaesthetic is a medication error	1	2	3	4	5
5. My thoughts or actions are commonly influenced by the risk of medication error during my anaesthetic practice	1	2	3	4	5
6. Inadvertent administration or failure to administer medication, that has no immediate potential to harm the patient, should be recorded as an error	1	2	3	4	5
7. Anaesthetic records should be computerised	1	2	3	4	5
8. New technology will prevent drug errors in anaesthetic practice	1	2	3	4	5
9. I have previously used computerised record keeping within anaesthesia	1	2	3	4	5
10. The introduction of new technology will have a positive impact on my future anaesthetic working practice	1	2	3	4	5
11. Whenever feasible, all drugs for parenteral administration should be supplied in pre-labelled and pre-filled syringes	1	2	3	4	5
12. On the balance of probabilities, technology, such as SAFERsleep™, would reduce syringe swap errors occurring	1	2	3	4	5

APPENDIX XVIII: Error Questionnaire – Non Participants (Chapter 5)

VASER error questionnaire

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. Drug errors are common in anaesthesia	1	2	3	4	5
2. Drug errors can cause significant harm in anaesthesia	1	2	3	4	5
3. Drug errors that are caught and corrected do not need to be reported	1	2	3	4	5
4. Failing to record a drug given during an anaesthetic is a medication error	1	2	3	4	5
5. My thoughts or actions are commonly influenced by the risk of medication error during my anaesthetic practice	1	2	3	4	5
6. Inadvertent administration or failure to administer medication, that has no immediate potential to harm the patient, should be recorded as an error	1	2	3	4	5
7. Anaesthetic records should be computerised	1	2	3	4	5
8. New technology will prevent drug errors in anaesthetic practice	1	2	3	4	5
9. I have previously used computerised record keeping within anaesthesia	1	2	3	4	5
10. The introduction of new technology will have a positive impact on my future anaesthetic working practice	1	2	3	4	5
11. Whenever feasible, all drugs for parenteral administration should be supplied in pre-labelled and pre-filled syringes	1	2	3	4	5
12. I would welcome the addition of new technology in anaesthetic practice which is designed to reduce the chance of medication errors.	1	2	3	4	5

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