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Improving Safety in High Workload Environment

By

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Abstract

Background: Recent advances in medical technology, primarily in the anaesthetic and operating rooms, has influenced a change of workload from being just a physical dimensional element to a mental dimensional component also. Evaluations of anaesthesia workload dimensions have become a necessity due to the ever-changing and complexity of such workplace environments, and most essentially, the need for patient safety.

Aim: This project aims to explore techniques for improving the safety of high workload anaesthetic environments.

Methods:

1) Two systematic reviews were performed: the theoretical framework and supporting data for currently used mental workload assessment tools in the anaesthetic environment; conflict resolution interventions for the improvement of patient safety through understanding and applying/teaching conflict resolution skills.
2) Two observational studies were completed: drug preparation and handling within operating theatres using a novel drug tray; actions and decisions involved in routine and complicated airway management was undertaken.

Results and conclusion:

The most commonly applied and best evidenced measurement tools for workload are self-reported measures. The Borg rating scale was the most commonly used method and showed a consistent association with expected variations in workload. Correlation between self-reported and observed rating was moderate to good.

The overall underlying theme for present educational programs is the enhancement of healthcare professional's ability to speak up and to positive confidence to challenge their superiors in a positive and effective manner when patient safety is a concern.

However, the evidence for training to improve conflict resolution in the clinical environment is sparse.

The Rainbow trays were perceived as likely to reduce drug errors and improve patient safety. Additionally, there was an overall preference for this novel system at all three sites, as they were easy to use and effective. However, there were some limitations to the feasibility of use; related to design and placement. Participants felt some compartments within the Rainbow trays needed to be made larger and there were issues around the best place to place the tray when in use within the operating room.

There were differences in airway practice and preparation between participants. The decisions were primarily made by the lead consultant anaesthetist, with the trainees and ODPs supporting these decisions. A lot of the team communication used code language, but the teams worked well together and this did not appear to cause any problems in the context of routine airway management. Most of the experienced lead consultant anaesthetists rely on their past experience of "work-as-done" during the airway process.

This thesis has shown that it is necessary to continue exploring the approaches to improve safety in anaesthesia environments. In addition, the results from this thesis illustrated that human factor, non-technical, skills are important for ensuring safe, high-quality intraoperative care.

Declaration

I declare that the author has written the present thesis and that the work has not been presented for any other degree or professional qualification. I also declare that the work submitted is my own, except where parts which has jointly authored publications has been included.

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Dedication

To my dearly beloved Dad and Mum,

To my precious brothers and sisters,

To my wonderful supervisors,

I dedicate this work

Published papers arising from the thesis

1. Almghairbi, D., et al., An observational feasibility study of a new anaesthesia drug storage tray. Anaesthesia, 2018. 73, 356–364
2. Almghairbi, D.S., T.C. Marufu, and I.K. Moppett, Anaesthesia workload measurement devices: qualitative systematic review. BMJ Simulation and Technology Enhanced Learning, 2018: p. bmjstel-2017-000263.
3. Almghairbi, D.S., T.C. Marufu, and I.K. Moppett, Conflict resolution in anaesthesia: systematic review. BMJ Simulation and Technology Enhanced Learning, 2018: p. bmjstel-2017-000264.

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1. The second Midlands Academy of Medical Sciences Research Festival was on 31st March 2017 at Warwick University.
2. Division of Clinical Neuroscience Research Day 26 April 2017 at university of Nottingham
3. The third Midlands Academy of Medical Sciences Research Festival: 23 March 2018 Loughborough University.
4. Division of Clinical Neuroscience Research Day: 17 April 2018 University of Nottingham

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List of abbreviations

UK	United Kingdom
NHS	National Health Service
DOH	Department of Health
QHCAC	Quality of Health Care in America Committee
IOM	Institute of Medicine
AOWM	An Organisation with a Memory'
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
HCC	Healthcare Commission
FGH	Furness General Hospital
NMC	Nursing and Midwifery Council
NAPs	National Audit Projects
NAP_4	National Audit Project 4
NAP_5	National Audit Project 5
RCoA	Royal College of Anaesthetists
DAS	Difficult Airway Society
ICU	Intensive care units
AAGA	Accidental awareness during general anaesthesia
AAGBI	Association of Anaesthetists of Great Britain and Ireland
HSIB	Healthcare Safety Investigation Branch
GMC	General Medical Council
AIMS	Australian Incident Monitoring Study
NTS	Non-technical skills
SA	Situational awareness
ODPs	Operating department practitioners
PIS	Participant information sheets
REC	Research ethics committee
R&D	Research & Development
GCP	Good Clinical Practice
HEI	Human Error Identification
HRA	Human Reliability Assessment
HTA	Hierarchical Task Analysis
SHERPA	Systematic Human Error Reduction and Prediction Approach
MeSH	Medical Subject Headings
IM	Iain Moppett
DA	Dalal Almghairbi
TM	Takawira Marufu

NASA-TLX	NASA Task Load Index
HR	Heart rate
HRV	Heart rate variability
LS	Lisa Sharp
SG	Shashi Gupta
RE	Rachel Evley
PTSD	Post-traumatic stress disorder
CDM	Critical Decision Method
WHO	World Health Organisation
NMB	Neuromuscular-blocking drug
IQR	Interquartile range
ECG	Electrocardiogram
BIS	Bispectral index
TIVA	Total intravenous anaesthesia
ETT	Endotracheal tube
LMA	Laryngeal Mask Airway
TCI	Target controlled infusion
IV	Intravenous
TOF	Train-of-four
ASA	American Society of Anaesthesiologists
ACGME	Accreditation Council for Graduate Medical Education
PICO	Population, intervention, comparator, and outcome
SIGN	Scottish Intercollegiate Guidelines Network
CRM	Crisis resource management
TeamSTEPPS	Team Strategies and Tools to Enhance Performance and Patient Safety
mAIS	modified Advocacy-Inquiry Score
T-TAQ	TeamSTEPPS Teamwork Attitudes Questionnaire
ACRM	Anaesthesia crises resource management

CHAPTER 1

Introduction

1.1 Patient safety in the last 20 years

1.1.1 Background

In the United Kingdom (UK), improving patient safety continues to be a significant challenge for the National Health Service (NHS). In the April 2016– June 2017 edition of the Patient Safety Update by NHS improvement, it was reported that nearly 1,378,144 complaints related to patient safety in acute and general hospitals [1], and from January-March 2017 alone, approximately 76,621 patients experienced some form of adverse event [1]. These incidents might be reduced if practitioners learned more from past incidents. Indeed, there is considerable literature indicating that certain incidents are sometimes repeated, such as providing inadequate information or clinical details to patients regarding diagnosis and drug errors or failing to record this information, thereby leading to in-hospital errors and accidents. Healthcare staff must consider how much the healthcare system can be improved through efforts to prevent avoidable harm to patients, such as decreasing drug errors, improving recovery, and reducing patient hospitalisation.

According to the Department of Health (DOH), the cost of hospitalisation from adverse events is around £2.5 billion per year [2]. Furthermore, medication errors impose a considerable financial burden on the NHS (around £0.5bn to £1.9bn per year) [3, 4] compared to its total income. It is crucial to point out that these figures are amalgamates of various periods and data sets. As such, it is difficult to know whether they are accurate. Nevertheless, even if only half are correct, they are enough to suggest the necessity of more thorough investigation of the problems of the UK healthcare system.

1.1.2 UK and USA key documents

1.1.2.1 New NHS modern dependable

The UK has prioritised improvement of patient safety over the last few decades. In December 1997, the government published a white paper ('New NHS: Modern, Dependable') detailing how it intended to alter the way in which the NHS operated by facilitating comparison of performance and sharing best practice between different sectors of the service. The white paper aimed to "elucidate the how the UK Government will build a modern and dependable health service fit for the twenty-first century" [5]. The NHS in this regard, thereby making such information accessible to the general public, healthcare professionals, and hospital managers to improve the outcome of healthcare system [5]. It was clear the NHS needed to change, and the strategies outlined in the white paper delivered the means to provide better and safer healthcare for patients across the UK. Nevertheless, such changes were difficult, as the costs of operating a modern and flexible healthcare system were considerable.

1.1.2.2 To Err is Human

The report ''To Err is Human: building a safer health system'' issued in 2000 which followed by the formation of the Quality of Health Care in America Committee (QHCAC), within the Institute of Medicine (IOM) [6]. The aim of IOM increased awareness of USA medical errors. This report was based on large studies and concluded that between 44,000 and 98,000 patients' die each year due to preventable medical care incidents [7].

The IOM was an independent, private sector body that called for a comprehensive plan to which health care professionals, leaders, government, and consumers can minimise and prevent errors which have already occurred.

The outcome of the report had a huge influence on the management of healthcare. For instance, the literature shows that there has been a considerable increase in the number

of research into patient safety after the publication of IOM [8]. In addition, the report brought the issues of medical errors and patient safety to the front line of national concern.

Generally, To Err is human raised awareness of the degree to which errors relating to patient safety are a significant problem and described that most of these errors were not rare. However, it only required a broad plan to diminish. As a result of this report a minimum goal of 50% reduction in error were suggested for next 5 years [8].

1.1.2.3 Organisation with a Memory'

In 2000, the report 'An Organisation with a Memory' (AOWM) was published. AOWM highlighted the fact that there were few statistics on patient harm at that time. Perhaps most interestingly, AOWM highlighted that the NHS had learnt little from system failures in the past. The report went on to make some useful recommendations, such as the establishment of an independent system for recording and learning from adverse events to prevent similar events from occurring in the future through reduction of various risk factors, all of which were endorsed by the government [9]. Indeed, the report led the government to establish the National Patient Safety Agency (NPSA) in 2001, which in turn created the National Reporting and Learning System (NRLS) in 2003. The NRLS allows for the summarising of data on NHS incidents, which can provide greater understanding of what makes patients suffer. This will be discussed in greater detail in the proceeding sections.

1.1.2.4 The Five Year Forward View'

The recent government publication, 'The Five Year Forward view' [10] is a step forwards from the preceding white paper, outlining a five-year strategy for the NHS [10]. Its aim is to identify the healthcare and healthcare system that is most desirable to the UK population and how this should be achieved by 2020. Various stakeholders including

patients, healthcare professionals, and the government were involved in consultations on this report and contributed to its relatively ambitious proposals for improving the healthcare system in the future. This agenda includes giving patients, their relatives, and caregivers more authority in their treatment and the choice of where to go for treatment. This will give patients the opportunity to see clinicians more than once, which would provide greater support for people with multiple conditions. Such changes will no doubt lead to changes in the way medical care is provided and will help to ensure delivery high level of patient safety in any healthcare institution in the UK. Furthermore, this will ensure that individuals with multiple conditions are treated in a safe environment and protected from avoidable harm. Notably, all of these alterations will improve patient safety and general understanding of how to improve care quality in the NHS in the future.

Although it is believed that the 'Five Year Forward View' is possible, it remains under debate as to whether it will be achievable given the challenges the NHS is currently facing, such as the shortages of healthcare professionals and funding. Nevertheless, the Five Year Forward View has acknowledged some of these challenges, and the government has invested at least £8bn in support of the proposed changes. This plan will help to elucidate the recent areas of concern with regard to patient safety in the NHS.

1.1.3 Key Enquires influencing the patient safety agenda

1.1.3.1 Report of the public inquiry on children's heart surgery at the Bristol Royal Infirmary'

Not infrequently, NHS organisations experience adverse events leading to patient harm. When such events occur, it is important to avoid a blaming response; still, it is important to develop a drive among staff to decrease the risk of incidents for future patients, as noted in the aftermath of the 'report of the public inquiry on children's heart surgery at the Bristol Royal Infirmary'. This report was conducted between October 1998 and July

2001 by Professor Ian Kennedy and colleagues [11]. It was prompted by the high mortality rate of babies who underwent cardiac surgery at Bristol Royal Infirmary. The failure of the organisation to respond openly and constructively to the high death rate was noted. A key recommendation was that the NHS should promote openness and preparedness, accept mistakes, and to learn lessons from them. In addition the healthcare professional should also have a duty of sincerity to patients.

In June 2016, the new Bristol inquiry review on children's heart surgery was published [12] and comments 'In several ways, not much has altered in children's heart surgery since the first review'. Furthermore, the Kennedy recommendations have not yet been implemented in full and the NHS director described this as a 'stain on the soul of the speciality'.

1.1.3.2 The Francis report

In 2013, Robert Francis published a report with the aim of examining critical failures in the Mid Staffordshire NHS Foundation Trust between 2005 and 2009 [13]. This independent enquiry was written because the Healthcare Commission (HCC), then the NHS care regulator, was concerned about the high mortality rate at the Trust. Responding to complaints from patients and their families, it can be considered a step towards improving patient safety, the standards of care, and public confidence in the healthcare services in the UK.

The Francis report, as it came to be called, demonstrated that there was an extensive insufficiency in care at the Trust, including an overall shortage of effectual governance and a high number of clinical workers potentially involved in events at Stafford Hospital. Furthermore, it noted that a number of NHS hospitals failed to identify any problem with patient safety or to share information and concerns about such problems. This may have been the result of a failure in communication between individual workers and failures in the monitoring and supervisory systems at the national level, which are in place to secure

the quality and safety of patient care. Such failures may have cost these systems to lose their fundamental accountability to deliver high-quality and safe care. The Trust had an obsession with meeting Government-imposed targets without worrying about the consequences.

The Francis report makes hundreds of recommendations. Key messages include:

- Openness, transparency, and candour throughout the healthcare system.
- Performance management and strategic oversight of medical training and education and professional regulation of fitness to practice.
- Creating the right culture and putting patients first
- Better healthcare leadership

The Francis report recommendations were ultimately accepted by the government and those working in the NHS, pushing patient safety and high-quality care to the front of the agenda. It must be noted that the Francis report was unlike any inquiry in the past, many of which merely concentrated on the deficiencies of the Trust. In other words, it examined the process of authorisation and the supervisory and regulatory bodies' accountability to the Trust. Overall, the inquiry suggests that the government understands the need for fundamental reform of the healthcare system.

There is widespread agreement by healthcare professionals that information on the efficiency of services delivered must be more accessible, and the need for honesty, transparency, and openness has been generally acknowledged as important. The inquiry further suggests that frontline organisations need not wait for directions from superiors in order to improve themselves in this regard.

However, some of the report's recommendations proved to have little influence on the Trust [14];such as caring 'culture' across the NHS. This is perhaps due to the inherent complexity of the system and the understanding of the managing organisations within

the system, who are working under the considerable pressure of restricted finances, structural reform, and the increasing demand of patients.

Robert Francis in his updated version [15], confirmed that although good progress has been made in carrying out his original recommendations, the healthcare system has still not come up with adequate plans to create a culture supporting staff to speak out about concerns relating to patient care. This re-highlighted the urgent need for extra support to encourage better staff communication.

The Francis report was followed by several related reports, the most prominent being the Morecambe Bay Investigation report, which also has implications for the NHS.

1.1.3.3 The Morecambe Bay Investigation report

The Morecambe Bay Investigation report was performed to investigate the quality of care received by mothers and infants in the maternity unit at Furness General Hospital (FGH) and in hospitals to which these patients were moved between 2004 and 2013 [16]. This report was commissioned by the Secretary of State for Health after concerns were raised by families following a number of avoidable deaths and major adverse incidents among mothers and infants in that period. The results of the Morecambe Bay Investigation report suggested that the maternity unit at FGH was dysfunctional, which overall led to a number of serious errors that caused unnecessary deaths among mothers and infants. Based on these findings, the report proposed 44 recommendations, none of them ***directly*** relevant to patient safety in anaesthesia, for the MBHT, regulators and the NHS as a whole, with the aim of ensuring that staff are fully aware of these failures and to promote action to address them. MBHT has fully accepted the results and recommendations of the report, and has begun the important work of implementing all them [16].

In summary, in response to the Francis report, the 6Cs for Nursing were launched by NHS England [17]. They are a group of values that support “Compassion in practice” in clinical practice. It could be say that they are a vision and strategy for all health and health care staff. Each one of the 6Cs “care, compassion, competence, communication, courage and commitment” hold a similar weight and concentrate on putting the patient who is being cared for the heart of care that they are given. Overall, these indicate that the healthcare staff can build on responsibility to enhance the patient care and give them opportunity to take actions to make the 6Cs a reality for health care.

1.1.4 National Audit Projects

Another effort to improve patient safety in the UK is the Royal College of Anaesthetists’ National Audit Projects (NAPs) programme. The main purpose of the NAPs are to enhance the outcomes and safety of patients following anaesthesia and increasing awareness of current issues concerning anaesthesia, pain and critical care in different medical communities and hospitals. Below, I discuss the 4th, and 5th NAPs (NAP4, and NAP5, respectively), as these are relevant to this thesis.

1.1.4.1 NAP4

In 2011, the Royal College of Anaesthetists (RCoA) and the Difficult Airway Society (DAS) devised the 4th NAP (NAP4) [18]. NAP4 used a prospective study to identify all major airway incidents that occurred across the UK. This report revealed that nearly 3 million general anaesthetics were administered annually in the UK, and it specified the most common airway devices used. Each chapter contains a variety of learning points and recommendations, and seeks to provide motivation to make systemic alterations that can improve the safety of airway management in anaesthesia and intensive care departments in the UK.

The NAP4 has a specific chapter which reported the events that happened during induction and/or maintenance of general anaesthesia. One third of the 55 events were generally reported in patients who would be considered as a low-risk and so treated by trainees alone with minimal supervision. The review panel believed that the airway management of events was poor in a large number of reporting cases. The main focus of anaesthesia specialty teams should be on having good protocols in place to ensure the airway management is appropriate for all patients and any events reported must be treated and changed. Furthermore, this report also demonstrated the incidents that occurred in the intensive care units (ICU) which was 20% of all airway incidents in the report. It also mentioned that the degree of harm was much higher in comparison with those which occurred during anaesthesia or in the emergency department. The review groups reported that lack of advanced airway equipment and advanced airway skills, played a high part in some of the events reported and all led to avoidable patient harm.

Airway management incidents may lead to significant harm to patients, such as airway trauma or brain death/serious disability. Additionally, such complications are more likely to feature highly in adverse publicity or resultant litigation. This is important, as it points to the fact that anaesthetic departments must have explicit plans for the management of difficult or failed airway emergencies. Healthcare systems might encourage anaesthetists to utilise the recommendations of the NAP4, as they may prove to be effective in reducing airway incidents and ensuring patient safety.

In a summary, there are many findings in this project which are not new but this project has comprehensively reviewed most of the major complications or accidents related to safe airway management in anaesthesia, ICU and emergency departments in the UK. Furthermore, it has yielded important information that has led to better understanding, new recommendations, and changes in clinical practice.

1.1.4.2 NAP5

The 5th NAP (NAP5) examined accidental awareness during general anaesthesia (AAGA) which has been a major concern among patients and anaesthetists over several periods of time [19]. NAP5 was the result of collaboration between two major UK organisations in the field—the RCoA and the Association of Anaesthetists of Great Britain and Ireland (AAGBI). Moreover, NAP5 expanded beyond the UK into the Republic of Ireland.

The results of NAP5 are considered robust, given its extensive coverage and depth [20]. More specifically, this project obtained data from all public hospitals in the UK and Ireland, and provides details on numerous prospectively developed reports and performed a multidisciplinary structured analysis of the subjects and content of these reports. The report is similarly distinguished for its singular reliance on patient-reported experiences of the complications of general anaesthesia. Furthermore, it will likely influence institutional and individual training in anaesthesia. Therefore, it has implications for decreasing the number of errors leading to AAGA and improving awareness and handling of such errors where they do occur, to prevent any long-term influences on patients.

The report has reported that the majority of drug errors that occurred due to neuromuscular blocking occurred without prior anaesthesia. This led to awake paralysis which accounted for approximately 10% of reports to NAP5 and the side effects were usually severe. It is notable that one of the impacts of paralysis generating distress and long-term harm. The majority of these mistakes were found to be due to organisational and individual latent factors; such as syringes swaps of comparable syringes in size and appearance, poorly organised operating lists, distractions and hurriedness. Prevention of such events could be by improving drug labelling and packaging, developing a clear personal plan for medication preparation.

In summary, all of the NAPs are globally important reports that might have a significant influence on patients' outcomes and experiences of anaesthesia and surgery, as well as on the wider healthcare field. Furthermore, their data collection and analysis processes were of high quality. It has been suggested that future NAPs be extended to involve the independent sector and to include other countries (as the NAP5 did).

1.1.5 Reporting Errors

There are a number of important reasons for reporting adverse events. Reporting them can help in identifying the real issues namely, lacking crucial knowledge (which calls for better education); poor communication (which calls for improving communicative environments in hospitals to improve education); and malfunctioning risk assessment/care planning systems (which call for the improvement of those systems). Failures of these important systems are often the result of poor decision making between operators in the health service. Below, I discuss the NRLS, and the anaesthetic e-form, respectively, as these are covered the most of the major complications or accidents related to anaesthesia and found them relevant to this thesis.

1.1.5.1 National Reporting and Learning System

The NRLS allows for the summarising of data on patient safety incidents in England and Wales, which can provide greater understanding of what makes patients suffer. Moreover, researchers can obtain a good overview of what is occurring throughout the NHS and other healthcare systems.

This system currently receives around 1.4 million reports per year [21]; the majority of reports are from secondary care and include data regarding patient safety incidents. Health professionals and safety experts have used this data to identify the most frequent patient incidents, as well as opportunities to enhance patient safety solutions and clarify

directions for future research [22]. Therefore, it is likely to highlight areas of practice where further work is needed to decrease errors.

There were incidents 470,480 reported to the NRLS between January - March 2017 and 496,683 April-June 2017 [1]. Drug errors are a serious source of avoidable patient harm and are the third most common patient safety incident reported to the NRLS.[1], which accounted 48,537 from January to March 2017.

1.1.5.2 Anaesthesia e-form

The e-form has been collaboratively established and piloted by the NPSA, RCoA and AAGBI [23].

The anaesthetic e-form was created to continue to allow particular medical information relating to anaesthetic incidents to be reported by anaesthetists and all members of perioperative team. The main purpose of this form would be to further involve the anaesthetic team in reporting patient safety incidents. Any incidents reported in this manor, could then be effectively documented, the trends highlighted, and the number of future incident may be avoided. . In addition, the anaesthetic e-form is especially useful because delivers a mechanism by which high level of quality information can be rapidly reported by members of anaesthesia team and distributed transparently. Reviewing the number of incidents that were reported from October-December 2016 using the anaesthetic e-form, the most frequent type reported were: medication (1,304) and medical device/ equipment (838) [1].

Overall, healthcare is rife with the potential for error. The majority of NHS front line staff and managers recognise this and are attempting to limit this potential; as such, they should not, in general, be blamed for errors occurring in spite of their efforts. However, in return, healthcare system staff who must answer to the community must be open and honest when things go wrong, as this can help them learn from what has occurred. The

results of the Morecambe Bay Investigation report suggest that, at FGH, this contract was broken.

1.1.6 Summary

In summary, the above evidence indicates that there is prevalent acceptance and recognition of medical harm within the UK healthcare system as a key factor for enhancing patient safety and delivering high quality of care. Nevertheless, there are several barriers to successful learning from reporting these incidents. For instance, healthcare workers lack knowledge on what they should report, and fear the damaged reputation, blame, and charges of negligence accompanying reporting of an incident; furthermore, they may also lack understanding of what data to collect or even lack awareness that an error has occurred [24, 25].

Enhancing patient safety is seen as a unique challenge reliant on a number of activities that are as diverse as the work in the healthcare system itself and covers all aspects of the system, from basic medical care to the system as a whole, its policies, and the supervisors enforcing those policies. Indeed, building a safer organisational culture, connecting with patients, confirming regulatory policies, prioritising safety at the level of staff, and regularly measuring and monitoring safety all may be seen as key solutions to improving patient safety in any healthcare system. Such as the recent Healthcare Safety Investigation Branch (HSIB) [26] which has offered support and guidance to the NHS organisations on investigations. It has been set up to create recommendations on how the new Independent Patient Safety Investigation Service would work. This service could invite other professionals and bodies to cooperate and share experience to further ensure patient safety.

1.2 Patient Safety

In the last decade, there has been an increase in the number of reported adverse incidents due to healthcare errors with potentially harmful effects for patients. As already discussed, this has generated a number of reports by the government and medical professionals on the requirements for improving patient safety within current healthcare systems. Since then, substantial efforts have been made to enhance safety within the UK healthcare system, particularly by raising awareness of medical harm and by improving methods of identifying, measuring, addressing, and preventing potential hazards [27]. Indeed, the government, in its efforts to improve quality of care and treatment experience for patients, has made the assessing and monitoring of patient safety a top priority in its healthcare reform agenda [27].

In the UK, healthcare researchers are showing greater interest in the evolution of patient safety and its assessment and monitoring within the NHS. Smith *et al.* [28] proposed that the main aim of recording and analysing incidents is to improve patient safety by learning from harm, previous incidents, and near misses. This is consistent with previous research highlighting how collecting incident information is necessary for improving healthcare systems and minimizing errors in hospitals [3, 29]. However, despite the considerable numbers of care indictors of quality outcomes specified by the government, most approaches to patient safety have been rather limited thus far, which has left many areas of safety unexplored.

Vincent, in a recent study, found that harm assessment, which is a crucial method of determining patient safety, has been largely neglected by NHS workers [27]. However, he also acknowledges that the methods for measuring harm, such as mortality statistics or the NRLS of the NHS differ among healthcare organisations and researchers. However, Vincent [27] noted that current methods of assessing patient safety may not all be as straightforward as they might sound. Furthermore, the various models and

approaches to assessing patient safety utilised in healthcare are fairly narrow compared with other high-risk industries. For instance, accuracy in measurement of both processes and behaviour, which is perceived to be crucial in assessment of safety in other sectors, has received little attention in healthcare [30].

In contrast, one early study [31] reported that the various domains of the healthcare system have changed considerably for the better that is, the healthcare system is continually providing new technology, drugs, assessment tools for prognosis and treatment, and new treatments. Additionally, one of the most recent studies on the topic noted that using a barcode system reduces preoperative drug errors by 21% [32]. Thus, evaluation and monitoring of patient safety has likely dramatically improved in recent years.

Overall, safety in healthcare requires constant improvement in order to match the ever changing methods and technology used therein. To evaluate current ambiguities in research on patient safety, it is necessary to address a number of conceptual issues, such as how one should define safety and whether researchers should concentrate on harm, errors, or the wider context of accuracy and quality.

1.2.1 Defining safety:

Although several definitions of safety appear in the literature, there is no widely agreed definition. The NPSA has defined safety as: ‘a process by which organisations make patient care safer’ [33]. Another accepted definition is that of the IOM in 2000: ‘freedom from accidental injury’ [34] as a result of medical care or harm.

Two issues arise concerning the generalizability of these two definitions. First, the NPSA definition is hardly helpful, given that it uses ‘safer’ in defining safety; second, neither includes the concepts of avoidance or prevention of adverse events resulting from healthcare in their definitions.

The most recent definition of safety is that by Vincent: ‘‘the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare’’ [27]. This definition is perhaps suitable because it, at least indirectly, acknowledges the inherent danger of healthcare. In addition, Vincent’s definition is arguably more workable, and can be used as a starting point for deeper enquiry.

1.2.2 Factors influencing safety

A number of factors influence the safety and the quality of healthcare delivered to patients [27]; they can be broadly defined as structural (e.g., buildings, equipment, and the advancement in technology) and human resources (e.g., number and qualifications of staff) factors. Both types of factors can influence staff confidence and the operational environment [35]. Understanding the precise relations of these factors with patient outcomes can help in changing and improving such outcomes.

All of the above factors are considered basic characteristics of healthcare organisations, and they influence other aspects of the organisation such as a safety culture, and staff morale. All of these affect staff attitudes and behaviour [36], which in turn will probably affect clinical outcomes. The same factors have been identified in the construction industries as influencing safety performance and poor outcomes [37].

In addition to the structured and human resources factors and technological advancement, other contributory factors relevant to patient safety include teamwork, individual staff characteristics, the use of technology, and the external environment [27]. Although they may not directly influence safety, they are associated with perceived safety of an organisation and how safety might be enhanced in the future.

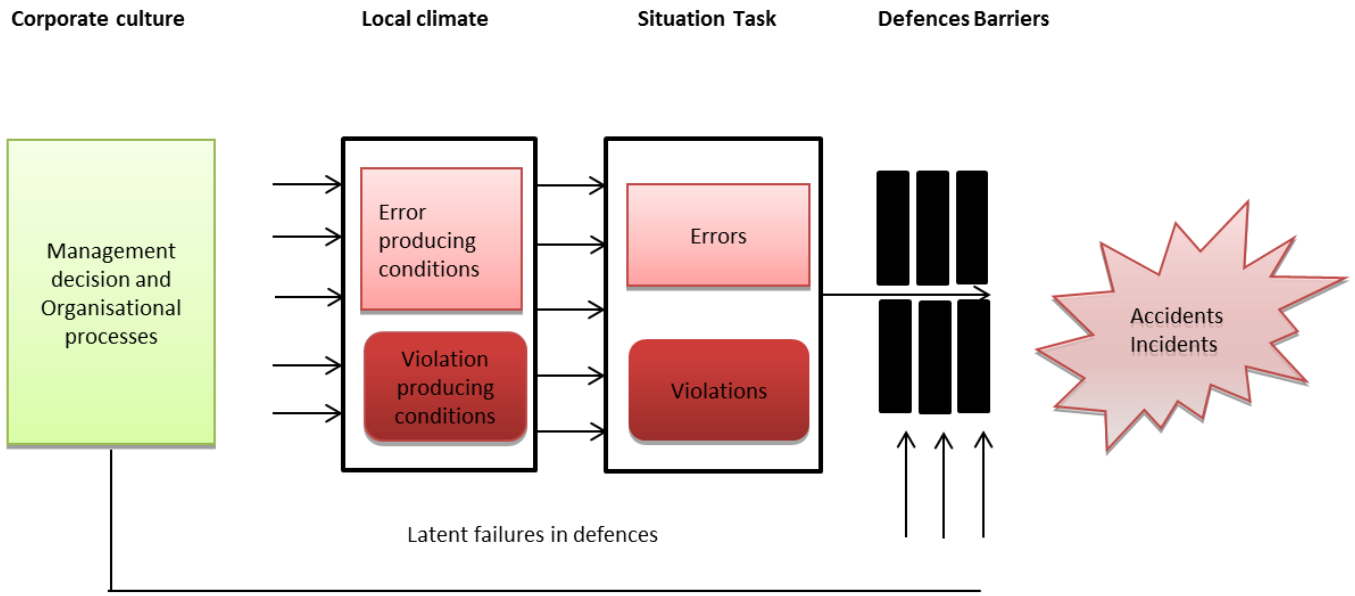


Figure 1: Adapted organisational accident causation model [38]

1.2.3 Human factors

As noted above, safe healthcare delivery is influenced by these factors. For example, given the complexity of anaesthesia and the environment in which it is performed, and the fact that anaesthetists are humans, one can safely conclude that errors will occur in the context of anaesthesia. Indeed, anaesthesia is often compared with other highly complex sectors, such as aviation and railways.

‘Human factors’ is also known as ergonomics [39, 40]. Indeed, the term 'ergonomics' has been used in the UK since 1950, whereas 'human factors' has been used in the US since around 1957. Non-English-speaking countries still primarily use the term ergonomics [40]. Wilson [41] noted that human factors/ergonomics is a multidisciplinary subject, which relies on knowledge from human sciences, psychology, organisational management, and design in order to support individuals’ performance and safety [39]. The main target of research on human factors in medical care systems is to support the mental and physical work of healthcare professionals and to promote high quality and safe care for patients.

Human factors can be essentially seen as anything influencing a healthcare operator’s execution of their duties. According to the Human Factors and Ergonomics Society, human factors refers to ‘environmental, organizational, and job factors, and human and individual characteristics, which influence behaviour at work in a way which can affect health and safety’ [42]. This definition is especially useful to my analysis because it allows me to view human factors in arguably the simplest way, by breaking it down into three parts; the job, the individual, and the organisation and how these parts influence individuals’ health and safety.

Catchpole and the Clinical Human Factors Group also provided a brief definition of clinical human factors: ‘Enhancing clinical performance through an understanding of the

effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities, and application of that knowledge in clinical settings'' [43]. This definition shows that the understanding and management of human factors concerns understanding of the interaction between operators, system elements, and the environment. Thus, addressing all three of these domains will contribute to improving the quality of healthcare and thereby patient safety. However, this will require action at multiple levels of the system and a good understanding of human limitations, and the workforce must be fully aware of the application of human factors in each aspect of clinical practice. In other words, the NHS must commit to comprehending the human factors in their staff as part of its routine work as well as when an incident occurs and requires investigation.

Overall, human factors are useful for exploring systemic problems by looking at the workforce in that system, operator's interference and their relationship between each other and the system. Furthermore, they can help in redesigning task performance, interventions, and the system as a whole. In other words, understanding human factors can provide both philosophically and practically valid methods for enhancing medical care.

The National Quality Board in the UK [44] has similarly noted that there are substantial advantages to considering human factors, more specifically that a wider understanding of the various principles and practices related to such factors will contribute significantly to improving quality of care for patients.

1.2.3.1 Contributions of human factors to accidents

Humans can contribute to or cause errors in a number of ways. A classification system of human errors was devised by Reason in 1995, which broadly grouped these errors into active and latent failures **Figure 2.** Both of these will be discussed in detail in the following sections.

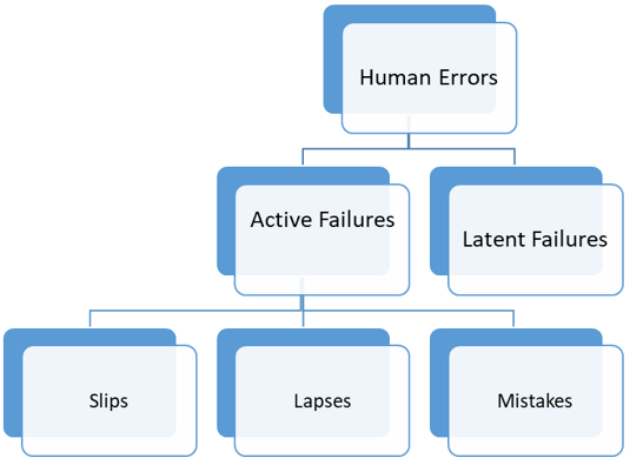


Figure 2: Types of human error [45]**.**

1.2.3.1.1 Active failures

Active failures are errors with immediate consequences. They are usually performed by frontline staff, such as healthcare professionals, drivers, and machine operators, and have a direct influence on health and safety. Reason divided them into subcategories of skill-based errors (i.e., 'slips' or 'lapses') and 'mistakes' and violations [43, 45].

Slips

Slips are the failure to perform an action as planned [45, 46]. They occur during performance of habitual tasks that require little or no conscious attention. Examples of

slips are when people incorrectly write the previous year just after a new year has begun, or when foundation doctors write ‘milligrams’ instead of ‘micrograms’. A variety of factors contribute to slips, including high workloads, multitasking, fatigue or lack of concentration. Glavin, in his review [47], pointed out that these factors are more likely to occur on on-call days, at the end of the working day, when staff are in an unfamiliar environment, and in departments with a shortage of staff. Anaesthetists work in an environment with high workloads and multitasks which could potentially lead to slips.

Lapses

Lapses, in contrast, may only be noticeable to those who make them. They result from memory failure: for example, when an operator forgets to carry out an action, or they lose their place in a task. According to a General Medical Council (GMC) study [48], lapses typically involve forgetting to write down necessary data or signing a prescription. The contributing factors to lapses are similar to those of slips [45, 46]. As such, clinicians can reduce the occurrence of lapses and slips by reducing distractions, providing operators with effective reminders, and by good design of equipment, drugs, and tasks. For example, in anaesthesia distractions are seen in some specific time as potentially harmful and they occur during drug preparation and administration; airway management and safe transfer to theatre [49].

Considering the above, there is a rather clear association between slips and lapses, which are together, termed ‘skill-based errors’, given that they occur during routine activities. Shifting now away from daily routine actions, I will talk about active failures in relation to managing new problems or challenges, or ‘mistakes’.

Mistakes

Mistakes are considered a more complex type of human error. In general, mistakes refer to actions that, while they might be going exactly as planned, the plan on which the action is based is not appropriate to achieve the desired outcomes. It can be argued that

mistakes only occur when a problem is identified. In this sense, a problem is considered anything that indicates a need to change the current plan of action. Mistakes can be further subdivided into rule-based and knowledge-based [45, 46]. Rule-based mistakes are the result of misapplication of rules or routines. Such mistakes often occur as a result of a lack of experience. For instance, a previous study [48] noted that the majority of errors in prescribing drugs are found among novice doctors. However, rule-based mistakes do not always occur as a result of inexperience: for instance, anaesthetists sometimes face emergency cases where administration of an emergency drug is required; such drugs are not a part of routine clinical use, and some of them require dilution (i.e., failing to dilute the drug). Additionally, the packaging of some drugs occasionally makes it difficult to identify the correct drug during emergency situations such as noradrenaline infusion.

In contrast, knowledge-based mistakes result from lacking knowledge of a rule or routine for a given action, and thus falling back on experience or first principles. In other words, such mistakes are not the result of a lack of particular facts or ideas. Such mistakes can also result from the misuse of appropriate knowledge during management of fixation mistakes.

Violations

Violations are defined as ‘intentional deviation from rules, procedures and regulations’. More specifically, in 1992, Reason [50] defined 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 systems’ and ‘deviations from safe operating practices, procedures, standards, or rules’. These definitions highlight how frontline workers are often considered responsible and are therefore blamed in the events of harm for the

prevention of standard direction by the system. Violations can be divided into three types [45, 46]: routine, situational, and necessary **(Figure 3)**.

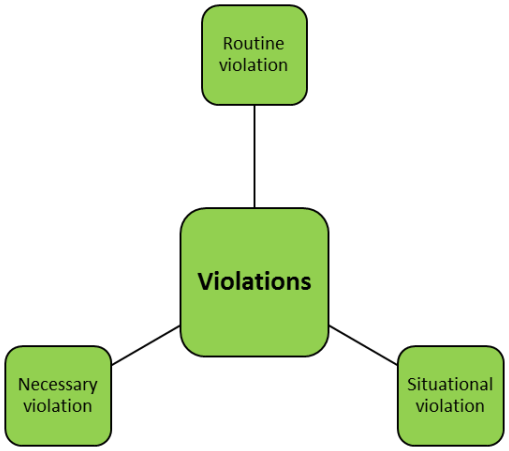


Figure 3: Types of violation [45].

Violations can be generally thought of as deliberate deviations from protocol and are seen as a crucial topic related to safety in high-risk fields such as anaesthesia. However, there are rather few studies in the healthcare field on violations [51], which may reflect a lack of knowledge and awareness of this subject. Amalberti *et al.* [51] noted that violations have been reported as underlying some major adverse events in healthcare. For example, one report described an incident involving five deaths due to a violation in Florida [52]. It is widely argued that the Australian Health Care Study offers the only available large scale data on healthcare violations; according to this study, only 4.8% of adverse events were due to violations [53-56].

Violations are observed in other industries aside from healthcare, including industries with very high safety standards such as aviation. One large study on air ground staff demonstrated that 'intentional non-compliance' made up 55% of all mistakes and violations [57]. Relatedly, Degani *et al.* [58] found that 50% of checklists on aircraft were not properly completed.

The absence of data on violations may be because the healthcare system has less defined rules compared with other high-risk fields. Another reason might be that most research on safety problems in healthcare have relied on information from incident reporting system. Such narrative data makes it difficult to accurately distinguish the incidence of errors from violations. Another possible reason is that reporting violations may open up operators to blames of negligence, even if they committed the violation without the intention to harm. Nevertheless, research in this area is necessary, given the fact that violations can be considered a serious source of hazards and are likely to become increasingly common as the healthcare system becomes safer.

1.2.3.1.2 Latent failures

Latent failures arise from the surrounding environment [43]; they are the inevitable 'resident pathogens' within the system. They are sometimes termed as 'factors or conditions' that result from decisions made by designers, builders, and top-level management. Latent failures are associated with two types of adverse event: namely, they can engender error-provoking conditions within the workplace (e.g. time pressure, excessive workload, fatigue, inadequate equipment, and a low level of experience), or they can cause long-lasting weaknesses in defences (e.g. untrustworthy alarms and indicators, unworkable procedures, and construction and design deficiencies) [59]. In other words, latent failures are the result of the total operating environment, or the location in which the accidents and incidents occur.

Latent failures differ from active failures in terms of their predictability, with the latter being more difficult to predict. Indeed, latent failures can be identified and addressed before they cause any adverse events. Thus, understanding these phenomena can lead to a more proactive, rather than reactive, approach to risk management.

1.2.3.2 System errors

Around 70–80% of incidents are believed to be related to human factors error [60-62]. However, in some cases, rather than blaming the operators, the systems are responsible for the errors. While Cooper *et al.* [63] reported that the vast majority of incidents involved human error, the Australian Incident Monitoring Study (AIMS) [64] found one quarter or so incidents were related to system failures. In total, almost one quarter of the total number of incidents was related to system deficiencies. Furthermore, studies of compound systems have indicated that more than 85% of incidents result from deficiencies in the layout and procedures of the organisation. For instance, NAP5 reported that drug errors occurred due to staff shortages and a pressure environment with busy list [43].

Before starting the operation, anaesthetists should think about the following questions: How can they create a technique that is less incident-prone? What are the barriers to errors? In essence, these questions are attempts to address systemic problems. The answers to these questions and past incidents in this system might be used to create scenarios that can be applied in the operating theatre to improve anaesthetists' performance.

Addressing system errors falls in line with the belief of some individuals that, although you cannot alter human nature, you can alter the workplace environment to minimize incidents. In summary, although one might argue that the main contributing factor to accidents in medical care is active failures, there is no doubt that system errors play a role in some incidents. Furthermore, it is likely that some system errors lead to active failures, which may mean that the system errors go unnoticed as they are attributed to the individual rather than the system. Indeed, discovering and addressing system failures is likely to have a greater influence on decreasing errors than merely reacting to active failures.

1.2.4 Safety Culture

Safety culture has been defined by NPSA as a willingness to report and learn from errors [65]. To create a safety culture, it is vital that NHS staff share a set of beliefs, attitudes, and perceptions in correlation to safety in the workplace. It is important because it is seen as a part of the organisational culture and found to be a key issue within an organisation. It has been suggested that a better safety culture can be promoted by the following points [65]

- Good leadership commitment to safety,
- Realistic practices for handling hazards,
- Continuous organisational learning,
- Care and concern for hazards shared across the workforce.

All of these can be achieved by the implementation of seven Steps to patient safety [66]. For instance,

Promote reporting any incidents that have occurred or prevented help, and encouraging staff to report patient safety incidents. The benefits of collecting incident reports contributes to improve patient safety and to enable effective management solutions. Furthermore, learning and sharing safety lessons can be a technique to analysis incidents. This could lead to the identification of sustainable solutions that might reduce the chance of the incidents occurring again.

1.3 Non-technical skills

As noted in the previous section patient safety in the operating theatre is significantly influenced by human factors [60]. Notably, previous studies have reported that about 70–80% of anaesthetic and surgical events are caused by human error [61, 62]. Working in the modern operating theatre is, at times, a highly stressful experience for anaesthetists, and it requires a high degree of competency in certain skills, requisite

knowledge, and certain attributes. Nevertheless, positive patient outcomes are likely to occur only when effective planning is performed. Such planning requires a unique set of skills, including situational awareness, decision-making, communication, and teamwork. These are known as ‘non-technical skills’ (NTS), and are believed to be crucial for improving operators’ technical skills. NTS have been studied throughout Europe, Australia, and North America [60], and there are several number of research on this topic in relation to anaesthesia. Poor NTS can increase the likelihood of mistakes as defined above , which in turn can lead to an increase in adverse outcomes [67]; conversely, good NTS can decrease the likelihood of errors and consequently of accidents.

1.3.1 Situational awareness

The term ‘situational awareness’ (SA) originated in the military, after which it expanded to aviation [68]. More recently, SA has been adapted to other environments, such as anaesthesia. Anaesthetists work in an environment wherein they must attend to numerous duties and sources of information (e.g. equipment, displays, and team members). As such, anaesthetists must be flexible and vigilant in their patient care by quickly orienting themselves to new information to make appropriate decisions; hence, patient safety heavily relies on anaesthetists’ SA, before, during, and after operations.

The most common definition of SA, used across many professional fields, is ‘the perception of the elements in the environment within a volume of time and space, the comprehension of their meaning and a projection of their status in the near future’ [69, 70]. There is, in addition, a more focused definition for healthcare staff working in the operating environment: ‘Developing and maintaining an overall dynamic awareness of the situation based on perceiving the elements of the theatre environment: patient, team, time, displays, equipment, understanding what they mean and thinking ahead about what could happen in the near future’ [71]. This latter definition regards the unit of analysis as not merely the providers (anaesthetists), but also the interaction of the

providers (anaesthetists) with their environment. It is crucial for anaesthetists to be aware of the features of management of the patient. To maintain greater SA, staff must constantly communicate and share ideas; this is seen as a fundamental step towards ensuring patient safety.

These definitions vary in terms of the importance they place on the process and outcome of SA. The process includes the workspace and nature of the interaction, whereas the outcome refers to improvement in their understanding of the circumstances of which they should be cognisant. I believe that these definitions are best combined, as they each have aspects that are crucial for a clear understanding of SA.

In a considerable number of fields, such as aviation and healthcare, SA is believed to help individuals to better comprehend the nature of the situations in which incidents or errors might occur in a highly complex environment. Shrestha et al. [72] found that it is important for operators to assume control of their environment, as this helps them address possible problems before they worsen. Controlling the environment means continuous monitoring of the setting, including noting what is occurring and any alterations in the environment. Another previous study has done by Mishra et al [70] concluded that SA in healthcare and other fields is useful in the planning of interventions and minimising diagnostic errors. SA can also be used as a guide for decision making [73, 74]; in anaesthesia, SA can help to increase safety outcomes by ensuring that anaesthetists, who must often work under considerable pressure or urgency (as in emergency cases), are able to make decisions with a full understanding of the situation. Elstein et al. [75] and Norman et al. [76] both suggest that application of the SA framework might help overcome some of the challenges faced in the application of current diagnostic decision-making models.

In contrast, poor SA in healthcare is associated with the occurrence of errors and incidents. Several studies have documented that poor SA is linked with reports of critical

incidents in anaesthesia and ICUs, and errors during laparoscopic surgery [73, 74, 77]. The outcomes of these reports showed that poor SA' was seen in bad outcomes, and is therefore presumed to be the cause, however, there is no information on relative risks when SA is 'good'.

In summary, SA can help anaesthetists obtain information from their surrounding environment to make sense of their work setting. Furthermore, incidents relating to SA are usually given as reasons for accidents or errors. Given the evidence above, SA should be included in the design and assessment of information systems, as it would enable anaesthetists to reduce error and maximise safety.

1.3.2 Decision-making

Decision-making is referred to as the process of making a judgment, sometimes termed a 'course of action', to meet the requirements of a given situation [78]. Decision-making involves a variety of techniques that are best utilised in certain situations. More specifically, decision-making is often dependent on the time pressure, task demands, available options, and the decision-maker's existing resources [78]. Research in high-risk sectors has identified three basic elements of decision making: 'problem detection', 'situation assessment', and 'choice of action' [79].

Although research on decision-making has spanned numerous industries, such as business, economics, and military, there is relatively little research relating to decision-making in anaesthesia. This is despite Fletcher et al.'s argument that decision-making is one of the most important NTS in anaesthesia [71]. Specifically, anaesthetists work in an environment wherein there are workers of varying levels of expertise, and judging how to communicate with individuals of each level of expertise, managing their own impressions, and selecting how to begin administering anaesthesia to the patient are all considered aspects of the decision-making process.

Clinical decision-making is a major challenge in the operating theatre, particularly because working in such an environment is often unpredictable and requires rapid situational assessment, urgent intervention, and effective communication. Decision-making must be rapid but as accurate as possible; failing to take note of accuracy can have important implications for patient safety. Some actions are easily decided on, such as turning a switch; others may be the result of experiential learning, such as managing mask ventilation and adjustment; sometimes, complex 'knowledge-based solutions' are required. Drawing a parallel from pilots' and surgical decision-making strategies, these three strategies can be described as intuitive, rule-based, and analytic and creative, respectively [79, 80].

The task environment can play a role in the decision making process. For instance, workplace environment problems can influence cognitive function namely, more complex environments correlate with higher cognitive function [81]. It can similarly be argued that the use of advanced equipment and computer-based diagnostic tools can sometimes add to the difficulty of the decision-making process. On the other hand, in another study, the complexity of an environment was found to correlate with the number of objectives, and the results indicated that fewer objectives and hence a less complex environment led to easier and more accurate decision making [82].

Drawing evidence from aviation and research in other safety professions, poor decision-making can result in major incidents. For instance, in aviation, almost all obvious accidents were related to a breakdown in crew communication and quick decision-making [83].

Overall, anaesthetists' decision-making practice should be studied to provide a more solid evidence base for teaching cognitive skills for the intraoperative environment. The considerable time pressure anaesthetists are often put under can make decision-making while seeking a positive outcome a far more complex and difficult process [84]. For

example, airway management requires rapid decision-making among all team members, which means that decision makers must take temporal alterations in the patient conditions into consideration. It must be noted that decision makers in safety critical environments hardly ever work alone; as such, it is especially important to consider the dynamics of team decision-making.

1.3.3 Communication

Communication in healthcare systems is a highly important factor for effective team functioning. Furthermore, it is fundamental for the management of emergencies, as its breakdown can compromise patient safety; similar results have been noted in other high-risk industries [6]. Communication, at least in healthcare, generally concerns the clear and precise exchange of patient-related information between team members. Effective communication is complete, obvious, brief, and timely, and can prevent negative patient outcomes. Inconsistency in team leadership, differences in communication style, distraction, and fatigue are all hurdles to effective communication [85]. Communication skills can help all group members, including leaders, work with others to achieve their goals or desired outcomes and come to an agreement [86]. In line with this, group work with better communication provides higher levels of patient care [87]. Furthermore, one of the most crucial steps that experienced team members must learn is to be open with other staff in the event of errors. Although this is not an easy task, not discussing what has gone or may go wrong can lead to repeating the same mistakes and preventing learning from mistakes.

Recently, the Joint Commission reported that about 82% of adverse events leading to mortality or morbidity occurred because of poor communication [88]. Additionally, research on the relationships among members of operating room teams found that nearly 30% of all observed incidents relating to communication could be classified as communication failures, and one-third of these failures threatened patient safety [86]. A

similar result was found in Kohn et al.'s IOM report 'To Err is Human' [6] namely, the most common source of errors is not a lack of clinical skills, but rather a failure of communication between team members.

1.3.3.1 Speaking up/out

Speaking up in the anaesthesia environment where rapid assessment and decision making, urgent intervention, and effective communication is vital because it is unpredictable.

In the literature, speaking up is defined as the raising of voice by healthcare providers for the benefit of patient safety and quality of care from any deficient actions from another member of the team in a practical environment. For instance, these actions include mistakes, lapses and rule breaking. In addition, Robert Francis suggested that speaking up can help to prevent human errors and improve technical and system deficiencies [89].

In healthcare environments, it has been shown that failures in speaking up between team members can occur for a variety of reasons. For instance, one study noted that a large number of anaesthesia providers in a given operating theatre environment usually led to inadequate communication between anaesthesia team staff [60]. Another reason might relate to concerns about being wrong or fears of retribution and embarrassment in front of others. Understanding the psychological barriers to speaking up is a crucial first step to improving teamwork and team communication. Another important step is changing the system such that operators are no longer blamed for their errors and encouraging team members to openly share their experiences when things go wrong. Ultimately, anaesthetists can accomplish effective communication (speaking up) by engaging in teamwork.

1.3.4 Teamwork

Fundamentally, delivery of healthcare relies on interdisciplinary team performance. Teamwork is defined as ‘Skills for working in a group context, in any role, to ensure effective joint task completion and team member satisfaction; the focus is particularly on the team rather than the task’ [60]. In other words, teamwork is the sharing of ideas and exchanging of information, as well as assessing capabilities and supporting others.

There is extensive research indicating that effective teamwork is important for achieving patient and workplace safety. However, the literature on patient safety has indicated that the healthcare system has largely limited its efforts to improve teamwork and there is currently a dearth of teamwork within and between disciplines [83].

There is a growing emphasis in a number of fields (e.g. aviation, healthcare, psychology) on the benefits of group work for flexibility and responsiveness among various specialists and experts [90-93]. These benefits may be due to the better ability of teams to explore different work styles, the opportunity for open discussion of varied opinions of group members, and a respect for the personalities and problems of other members [94].

Teamwork is an important means of increasing safety and minimising errors [83]. For instance, in aviation, teamwork is seen as a primary area for improvement [83], while the National Aeronautics and Space Administration has reported on the deficiency of human performance and the crucial role of effective teamwork. This report led to the adoption of crew resource management, which has been found to be an effective means of improving NTS [85], which are beneficial for flight safety [95].

In the context of the healthcare system, one survey indicated that more than 80% of medical staff believe that group work, including that outside of their own team, is an important part of increasing patient safety and minimising errors [83]. Teamwork is considered especially crucial for environments such as the operating theatre, where

anaesthetists must work in multi-professional teams in situations where any error can rapidly result in an adverse outcome for patients. Moreover, it has recently been reported that teamwork can help to reduce the negative effect of stress and fatigue between members [94]. It is not enough; however, to merely have anaesthetists work in a team rather, they must make efforts to continually perfect their teamwork, as a team of experts is not always an expert team.

Relatedly, poor teamwork has been associated with a greater number of medical errors [94]. This is likely the result of poor communication, a lack of role clarity, and an overall lack of preparedness among team members to function as a team. Conversely, good teamwork is associated with avoiding incidents, higher performance, and shortened operating times. In addition to better error management, effective teamwork has a number of other positive effects, such as fewer and shorter delays and increased job satisfaction and efficiency. Therefore, teamwork can have a positive influence on the success and functioning of an organisation.

In summary, within the literature from the last decade I have observed that attention from anaesthetists to the practice of NTS has been growing. This may be associated with the increasing attention paid to patient safety. An important point to note is that the common thread between the above NTS was communication. Several studies have demonstrated that communication is far more important than the other NTS, which may suggest that communication is an appropriate method of achieving high patient safety. One way of promoting communication among staff is by encouraging teamwork. However, it must be noted that communication can be influenced by a variety of factors, such as hierarchy, lack of confidence, and embarrassment of taking leadership; these factors can lead to a reduced discussion of plans and voicing of safety concerns.

1.4 Purpose/scope of the study

There has been a rising acceptance that the safe delivery of healthcare is influenced by the way in which individuals delivering it interact with their environment. In particular, anaesthetists work in an environment where human error, equipment failure and organisational conflicts can have catastrophic results. They are expected to perform effectively variant clinical conditions in both elective and emergency conditions and sometimes in a pressured environment [96, 97]. These issues can lead to significant negative impacts such as stress, fatigue and poor decision-making and errors in actions, resulting in increased health care costs, reducing patient safety and job satisfaction.

The elucidation of clinical workload can help improve understanding of anaesthetic care by defining and providing a more inclusive basis for improvement in the designing of anaesthetic equipment, better training, as well as improved decision-making and communication in demanding environments, and ultimately, for the safety of patients.

1.5 Aim of the thesis

The aim of this project is to explore techniques for improving safety in high workload environment. This will be achieved in four steps;

i. To conduct a systematic review of currently used mental workload assessment tools in the anaesthetic environment and the generation of a framework of normative data for future research.

ii. To explore the potential impact of a simple adjunct to drug preparation and storage on safe drug administration during anaesthesia. This will be done through an observational feasibility study of “a Novel Drug Storage Tray” in anaesthetic practice at three NHS Trusts.

iii. To explore the process of airway management during routine and complicated cases, to establish qualitatively when and why airway

management fails, and to develop a model of routine airway management and decision making using systematic reliability assessment tools. This will be done through a single centre qualitative study, using observational methods (video and audio recordings).

iv. To conduct a systematic review focused on conflict resolution interventions for the improvement of patient safety through understanding and applying/teaching conflict resolution skills that critically depend on communication and improvement of staff members' ability to voice their concerns.

Chapter 1, is overviewed of what has been done in the last 20 years with regard to patient safety in the UK, in particular the efforts to improve it, the reasons for these changes, and factors that affect safety. Furthermore, I explored the factors that influence the delivery of healthcare and the skills that anaesthetists require to operate in the highly stressful environment presented by modern operating theatres.

In this thesis, to comprehend in depth anaesthetists' perceptions and the feasibility of introducing methods aimed at increasing patient safety, job satisfaction, and incident reduction in high workload environment, I have employed qualitative methodology.

Chapter 2 will describe the methodology of this thesis, in particular the data collection approaches, for the research studies described in the following chapters 4, 5, 6 and.7.

CHAPTER 2

Research Methodology & Methods

2.1 Introduction

In this chapter, I will define qualitative research and discuss the theory behind the methodology used in the present research; specifically, I will focus on the strengths and weaknesses of qualitative research. This chapter also describes the research methods, such as grounded theory, that I selected for the collection and analysis of data. The chapter ends with a description of the principal subjects of my studies.

2.2 The nature of Qualitative Research

Qualitative research is a method used in social sciences to explore and understand the underlying reasons, opinions and motivations experienced by people in a given and/or varied set of circumstances. It uses a wide variety of techniques which Atkinson et al [98] describes as “an umbrella term for a number of methods sharing a broad framework, most of the methods have the same technique”. In the case of this, study particularly useful to explore healthcare system, organisation/s, ways of working and interactions between different health-care professional.

2.2.1 Defining qualitative research

To discuss qualitative methods it is important for the researcher to know and understand its definition, because of its potential differences. However, Ritchie et al [99] argued that providing an accurate definition of this term is no mean accomplishment. Strauss and Corbin broadly defined qualitative research as ‘any type of research that produces findings not arrived at by statistical procedures or other means of quantification’ [100]. Furthermore, Denzin and Lincoln defined qualitative research as ‘multimethod in focus, involving an interpretive, naturalistic approach to its subject matter’ [101]. Denzin and Lincoln’s is a more focused definition, and refers to how qualitative investigators study objects in their natural settings, trying to make sense of or explain phenomena in terms of the meanings that people bring to them.

2.2.2 Strengths and Weakness of qualitative research

A full understanding of the strengths and weaknesses of qualitative research is highly important for researchers, as it helps them appropriately plan and design their research project to obtain truthful results with adequate consideration and transparency of the limitations.

2.2.2.1 Strengths of qualitative research

Regarding the strengths, qualitative methods concentrate on 'naturally occurring', ordinary actions in real-life settings [102]; as such, they tend to better reflect reality as opposed to quantitative methods. Similarly, qualitative data are usually gathered in naturalistic locations using observation, interviews, and documentation; data gathered from these methods are usually in the form of words and images rather than numbers. Additionally, qualitative data are considered 'rich and holistic', and thus highly complex. These data provide 'thick descriptions', which are powerful and can emotionally resonate with the reader, and, in that way, can be more influential [102, 103]. Qualitative methods are normally regarded as the best way for exploring and developing hypotheses in new areas, or to 'supplement, validate or illuminate' quantitative data collected in the same field.

2.2.2.2 Weaknesses of qualitative research

Although qualitative methods can be performed in real-life settings, data collection and analysis can be time consuming and expensive. For this reason, qualitative studies commonly have a comparatively small number of participants, which means that the results might not be generalizable to other people or locations. Qualitative research is also often described as highly subjective [102], with the data collection process and results of such research being more directly influenced by researchers' personal beliefs about what is significant. In particular, researchers' experience and background

knowledge can bring about some biases in the research. Furthermore, the researcher must develop relationships with the individuals being studied in order to obtain quality data.

2.3 Research Methods

In this section, I will individually look at each of the methods used in the present studies.

2.3.1 Observation

In qualitative research, observation provides the investigator with an understanding of the routine and unremarkable characteristics of participants' daily lives within a given setting. In this way, it gives investigators direct access to what participants do as well as what they say they do [104]. The knowledge obtained from observation has been described as 'rich, rounded, local and specific' [105]. Observation is considered essential to qualitative research, and even has been defined as the 'fundamental base of all research methods' [106]. Researchers use this method in order to examine how individuals act in their natural setting, thereby allowing researchers to put the individuals' performance and utterances into their appropriate contexts.

According to Bryman and Beecroft et al. [102, 107], observation can be performed in a number of different ways, depending on the researchers' objectives, the nature of the data being gathered, and the participants accessible. They classified observation into two categories: structured observation and participant observation [102, 107].

Structured observation refers to a system observation that follows specific rules [102]. The focus of these methods is on finding and recording the rate of occurrence of specific incidents or actions. These methods have some advantages, in particular cost effectiveness, relative ease of implementation, and high validity and reliability. However, a shortcoming is that they might occlude opportunities for capturing certain naturally

occurring actions [107]. Further, although they can help investigators observe what participants do, they fail to elucidate the underlying reasons for these behaviours [107].

By contrast, participant observation is more flexible; it can be considered, in some ways, both the most natural and the most challenging method of data collection. Moreover, it requires the investigator to become familiar with the culture they are observing to comprehend the motives and actions of the people, as well as to understand the meanings that can be attributed to environmental and behavioural characteristics [102].

When opting for participant observation, it behoves the investigators to attempt to improve the observers' trust in them and to design questions for use in interviews and focus groups that are specific to those being observed, as this can help them best comprehend the phenomenon being studied.

However, one of the greatest disadvantages of using this technique is that is highly time consuming. This makes researchers view it as impractical for most research studies, which tend to have relatively little time for data collection. Another disadvantage is the complexity of documenting the data. Some researchers find that it is difficult to record all crucial data during the observation, and often must depend on their memory and on their own personal discipline to write down and expand their observations as soon as they finish them. Finally, it is inherently a subjective method Thus, the investigator must understand the variations in their reporting or descriptions of what they observe [102].

I employed participant observation in my studies. In the first study (described in Chapter 5), I utilise my own observations as well as those of independent observers (two consultant anaesthetists). However, I faced several problems during my observations, in particular selecting what to observe in the short time allocated to the observation. It also took me time to accrue the skills for quality observation; I realised that this process was not merely watching and reporting, but rather the process of identifying what precisely to look for and how to reflect on that. Furthermore, the locations where I

performed the observation were sometimes unfamiliar. As such, I created an observation schedule for all observers to use throughout their observation periods **[Appendix 1]**. This ensured that both myself and the other two observers clearly concentrated on the study questions in the observations periods and helped reduce performance bias [108]. The independent observers both agreed that the schedule helped them to quickly record a considerable amount of data and ensured coherent record keeping. In terms of consistency and validity, an observation schedule has been shown to be a crucial factor [107]. Sunstein et al [109] has suggested that all observations must be labelled with the time, location, and codenames of subjects. As such, all notes included these details.

All of us engaged in reflection on our observations as soon as possible after making them. This was recorded in the reflection section of the observation schedule. There was a part on the observation schedule especially for reflection. This encouraged observers to write down all the objects that come in mind about the observation, as an irrelevant point to the observers might turn out to be highly significant to the research. I was also encouraged to record any personal details on these reflections, such as our own interpretations or individual feelings.

2.3.2 Videotaping

In the second study (Chapter 6), I employed video recordings to collect data of the actions and decisions involved in routine and complicated airway management. I initially completed recordings of 20 cases of routine anaesthesia.

The use and analysis of video recordings is often employed in high-risk industries, and in actual clinical settings, this method can deliver information beneficial for improving patient safety via improvement of actual health care procedures [110, 111]. In particular, to improve patient safety, it is vital to understand how actual clinical care systems work and why adverse incidents occur, which is why this is a popular technique for that purpose [112]. Some investigators argue that to understand the nature of clinical

settings, real time observation [97, 113] or use of videotaping and analysis thereof [114-116], is necessary. Acknowledgment of these facts has led to increased application of this method in anaesthesia patient care in the operating theatre to identify deviations from optimal care.

Other benefits of utilising video recording include the creation of a permanent record that can be studied offline as often as required, which is helpful for clinical education or quality improvement and decision making [110]. Furthermore, this research method can be used for re-analysis of the same procedures by the original researcher or by other researchers to examine new assumptions [117].

As with any technique, video recording has some disadvantages. First, it can be costly and time consuming [117], as the location, capture, storage, and use of video data require time to complete adequately, even without considering the time needed for analysis. Second, for legal or practical reasons, video recording is sometimes impossible. Third, according to Wilson et al [118], the distance and angles of the cameras can lead to 'distorted or obstructed' images, thus making it difficult to clearly and consistently record all activities or interactions completed within the environment. This represents a mismatch between 'work-as-imagined' versus 'work-as-done' [119].

Overall, all data gathering methods have their strengths and weaknesses, meaning that it can be difficult to identify which is superior to another for a given study. Indeed, which method is optimal depends on the nature and framework of the research; the investigator must decide which method or methods will be best able to elucidate the phenomenon in question. In this study, data from video and audio recording enabled a deeper understanding of how airway management is affected by the clinical decision making process.

2.3.3 Interviews

Semi-structured interviews, sometimes called focused Interviews, were used in the first study **(**see Chapter 5 and 6**)**. These interviews are guided by preconceived questions and themes. The main reason for employing these interviews was to ensure an adequate depth, rather than breadth, of information. Furthermore, using this method, the investigator attempts to build a relationship with the participants and, in doing so, make the interview more like a conversation. Not all questions asked need to follow the interview schedule—indeed, the researcher will often ask such questions in response to what interviewees have said in order to give more detail on a topic.

Semi-structured interviews are used as part of a considerable range of qualitative approaches [102], all of which, according to Mason [105], are seeking 'the construction or reconstruction of knowledge more than the excavation of it'. As such, semi-structured interviews can be an effective method of identifying groups within subject populations as well as rules that might be infrequently deliberated in everyday practice [102]. Semi-structured interviews are also helpful for exploring the attitudes, beliefs, and values of individuals, all of which are simple, efficient, and practical ways of understanding what cannot be easily observed. Furthermore, complex questions or subjects can be easily discussed and clarified by the interviewer [102]. Such discussions are also easily recorded via audiotaping, which allows the researcher to focus during the interview and not be distracted by taking notes. Overall, I utilised a semi-structured interview format because it is both uniform and flexible, permitting the emergence of new topics and use of follow-up questions [120].

On the other hand, this method has some limitations [102]. For instance, the depth of qualitative data can make these data difficult to analyse. The analysis can also be obscured by the participants' attitude toward the interview. In addition, semi-structured

interviews can be time consuming ways of gathering qualitative data. Finally, unconscious bias may have occur due to researcher-participants relationships.

The use of semi-structured interviews gave me the opportunity to explore participants' views on how drugs are currently used and stored and how novel drug storage systems interact with normal practice. Furthermore, I could examine their opinions on novel drug storage systems; such as if they helped to reduce the risk of drug errors and increase patient safety. Subsequently, I asked them what new systems needed to add or change in order to be improved. In my second study (chapter 6) it gave me the chance to ask the participants about their actions and decisions-making they took during both routine and complicated airway management.

2.4 Sample size

According to Morse, five criteria determine what would be an appropriate sample size in qualitative research: the scope of the study, the nature of the topic, the quality of the data, the study design, and the use of shadowed data [121, 122]. A large sample size is not a requirement to ensure generalisability, as in quantitative research; instead, the objective is usually to obtain rich data [123]. This argument is supported by Sandelowski et al. [124], who have pointed out that an adequate sample size in qualitative research is generally a subjective judgment based on prior experience; alternatively, researchers can assess the quality of the data they have collected in light of their aims when deciding if more participants are needed.

The sample size for qualitative research should have enough participants to answer the research question with some confidence; an inadequate sample size might make it difficult to claim theoretical saturation. In grounded theory studies, the sample size ranges from 10 to 60 participants [123]. In the present studies, theoretical saturation was achieved in the first study through 20 anaesthetists and 30 observations, while in my second study; it was reached after observing 20 observations.

2.5 The Philosophy Underpinning this Study

2.5.1 Symbolic Interactionism & Grounded Theory

Symbolic interactionism is a major philosophy devoted to comprehending people's behaviour via their interactions and social processes [125]. The main target of this tradition is to recognise 'the complex world of lived experience from the point of view of those who live it' [126]. Grounded theory was developed in the context of this movement by Glaser and Strauss [125], with the aim of providing a more accurate and logical method of gathering and analysing qualitative data. They named this method 'grounded theory' to demonstrate its basic principle: namely, that the information gathering is grounded in the behaviour, arguments, and actions of those being studied [127]. I have used grounded theory in both of my studies **(**Chapters 5 and 6**)**.

2.5.1.1 Grounded theory

Grounded theory was originally a method used in sociology, and, as noted previously, derives from the 'symbolic interactionism' tradition, which seeks to explain people through their interactions with others and social practices [125]. Glaser and Strauss [125] said that investigators required a method that would let them to progress from data to theory, and thereby create new theories. These new theories would be specific to the frameworks in which they had been established. Furthermore, they would be based on the information from which they emerged instead of analytical concepts or variables from pre-existing theories. Overall, the aim of the grounded theory method is to provide a method for creating new, contextualised theories [128]. In essence, it is a data-driven method of systematically creating a theory that defines, explains, and predicts a phenomenon of interest.

2.5.1.2 Methods of grounded theory research

The main aspects of grounded theory are theoretical sampling, the constant comparative method, coding and categorising, memo writing, and theory generation [125]. Some researchers have indicated that all of these aspects are in play simultaneously throughout the entire project [129, 130]. In particular, the constant comparison and simultaneity are believed to be important features of information gathering and analysis in grounded theory. However, time, available resources, and access to the research setting might require investigators to be flexible and adaptable to achieve the whole data.

2.5.1.2.1 Theoretical sampling

Morse [131] noted that every research project must give adequate consideration to the size and adequacy of the sample, as it can greatly influence the accuracy of the data (i.e., reliability and validity). Although the sample size is not as big an issue in qualitative research as in quantitative research, it is nevertheless a key feature of the grounded theory method because it can determine the quality of the theory being generated. As such, theoretical sampling is typically adopted for grounded theory. More specifically, theoretical sampling is useful for checking the emerging concept against reality through sampling incidents that might challenge its developing characteristics. Although the primary phases of grounded theory require higher openness and flexibility in order to determine a broad range of categories, theoretical sampling is used to refine these categories until theoretical saturation is reached.

As noted by Jeon [125], theoretical sampling is a rather different method from the sampling strategies typically utilised in qualitative research, such as purposive (or selective) sampling. More specifically, purposive or selective sampling is commonly utilised in the first stage of qualitative research to select participants who are most likely to deliver data about the knowledge or phenomena related to the research topic [102].

In this sampling strategy, the research question dictates who, as well as what, is of importance.

Whether purposive or selective sampling is used, the main aim is to choose a sample that is likely to have the skills and experience relevant to the main topic of the research. In my first study, I used purposive sampling within three NHS Hospital Trusts; I chose these three different trusts to represent the differing methods of practice, preparation, and administration of anaesthetic drugs. Furthermore, in my second study, participants were chosen from among consultant anaesthetists and qualified ODPs who were willing to participate by sharing their process of decision making and ideas.

Ideally, theoretical sampling is utilised throughout the study process, including during decision making about the interview questions and consultations with experts in the research area. However, theoretical sampling is not always possible because it can be time consuming. However, the time-consuming nature can be resolved, according to May [132], by using pre-existing data—that way, the hypothesis can be further supported without needing to go out and collect further data.

Overall, the sufficiency of the theory relies not only on the quantity of information, but also on the quality.

2.5.1.2.2 Theoretical saturation

Theoretical saturation refers to the process of sampling and coding data until no new categories emerge [125], and no new examples of existing categories appear. When such saturation is reached, the categories and subcategories all available data on the topic. However, theoretical saturation operates as a target, rather than as a reality—while researchers endeavour for saturation, it is likely that the categories can always be amended or their perspectives changed.

2.5.1.2.3 Constant comparative method

The constant comparative method is a major aspect of grounded theory, and refers to how researchers must have theoretical sensitivity in each stage of the research method [125]. This ensures that investigators create a theory grounded in the study data as opposed to existing concepts.

More specifically, the constant comparative method is a basic a way of thinking about incidents, ideas, and categories, as well as their properties, and helps guide the theoretical sampling. In my view, the process of comparing data and asking questions can help researchers understand the main concept of their research. This accords with Glaser and Strauss [133], who stressed that the aim of this strategy is to clarify concepts and investigate hypotheses resulting from the data.

In my studies **(**Chapters 5 and 6**)**, I constantly compared emerging information with the main concept. In particular, I compared within and between the codes and emerging categories to identify similarities and differences. Furthermore, data were compared between previous and later observations and interviews as well as within the same observations/interviews. Furthermore, the participants' statements and events across different observations and interviews were also compared. Data were not finalised once coded or categorised; they were repetitively combined and compared throughout the study process.

2.6 Data Analyses

2.6.1 Coding and categorising

Coding, as noted by Jeon [125], is crucial to the data analysis process of grounded theory and is the process by which the value of emerging concepts is determined. Charmaz [129] defines coding as the first step of the analytic method, wherein the

researcher categorises and stores their data. I essentially followed the process of coding as described by Charmaz [129], which is grouped into three stages: open coding, focused coding, and theoretical coding.

2.6.1.1 Open coding

Open coding is the process whereby investigators parse out their data, word-by-word, line-by-line, and incident-by-incident to identify all of the potentially relevant aspects of the issues and concepts being studied. This also generates descriptive information, or labels, related to subjects' feelings and ideas. This method of coding ensures that I would avoid injecting my own perceptions and opinions into the data. Furthermore, line-by-line coding allowed me to make a more comprehensive study of the data and ground the structure of the theoretical perspective. It further helps in structuring the theoretical framework. In this research, it allowed me to view the participants' words and actions in a different way.

One of my supervisors helped me in the open coding of the initial data set, which aided me in verifying the coding structure. It further brought a different perspective to the actual process of coding, thus guiding it in new directions. Furthermore, any suggestions from my supervisor during the coding process led me to revisit the raw data for further exploration.

The actual process of open coding proceeded as follows: I systematically went through the transcripts from the observations and interviews, highlighting each word and line and coding them in such a way that their inherent meaning was preserved. Charmaz [134] stresses that the main idea behind coding full transcripts is to make sure that no concepts contained in the data are missed, thus ensuring that the investigators obtain a much deeper understanding of the study area. Overall, open coding provides descriptive power to the generated theory.

2.6.1.2 Focused Coding

Focused coding is the second stage of the coding process. This involves merging the codes and relating larger fragments of data to the themes that are emerging from the data. Charmaz [134] defined this kind of coding as utilising the 'most significant and/or frequent earlier coding' to organise larger quantities of data. It further involves making decisions about which codes generated in the open coding process create the most understanding and classify the researcher's data concisely and absolutely.

In my studies, the focused coding process involved working through the codes in a group with my supervisors; everyone then voiced their interpretations, which helped to ultimately explain the codes and determine how the themes evolved from our perceptions.

2.6.1.3 Theoretical Coding

The last stage of the coding process is theoretical coding; it is an advanced level of coding that involves relating the higher-level codes generated during focused coding [125]. This process has been described as weaving a fractured story back together. Jeon [125] noted that theoretical coding is often carried out simultaneously with focused coding to describe the theoretical relationships between the categories that emerge within focused coding.

2.6.2 Memo writing

Memo-writing helps investigators become more analytical and thoughtful and to help them form coherent ideas about the study topic, which in turn can help to improve the theoretical codes [125]. Researchers can use memos to develop additional questions and help guide the analysis process, in particular improving theoretical coding [125, 134].

I found that the continual writing of theoretical memos was exceedingly important in formulating and refining the theory in my studies; it was inseparable from the processes of theoretical sampling, coding, and categorising and was continued until the end of the analysis. Glaser [130] has argued that, in grounded theory studies, an accurate theory cannot be generated without the use of memos. This accords with Charmaz [129], who suggested that writing memos helps to generate systematic categories to clarify and expand the theories.

Overall, writing memos helped resolve inconsistencies in the data and direct the formulation and testing of hypotheses.

2.7 Systematic review analysis

2.7.1 Assessment of main studies included in systematic reviews

A key factor of systematic reviews is an assessment of the limitations of the primary studies that are included. Bias in primary research can result in bias in systematic reviews and Meta—analysis [135]. Assessment of quality and risk of bias is important when performing a systematic review because it will provide reliable findings from which conclusions can be drawn and discussion made.

Huwiler-Muntener and colleagues [136] indicated that there is a difference between quality of methodology, risk of bias and quality of reporting of the study. For instance, a well-performed study that is well repeated may hide the fact that it has design errors that put it at high risk of bias. Likewise, a poorly repeated study may hide a study that has a lowest of bias because it is well designed in both cases this limits the ability to assess the strength and weaknesses of those studies.

Scales, checklists and domain-based evaluations are tools that have been recommended for evaluating quality and risk of bias in studies that are included in

systematic reviews and meta-analysis. The partnership between editors, systematic review authors and methodologists under the umbrellas of the Cochrane Collaboration led to the development of the Cochrane Risk of Bias tool that is well-validated, however much less attention has been given to using the same tools for observational studies [135] that are included in systematic reviews which is an area that requires further development.

It has been found that six tools were useful for use in assessing the quality of non-randomized studies in systematic reviews, however, all of them need revision [135]. A systematic review done by Sanderson and colleagues [135] studied 86 tools for assessing the quality of observational studies. Although, they found that there was a clear difference between the number and the nature of the items, they reported that there is no one a clear single tool for evaluating the quality of observational studies. In addition, they also mention that such tools should be rigorously improved, valid, and easy to utilise with a focus on the assessment of sources of bias.

Kim et al [137] and Palmer et al [138] point out that Based on the “Cochrane Collaboration’s domain-based Risk of Bias assessment”, some tools are being developed for assessing observational studies (non-randomised studies). They showed moderate reliability, and acceptable feasibility and validity, but additional validation and improvement are still required.

2.7.2 Risk of Bias assessment

To ensure that results were a reliable interpretation, I assessed the quality and risk of bias in the data included in the systematic reviews.

According to the criteria defined in Cochrane Handbook for Systematic Reviews of Interventions [139], RCT studies were assessed.

In addition, the quality of the reporting of each observational study was evaluated by using the Quality Assessment Tool for Before-After (Pre-Post) Studies With No Control Group (BAQA) [140]. BAQA is a self-developed tool and Quality Rating was reported as Good, Fair, or Poor.

2.8 Ethical Issues

I did not begin either study before the protocol, consent forms, and participant information sheets (PIS) received approval from the research ethics committee (REC) and Research & Development (R&D) department of each NHS Trust **[Appendix 2**, **Appendix 3]**. The aim of research ethics in healthcare research is to protect study participants from harm [141]. In qualitative research, such harm may derive from negative feelings or invasions of privacy [104]. Thus, researchers must closely adhere to research guidelines to ensure that no harm comes to those who participate.

The DOH has laid out some basic guidelines to protect the dignity, rights, safety, and well-being of research subjects [142]. In these guidelines, a crucial aspect of ensuring ethics in qualitative research is endeavouring to treat people as individuals rather than as a means to an end.

In neither study did I anticipate ethical issues. In Chapters 5 and 6, wherein I observed participants during clinical practice, I conducted these studies in accordance with the ethical principles of the Declaration of Helsinki, as revised in 1996; the principles of Good Clinical Practice (GCP); and the Department of Health Research Governance Framework for Health and Social care, devised in 2005. In Chapter 6 only, I used video recording, which is not a novel method; rather, it has been used broadly in research and education [111].

Ethical implications must be addressed in each step of the research process [142]. This would include steps taking to protect participants and researchers from harm, utilising

only voluntary contributions, ensuring anonymity and confidentiality, and obtaining informed consent.

In the following sections, I will discuss these ethical issues in detail and how they were managed in my studies.

2.9 Informed consent

In most ethical guidelines since the Nuremburg Code and Declaration of Helsinki, informed consent has been viewed as a cornerstone of ethical research [143]. Hansen [141] has argued that participants must fully understand what their participation involves, the main purpose of the research, and what will happen to their confidential information **[Appendix 4, Appendix 5]**.

In both of my studies, the procedure for obtaining participant informed consent was performed in accordance with the REC guidance and GCP. The information sheets given to all participants fully clarified the main purposes of the research, the procedure of the study, and the researcher's responsibilities. They further clearly stated that the participant had the right to withdraw from the study at any time, without penalty **[Appendix 6, Appendix 7]**.

Both the researcher and participants had to sign and date the consent form before the participant could participate in the study. All participants received a copy of the signed and dated forms, while the originals were retained in the study records.

2.10 Anonymity and Confidentiality

The anonymity and confidentiality of participants are similarly regarded as essential to ethical research. Where possible, investigators must ensure that every effort is made to ensure that the data cannot be linked to participants in any way. Edmondson [144] points

out that assurances of confidentiality in research mainly involve acknowledging who will have access to the data and how the data will be utilised.

In both studies, the participant information sheet clearly stated that the names of the participants would always be kept confidential and that their data would be anonymised. To do so, I ensured that participants' names were removed from all observation sheets, transcripts, and audio files; in place of names, each participant was assigned a code. The code numbers were also used to anonymise the data in the computer files. I also anonymized all quotations used in the write up and publication of this study. All recordings and transcripts were kept secure in accordance with the Data Protection Act and the standard operating procedures of the University of Nottingham. All files were named with a random code without participant identifiers. All of these efforts ensured that the data could not be traced back to specific individuals.

Past literature has indicated that it remains contested to what extent anonymity benefits the quality of the data. In fact, Edmondson [144] noted that it is possible that the more anonymous the data is, the further away it is from its original meaning and thus the less valuable it becomes. Within both studies, participants were given specific numbers, which I found sufficient for identifying participants from the list during analysis. However, I am mindful that this, of course, can threaten anonymity.

2.11 Ensuring rigour in qualitative research

To ensure that my results were credible and robust, I endeavoured to maintain validity and reliability in the data. There is substantial debate about the use of the more quantitative terms validity and reliability (and their criteria) in assessing qualitative research [125]. This issue has been much discussed in the literature, and I have not repeated the debate [145]. Guba et al [146] addressed four factors to demonstrate the rigour of qualitative research and they use them as a framework. These include "truth value, consistency, and applicability and neutrality". On the other hand, Seale et al [147]

suggest that the reliability and validity of such research methodology is improved by using robust techniques and approaches of research data. For the objective of the study, I have used the criteria developed by Glaser and Strauss [128]. Glaser and Strauss [128] maintain that the accuracy of qualitative research relies on the level of validity, credibility, and plausibility of the results and ideas generated therein, not just on the research method itself. To this end, they stressed the importance of theoretical sampling, coding, and memo writing. The same researchers also argue that constant comparison can increase the rigour of the data.

Rigour in qualitative research is also based on how transparent the researcher is in presenting the details of the data gathering, coding, and analysis processes, as well as how well they produce data relevant to the theory.

The literature has touched on several approaches to improve the rigour of qualitative research, such as reflexivity, triangulation, and purposeful sampling. In this research, I utilised triangulation, which involves the use of more than one source of data or method to answer a research question [148]. A number of researchers have utilized triangulation as a method of providing a balanced view and broadening the perspective of qualitative research [148, 149]. More specifically, in my studies, I used a combination of qualitative approaches: observation and semi-structured interviews. Using such a combination allows me to better assess the data gathered, as well as to reflect on and compare the various kinds of data in answering my research question.

2.12 Summary and conclusion

In this chapter, I have outlined the methods used in my research. Qualitative data analysis is a complex process that is continuous and inductive. The data analysis of my studies persisted throughout the entire study process, from the beginning of data collection until publication of this manuscript. I utilised a number of strategies to ensure rigour, including purposive sampling and three coding processes. Finally, I deliberated

on the analysis methods, including the nature of grounded theory, and all of the ethical issues inherent in this research.

CHAPTER 3

Human Error Identification (HEI) techniques

3.1 Introduction

This section details the methodological analysis of my second study, Modelling Airway Management Using System Reliability Assessment Tools, described in Chapter 6.

3.2 Human Error Identification (HEI) techniques

Human Error Identification (HEI) techniques have been reported as a part of “Human Reliability Assessment” (HRA), which defines the influence of human errors and their recovery on a system [150]. For a long time, HEI approaches have been utilised in high risk industries to demonstrate anticipated human errors and the related consequences [151]. HEI approaches are used as a production feed into risk assessment which describes the risk of the system.

In 1992, Kirwan reviewed twelve HEI approaches, when a number of new approaches had been published [150]. He found that some of these were similar to existing approaches, while others were not currently ready to be utilised in risk assessment [150]. The present author used HEI approaches, in particular, Hierarchical Task Analysis (HTA) and the Systematic Human Error Reduction and Prediction Approach (SHERPA) to analyse the context of airway management processes.

3.2.1 Hierarchical Task Analysis (HTA)

Hierarchical Task Analysis is an one approach to the assessment and reduction of human error [152]. It was developed by Annett and Duncan [152] to deliver a comprehensive description of tasks in a hierarchical construction of goals, sub-tasks and plans. It was originally established for individuals in the steel and petrochemical industries and now is broadly utilised in a variety of settings, such as interface design and error analysis in either individual or team tasks [152]. According to the literature, since it was developed by Annett and Duncan [152], several improvements have been observed in ergonomic research and methods, and HTA has continued as a fundamental

method of task analysis. Kirwan and Ainsworth [153] argue that HTA is the best-known task analysis technique. This is in a line with Phipps et al [154] who mentioned that it is well established as a general task analysis method.

The process of this type of analysis is to consecutively break down tasks into subtasks up to any level of analysis that is required [154, 155]. Subtasks must be achieved in order to attain the main task. The term plan is used for the relationship between the subtasks and superordinate tasks. It allows for many types of plan to be distinguished. These include “procedures, selective rules, and time-sharing tasks”. The final result is a hierarchy of task steps which demonstrates actions that need to be performed in the conduct of a task. In addition, the main target of this method is to find out actual or potential performance error and to suggest appropriate reform. This may include adjusting task design and proposing suitable training programmes.

3.2.1.1 Advantages and disadvantages of HTA

The advantages of HTA is that it can help the researcher to learn about the construction of different tasks and might be able to allow the analyst to focus on unnecessary task steps or potential errors that might occur in task execution. In the field of medicine, HTA has previously been used in surgery, anaesthesia and intensive care units (ICUs). In particular, HTA has been used in anaesthesia by Phipps and colleagues [154]. They used it for categorising the goals and sub-goals in over 200 hours of anaesthesia across a range of different clinical areas along with a preliminary failure analysis utilising the Systematic Human Error Reduction and Prediction Approach (SHERPA). The combination of HTA and SHERPA was to enable identification of errors that might occur and in which part of the task they might occur. They concluded that HTA aided in the identification of relevant human factor issues and they proposed methods with which these issues could be handled. They also suggested that they would use HTA in future interventions and research in this area.

On the other hand, one of the drawbacks is that it is a fairly time-consuming method as each individual action in a task requires analysis.

3.2.2 Hierarchical Task Analysis (HTA) in Study 2

I employed HTA in my second study (described in Chapter 6), to break down the video recording of the airway management process into its component parts. I used HTA because it differs radically from earlier methods of analysis by beginning, not with a list of activities, but by identifying the goals of the task. Furthermore, I found it helpful to analyse all my recordings in terms of their goals, which were stated in terms of goals, these goals were based on consensus standard current practice and textbooks descriptions. In addition, HTA is capable of breaking down the overall task into subordinate sub-tasks, and presenting plans that showed possible sequences of sub-task performance. I described sub-task performance in terms of measurable performance criteria.

In addition, graphic demonstration of the task and its structure was easy to comprehend as it provided an overview of the task. This allowed me to document and understand the thoughts and decision-making processes of anaesthetists and anaesthetic practitioners involved in routine / non-routine airway management. The top level of the HTA was airways maintained and secured in the anaesthetised patient. The task steps that were necessary to achieve this were outlined as plans within the next level of the hierarchy. Plans prescribed how tasks interrelated to meet the overall goals. In addition, they usually included ordering information. Plan 0 outlined preoperative assessment, which was carried out in the patient department before the recording started and then indicated subordinate sub-tasks (preparation, action of anaesthesia and maintenance of airway and ventilation and action of paralysing and intubation) to achieve the goal. These subordinate subtasks were broken down further at the lower levels. Each goal, task and

sub-task were assigned a hierarchical number and represented by using a flow chart diagram **[Appendix 8]**.

Previous studies that used a similar method have highlighted that to achieve their main goal plans should be made in order [154, 155]. However, in this study, it was sometimes difficult to do them in order. This was because every case has its own situations and each anaesthetist has their own practice. I chose the SHERPA to examine the task steps at the lowest level of HTA in more detail.

3.3 Systematic Human Error Reduction and Prediction Approach (SHERPA).

In 1986, Embrey [156] developed the Systematic Human Error Reduction and Prediction Approach (SHERPA). SHERPA is a construction of the human error identification technique (HEI) that utilises HTA [152] in combination with error taxonomy **[Appendix 9]**. The main goal of this technique is to find potential mistakes, in order to develop useful strategies to decrease or eliminate those errors.

SHERPA has been demonstrated in the literature to be the most favourable general functional method accessible for the human factor analyst. Kirwan [157] compared SHERPA with five other HEI on the criteria of “comprehensiveness, accuracy, and theoretical validity and acceptability”. He reported that SHERPA achieved the highest rating from expert users when compared with other techniques. Furthermore, the experts’ users pointed out that SHERPA is a powerful HEI approach [157]. Moreover, several researchers all agreed on the validity and reliability of these SHERPA statistics (0.8 and 0.9 respectively) [158]. These results are in agreement with Stanton and Stevenage’s [151] findings which showed that concurrent validity was 0.74 and reliability was 0.65 for the application of SHERPA via 25 trainee users for the prediction of mistakes in sweet marketing machines. The reliability and validity of this technique led me to believe that SHERPA had a reasonable provenance and thus it was selected for my study.

3.3.1 Advantages of SHERPA

Advantages of SHERPA are that it is a structured and inclusive method which can be simply learnt and is practical. It has also been found to be considerably more time economical than observational techniques. In addition, it has acceptable inter-rater reliability [151]. It also has been effectively applied in high-risk industry situations, such as aviation, and gas exploration and exploitation [159]. Recently, it has been successfully applied in the evaluation of medical devices [159].

3.3.2 Disadvantages of SHERPA

The disadvantages of SHERPA is that the task/process is drawn up in advance and does not account for any potential unforeseen errors that might occur [151]. In addition, it is very time consuming, as it requires descriptions of several long HTAs [151].

Overall, SHERPA helped to examine the task steps at the lowest level of HTA in more detail. However, the reliability of prediction attained during a given analysis was shown to depend on the task at hand. This might be as a source of potential bias, as the person who did the analysis decided which errors and /or decisions should be involved.

3.4 Summary and conclusion

In this chapter, I have demonstrated how HEI approaches can be used to analyse the process of airway management. The main aim of doing this type of analysis was to illustrate, document and understand the decision making of anaesthetists during routine and non-routine airway cases. It also explored the types of error that could occur during the airway process and at what points in the airway process these errors happen.

HTA was found to be a process that can be sub-divided into several levels of constituent tasks and analysis, and can therefore provide a comprehensive description of the airway process task. In addition, SHERPA could be used to analyse the process at several levels and examine the task steps at the lowest level of HTA in more detail. The

combination of HTA and SHERPA enabled identification of any errors which might occur and where in the anaesthetic pathway they are most prevalent.

Overall, every method of analysis has its strengths and weaknesses. This means that it can be difficult to identify which is superior to another for a given study. However, which analysis is optimal depends on the nature and framework of the research; the investigator must decide which method of analysis will be best able to elucidate the result.

CHAPTER 4

Anaesthesia workload measurement devices - Qualitative systematic review

4.1 Introduction

Mental workload has been defined in terms of level of attention and resources required to meet objective and subjective performance criteria of an individual task, which may be mediated by task demands, external support and past experience [160]. It has been identified as key performance factor in various complex working environments [161]. Anaesthetists work in an environment where mental workload may impact on safety through slips, lapses and conflict [47]. Managed workload may have an impact on job satisfaction within the operating team, and provide cost effective care. Studies [162, 163] have demonstrated that workload may lead to increase anaesthetist stress (in part an imbalance between workload and resources) [164], burnout and fatigue. Both aviation and nuclear industries report associations between mental workload, system performance and safety [165, 166].

Mitigating effects of workload / capacity mismatch requires understanding of temporal, individual and contextual-sensitive changes in workload. However, although it might be relatively easy to identify times of increased or reduced mental workload, it is not a simple issue to reliably quantify this [167]. Several methods have been proposed to measure anaesthesia workload based on metrics used in other industries, but to date none of the assessment tools available have been considered standard for use across healthcare. Whilst it is unlikely that any single tool will ever be optimal for all situations, it is important for researchers and practitioners to understand what various tools can and cannot be expected to do when used or reported in studies.

Current mental-workload measurements are conceived from four parallel conceptual frameworks (scoring / task oriented, task performance, response time capabilities and physiological changes). Criteria for workload measurement methods are detailed in (**Table 1)**. Subjective task oriented methodologies are multidimensional constructs of subscales that include: mental, physical, temporal demand, frustrations, effort and performance. The theory of such tools is that a combination of specific elements is more likely to describe

the workload experienced by most operators doing the tasks [165]; and most importantly the operator is the best individual to rank / score how difficult the task is perceived. Other tools work from the premise that if a primary (clinical) task is associated with high level of workload, limited spare mental capacity will be available. This will be observed by delays in reacting to a secondary task – analogous to a computer slowing down if it has insufficient memory or processing power. It may also be observed in error rates or time taken for the primary tasks themselves. Physiological measurement tools assume that increases in mental workload are associated with observable changes in physiology, mediated via the autonomic nervous system [168]. This review assesses the theoretical framework and supporting data for currently used mental workload assessment tools in the anaesthetic environment, in order to allow researchers and practitioners to understand the relative merits of the available tools.

Table 1: Criteria for workload measurement methods [167]

Criteria	**Explanation**
Simplicity and usability	minimum equipment, non-intrusive /non-interference with performance, acceptable to subjects
Availability	timely and sufficiently rapid for use
Performance characteristics	sensitivity to changes, selectively sensitive, insensitive to other task demands, inter- and intra-rater reliability, adequate floor and ceiling effects, face validity
Diagnostic	indicating the source of workload variation

4.2 Methods

A systematic literature search was performed across five databases; Cochrane, EMBASE (via Ovid platform), MEDLINE (via Ovid platform), SCOPUS and Web of Science. The search strategy was piloted and tailored to the individual databases. A combination of Medical Subject Headings (MeSH) and free text terms were used to increase sensitivity for identification of potential studies. Search terms used ([workload* OR work load* OR over load* OR taskload* OR burnout* OR stress* OR anxiety* OR fatigue] AND ([anaesthesia* OR anaesthetist* OR anaesthesiology*]) were initially run individually and then combined in each database. References list of identified papers and previous reviews were checked for further data and citing articles were also sought from Google Scholar.

I included primary published research papers focusing on mental workload assessment tools used in anaesthesia and / or impact of workload on anaesthetists and patient safety up to February 2018. Studies in other languages were considered if an English translation version was available. I excluded reviews, descriptive articles, letters to the editor and opinions.

4.2.1 Data Extraction

DA and TM both performed the search strategy and independently identified potential studies for inclusion at abstract stage. Data extraction was performed individually with disagreements resolved by the discussion and involvement of a third researcher (IM). Data extracted from individual studies included: sample size, study region, date of study, validity and reliability of workload measurement tool. Data are reported as presented in the studies. Due to heterogeneity of study results presentation, populations and tools used, no attempt has been made to pool data.

4.3 Results

4.3.1 Overview

Primary search produced 2388 articles. 2313 studies were screened by title after removal of duplicates; 40 were eligible for abstract screening. Thirty - two studies were considered for full text analysis and twenty - four [96, 113, 169-190] met the inclusion criteria with outcomes given with adequate data to assess study results. Most studies screened at full text phase looked at effects of workload in general, not its measurement, and therefore were excluded [114, 191-197]. Flow diagram of included and excluded studies is detailed in **Figure 4** and characteristics of included studies are outlined in **Table 2**.

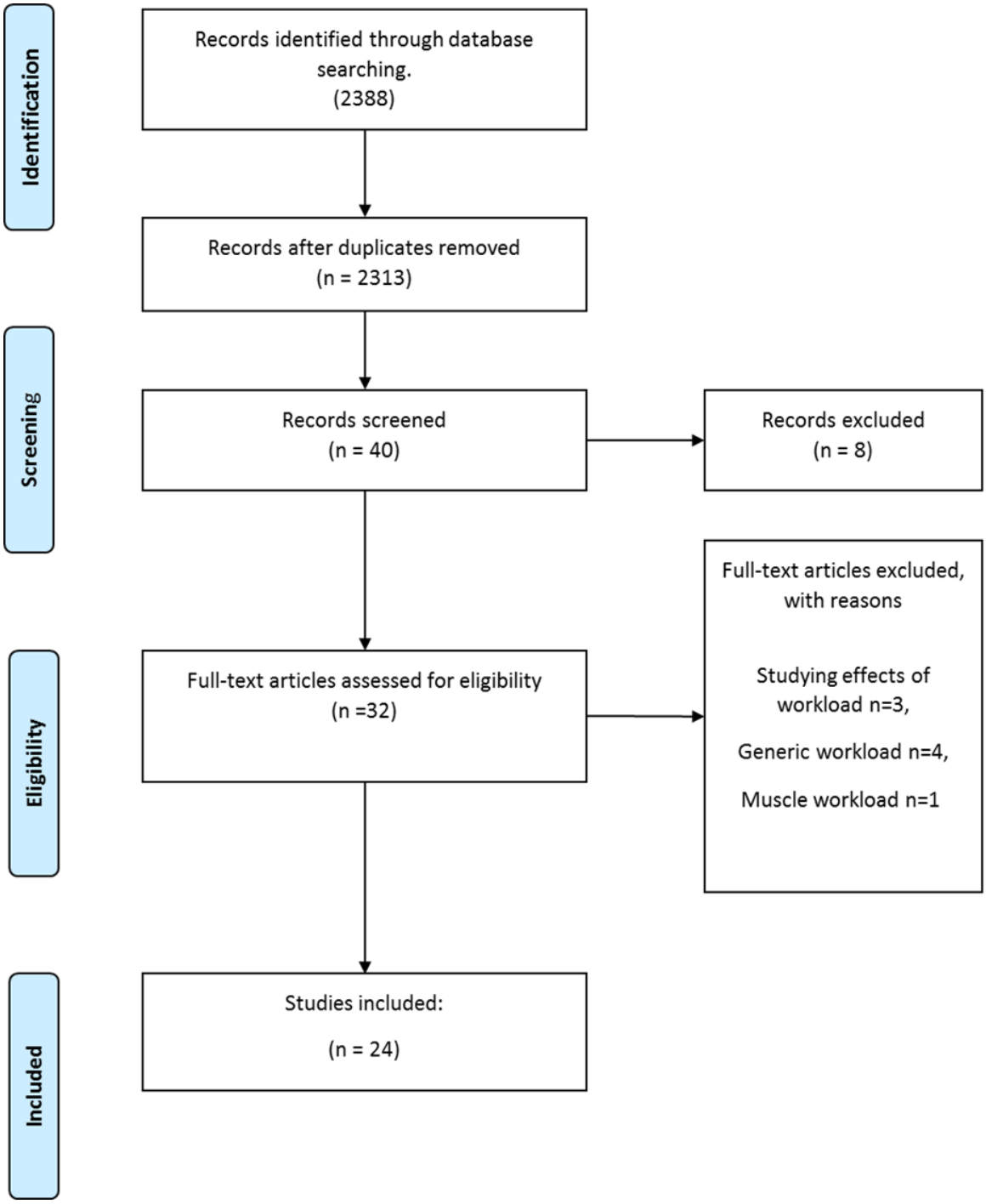


Figure 4: Flow diagram of included and excluded

Table 2: Characteristics of included studies

Study	Study title	Country	Participants (n)	Type of study	Workload construct	Results
Byrne, 1998 [169]	Errors on anaesthetic record charts as a measure of anaesthetic performance during simulated critical incidents	UK	Trainee anaesthetists (10)	Simulation - non randomised	crisis period: (hypotension and tachycardia)	A greater number of errors during critical incidents. Number of errors decreased when patient had stabilised.
Byrne, 2002 [170]	Effect of videotape feedback on anaesthetists' performance while managing simulated anaesthetic crises: a multicentre study.	UK	Trainee anaesthetists (32); average work experience 2 years	Simulation - non randomised	crisis period: (hypotension; bradycardia; tachycardia; and anaphylaxis or hypoxia)	Videotape group feedback had a shorter median time to solve problem and smaller rate of chart error when compared with other group who not exposed to video feedback. The differences were not statistically significant.
Byrne, 2010 [171]	Novel method of measuring the mental workload of anaesthetists during clinical practice.	UK	Anaesthetists (46); 24 trainees, 3 staff grades, 19 consultants	Observational clinical	46 - Cases complexity: (30 – simple; 13 moderate; 3 – complex)	Small, significant increase in response time during complex / moderate cases compared with simple ones The standardized delay of each subject differed by phase of anaesthesia. The difference between induction and maintenance was statistically significant; the difference between maintenance and emergence was not. Non-significantly lower response times for simple cases for consultants compared with trainees.

						Higher NASA - TLX scores for mental demand, physical demand, and frustration for moderate / complex cases compared with simple.
Byrne, 2013 [172]	The relationship between experience and mental workload in anaesthetic practice: an observational study.	UK	Anaesthetists (20); mix of grades	Observational clinical	100 - cases complexity:(69 – simple; 29 – moderate; 1 - complex)	Inverse correlation between average delay and experience. Considerable inter - subject variation, greater than the differences between trainees and 'qualified' anaesthetists.
Byrne, 2014 [173]	A pilot study of the mental workload of objective structured clinical examination examiners	UK	OSCE examiners (10); trainee anaesthetists as control group (24) (data from Davis study [174])	Comparison of responses from examiners and anaesthetists	Performance comparative	Longer average delay in examiners than that in the control group Greater overall median NASA – TLX scores in examiners (8 out of 10) than anaesthetist controls (3 out of 10). Formal analysis of sub-domains not performed but greatest difference in median scores in mental and temporal demand.
Davis, 2009 [174]	A novel method of measuring the mental workload of anaesthetists during simulated practice.	UK	Trainee anaesthetists (10)	Simulation - non randomised	crisis period: (hypoxia; hypotension and bradycardia)	Response times increased significantly during the crisis period. In the experimental period, there was a statistically significant increase in mean increase in response time
Schulz, 2011 [175]	Eye tracking for assessment of workload: a pilot study in an anaesthesia simulator environment	Germany	Trainee anaesthetists (11)	Simulation randomised	Critical incident: (anaphylaxis)	Pupil diameter and heart rate varied by phase of incident scenario. Duration of fixation decreased with increased workload. Saccadic amplitude unaffected by incident. Borg workload rating higher during incident than sessions.

Schulz, 2011 [176]	Assessment of subjective workload in an anaesthesia simulator environment: reliability and validity	Germany	Anaesthetists (17); 1 - 30 years' experience.	Simulation randomise.	Critical incident: (anaphylaxis)	Greater Borg rating scales after critical incident sessions than after uneventful session.
Schulz, 2014 [177]	The influence of anaesthetists' experience on workload, performance and visual attention during simulated critical incidents.	Germany	Trainee anaesthetists (12); 4 < = 2 years' experience, 8 > 2 years' experience	Simulation randomised	Critical incident: (anaphylaxis)	Non - significant differences in mean pupil diameter and heart rate increases between less and more experienced groups.
Weinger, 1994 [97]	An objective methodology for task analysis and workload assessment in anesthesia providers.	USA	Anaesthetists (22); 11 experienced certified registered nurse anaesthetists, 11 novice anaesthetists	Observational clinical	11 - routine cases of general anaesthesia	Significant differences in overall task duration and mean task density between less and more experienced groups. Alarm - light response latency (a measure of clinical vigilance) was significantly increased at time of increased workload. Self - and observer - reported workload values were well correlated. Positive correlation between subjective workload and workload density than with response latency to the vigilance light.

Weinger, 1997 [113]	The effect of electronic record keeping and transesophageal echocardiography on task distribution, workload, and vigilance during cardiac anesthesia.	USA	Anaesthesia residents (9)	Observational clinical	20 - cases of coronary artery bypass graft: (10 ERK and 10 MAN)	Alarm - light response latency was significantly prolonged when manging the TEE compared with record keeping or observing monitoring. Self - and observer - reported workload values were well correlated. Positive correlation between subjective workload and workload density. Non - significant difference in two record keeping groups in their workload scores, workload density, or vigilance latency
Weinger, 2004 [179]	Multiple measures of anesthesia workload during teaching and nonteaching cases.	USA	Faculty anaesthesiologists (2), nurse anaesthetists (8), resident anaesthesiologists (14)	Observational clinical	24 - elective general anaesthetic cases: (12 - teaching cases and 12 - nonteaching cases)	Higher HR during induction and emergence, lower HR during maintenance phase in both teaching and nonteaching cases. Self - and observer-reported workload values were higher during induction and emergence than during maintenance in both teaching and nonteaching cases. Non - significant difference in two record keeping groups in their workload scores, workload density, or vigilance latency

Gaba, 1990 [96]	Measuring the workload of the anesthesiologist.	USA	Trainee anaesthetists (9)	Observational clinical	19 - cases: (mathematical addition) as secondary task	Greater response times, and proportions of skipped tasks, observed during manual activities, conversation and interaction with senior. Subjective workload increased with induction and emergence across all domains (attention, complexity, time pressure, mental effort, busyness, and difficulty)
Slagle, 2009 [180]	Effects of intraoperative reading on vigilance and workload during anesthesia care in an academic medical center.	USA	Anaesthesia residents certified registered nurse anaesthetists, postdoctoral fellows, and faculty anaesthesiologists (9).	Observational clinical	172 - general anaesthetic cases: (intraoperative reading cases and non-reading cases)	Reading was observed in 35% of cases. In these 60 cases, providers read during of maintenance but not during induction or emergence. Non - reading cases and non - reading periods of the reading cases did not differ in their workload, vigilance, or task distribution. They both had significantly higher workload than periods when reading occurred. Vigilance was not different among the three groups. When reading, clinicians spent less time performing manual tasks, conversing with others, and recordkeeping

Slagle, 2018 [181]	Prevalence of potentially distracting noncare activities and their effects on vigilance, workload, and nonroutine events during anesthesia care	USA	Primary anaesthesia providers, resident anaesthesiologist, nurse anaesthesiologists (89)	Observational clinical	364 - elective general anaesthesia cases: (nine task categories: manual, observing, conversing, recording, miscellaneous clinical tasks, and electronic communication tasks)	Borg rating scales higher during cases without distractions than cases with distractions Positive correlation between participants reported and observer - scored workload rating. Vigilance was significantly longer in cases without any distraction
Merry, 2011 [182]	Multimodal system designed to reduce errors in recording and administration of drugs in anaesthesia: prospective randomised clinical evaluation	New Zealand	Anaesthetists (89); 54 specialists, 35 trainees.	Clinical randomised	Routine clinical anaesthesia	The mean self - reported Borg rating scores identical for the two systems. Positive correlation between drug administration error rate and self - reported anaesthetists' workload. Non - significant difference in vigilance lapses
Merry, 2017 [183]	Retesting the Hypothesis of a Clinical Randomized Controlled Trial in a Simulation Environment to Validate Anesthesia Simulation in Error Research (the VASER Study).	New Zealand	Anaesthetists (40); 15 trainees, 25 specialists	Simulation randomised	Routine simulated anaesthesia	Mean Borg rating scores not statistically different between the SAFERsleep system and conventional methods. Non-significant difference in vigilance lapses.

Martin, 2016 [184]	Linear and non-linear heart rate metrics for the assessment of anaesthetists' workload during general anaesthesia	Germany	Anaesthetists (40); average work experience 31 months	Observational clinical	Routine cases without critical incidents	Mean HR and HRV - derived parameters varied significantly between anaesthesia stages. Permutation Entropy (PeEn) discriminated best between anaesthesia phases induction and maintenance. Higher Borg rating scales and NASA - TLX sub - domain scores for mental, physical, and temporal demand and effort (but not frustration and performance) during induction and emergence.
Sato, 2016 [185]	Influence of Mental Workload on the Performance of Anesthesiologists during Induction of General Anesthesia: A Patient Simulator Study	Japan	Anaesthetists (22); 13 trainees, 9 board certified.	Simulation - non randomised	Critical incident: (used simple two – digit integer additions every 5 seconds) as secondary task	No difference in proportion of correct answers between trainees and seniors in uneventful induction. Lower proportion of correct answers in critical incident scenario. Lower proportion of correct answers by trainees than seniors in critical incident scenario
Prottengeier, 2016 [186]	The effect of a standardised source of divided attention in airway management: a randomised, crossover, interventional Manikin study	Germany	Anaesthetic consultants (41), Anaesthetic registrars (41).	Simulation randomised	Airway management intervention (secure airway of a manikin using a supraglottic airway, conventional endotracheal tube and video - laryngoscopy)	Under secondary task conditions, all three interventions demonstrated an increased in level of workload of about 30 points on the NASA -TLX. Video - laryngoscopy technique higher workload than the others.

Garden, 2012 [187]	Fifteen-hour day shifts have little effect on the performance of taskwork by anaesthesia trainees during uncomplicated clinical simulation.	New Zealand	Trainee anaesthetists (12)	Simulation randomised	Comparing performance in rested and fatigued states: (end of a 15 hour shift)	No difference in proportion of machine check tasks performed. Small increases in mean time per task for 4 / 42 tasks in the fatigued condition (explanations to patients; looking at and adjusting intravenous fluids).
Man, 2014 [188]	The effect of audible alarms on anaesthesiologists' response times to adverse events in a simulated anaesthesia environment: a randomised trial	Netherlands	Anaesthetists (27); 10 anaesthetists,17 resident anaesthesiologists	Simulation randomised	Simulated routine anaesthesia: absence and presence of audible alarm.	No differences either in response time or in perceived workload in the absence or presence of a sounding alarm.
Vredenburg, 2000 [189]	Developing a technique to measure anesthesiologists' real-time workload. in Proceedings of the Human Factors and Ergonomics Society Annual Meeting.	USA	Anaesthesia providers (241)	Observational clinical	Routine anaesthesia	Induction and emergence phases of anaesthesia were significantly greater in workload than maintenance phase. Then main effect of type of tasks indicated that emergency procedures have higher workload than all other tasks.

Cao, 2008 [190]	Differences in day and night shift clinical performance in anesthesiology.	USA	Anaesthesia residents (14); 9 first year, 1 second year, 4 third year anaesthesia residents.	Observational clinical	Night shift against day shift	No significant differences either in workload rating and response time to alarm light latency between night and day cases.

NASA TLI - NASA Task Load Index, Vibrotactile device - response to a prompt from a vibrotactile device, OSCE, objective structured clinical examination, HR - heart rate, HRV - heart rate variability, PeEn - permutation Entropy, TEE - Transesophageal echocardiography, ERK – Electronic anaesthesia record keeping.

❖ Byrne, 2014; used data from Davis study [174]

\+ Schulz, 2011; used data from Schulz study [175]

\+ Routine cases used expected differences in workload between induction, maintenance and emergence as a self-generating variation in workload.

4.3.2 Types of mental workload measurement tools

Six mental workload measurement tools were identified **Table 3**. Rating scales of workload were used in sixteen of these twenty-four studies. The Borg rating (6 to 20) scale was used in nine [97, 113, 177, 179-184] and NASA-TLX in five [171, 173, 184, 186, 188]; Gaba, [96] used a bespoke rating scale and Vredenburgh, [189] used a survey instrument, both similar to NASA-TLX. Analysis of primary task performance (tasks required as part of anaesthesia care) was assessed in four studies [96, 169, 170, 189], and performance of secondary tasks (arithmetic) was reported in three studies [96, 185, 190]. Of the twenty-four studies, eleven assessed only one of the four concepts (scoring / task oriented - 2, task performance. – 5, response time capabilities - 2 and physiological changes – 2); ten studies assessed scoring and response times, two scoring and physiology; one study assessed scoring, response time capabilities and physiology. Vigilance was assessed in thirteen studies using either [171-174] the Vibrotactile device or response to a randomly illuminated light [97, 113, 179-183, 190] or alarm - sound response latency [188]. Physiological monitoring was reported in five papers [175-177, 179, 184] from three studies. Pupil responses were reported in two papers from the same study [175, 177] and one from a different study [176].

Type of tools used for each study are outlined in **Table 4.**

The Borg rating scale is widely used to assess workload in anaesthesia. It assess workload using a perceived exertion numerical scale from 6 (no exertion at all) to 20 (maximum exertion). Its use in the anaesthesia settings, such as clinical environments simulated critical incidents and non-simulated critical incidents, showed similar results. Essentially, during routine cases of anaesthesia the Borg rating scale showed an increase in workload values during induction and emergency compared with maintenance. Similarly, comparatively high Borg rating values were observed during complex and moderate cases compared with simple cases. More experienced anaesthetists appeared

to have spare mental capacity during standardised primary anaesthetic tasks as observed in their reporting of lower workload values from standardised incidents in comparison with less experienced anaesthetists. It could be argued the Borg scale is unidimensional and do not explicitly differentiate between physical and mental workload. Nevertheless observed results from its use across included studies support the Borg rating scale to be an effective tool workload measurement tool.

The NASA-TLX workload measurement tool uses six categories: effort; mental demand; physical demand; temporal demand; frustration; and performance to measure workload. Variations in NASA-TLX were comparable with Borg rating scale and / or physiological monitoring tools [176, 184], when both tools were used. When used with physiological measuring tools, significant positive correlation was observed between physiological outcome measures (heart rate ,heart rate variability, and pupil size) and NASA-TLX scores [184]. For NASA-TLX domains across all included studies, higher workload scores were consistently observed in temporal, mental domains but physical domains did not change. However, there were inconsistent results for the frustration and performance domains across studies.

Tasks were used in two ways. First, accuracy of completion of a primary tasks (directly related to anaesthesia care) was used as a measure of workload. Alternatively, a secondary task was used to increase workload and / or assesses spare capacity. A positive correlation between subjective workload and primary workload density was reported [97, 113]. Workload assessment using secondary task measurements reported high levels of workload.

Alarm - response latency (using either a light or Vibrotactile device) was used to measure vigilance among anaesthetists. Response latency increased significantly at times of increased workload, whether during routine or crisis induced variation. The results of increasing workload with secondary tasks was inconsistent. Some studies reported a

statistically significant increase in mean response time and others not; this may have been due to individuals' performance variability (inter-interindividual variation).

Physiological workload measurement tools uses physiological responses as a surrogate marker of mental workload including the assessment of subjects' visual focus of attention. Heart rate alone had inconsistent relationship with workload with marked inter-individual variability. More advanced metrics of autonomic function (derived from heart rate variability) showed better discriminative ability in one study [184]. Pupil changes were inconsistently related with workload with marked inter-individual variability.

4.3.3 Reliability

Two studies reported reliability of the tools measurement used. One study [174] reported reliability ($\alpha = 0.922$) for the Vibrotactile device. Another study [183] reported reliability of the Borg scale which found to be moderate (concordance coefficient = 0.55). Several studies [97, 113, 179, 181, 182] reported moderate to good correlation between self-reported and observer workload rating using the Borg scale.

Table 3: Tools used to measure mental workload in anaesthesia

Tools	**Measurement**	**Outcome**
Borg workload	Self - reported workload score	6 (no exertion) - 20 (maximum exertion)
NASA - Task Load Index	Self-rating workload chart in six subscales; mental, physical, temporal demand, frustration, effort and performance / success.	Score ranges from 0 (minimal) to 10 (maximum possible)
Tasks	Response time	Primary Task (response to task-related demands) Secondary task performance (measure of spare capacity) Absolute response time of mathematical addition task The rate of correct answers to the mathematical questions every 5 seconds
Vibrotactile device	Response time to a vibration on the upper arm	Absolute response time (ms) Response time (ms) above statistically derived 'threshold'
Eye - tracking device (EyeSeeCam)	Pupil diameter and eye movements	Absolute (mm) and change in pupil diameter Mean duration (seconds) of fixation episodes Amplitude (degrees) of saccades
Autonomic responses	Heart rate Respiratory rate	Absolute and relative changes in HR Heart rate variability (HRV): time, frequency and entropy derived metrics

Table 4: Types of tools used for each study

Study	Study title	Workload scoring	Task performance	Vigilance / response times	Physiological
Byrne, 1998 [169]	Errors on anaesthetic record charts as a measure of anaesthetic performance during simulated critical incidents		Primary tasks		
Byrne, 2002 [170]	Effect of videotape feedback on anaesthetists' performance while managing simulated anaesthetic crises: a multicentre study.		Primary tasks		
Byrne, 2010 [171]	Novel method of measuring the mental workload of anaesthetists during clinical practice.	NASA - Task Load Index		Vibrotactile device	
Byrne, 2013 [172]	The relationship between experience and mental workload in anaesthetic practice: an observational study.			Vibrotactile device	
Byrne, 2014 [173]	A pilot study of the mental workload of objective structured clinical examination examiners	NASA - Task Load Index		Vibrotactile device	
Davis, 2009 [174]	A novel method of measuring the mental workload of anaesthetists during simulated practice.			Vibrotactile device	

Schulz, 2011 [175]	Eye tracking for assessment of workload: a pilot study in an anaesthesia simulator environment				Eye - tracking device (EyeSeeCam); pupil size, heart rate
Schulz, 2011 [176]	Assessment of subjective workload in an anaesthesia simulator environment: reliability and validity				Eye - tracking device (EyeSeeCam); pupil size, heart rate
Schulz, 2014 [177]	The influence of anaesthetists' experience on workload, performance and visual attention during simulated critical incidents.	Borg rating Scale			Eye - tracking device (EyeSeeCam); pupil size, heart rate
Weinger, 1994 [97]	An objective methodology for task analysis and workload assessment in anesthesia providers.	Borg rating scale		Alarm - light response latency	
Weinger, 1997 [113]	The effect of electronic record keeping and transesophageal echocardiography on task distribution, workload, and vigilance during cardiac anesthesia.	Borg rating scale		Alarm - light response latency	
Weinger, 2004 [179]	Multiple measures of anesthesia workload during teaching and nonteaching cases.	Borg rating scale		Alarm - light response latency	Heart rate

Gaba, 1990 [96]	Measuring the workload of the anesthesiologist.		Primary and secondary tasks		
Slagle, 2009 [180]	Effects of intraoperative reading on vigilance and workload during anesthesia care in an academic medical center.	Borg rating scale		Alarm - light response latency	
Slagle, 2018 [181]	Prevalence of potentially distracting noncare activities and their effects on vigilance, workload, and nonroutine events during anesthesia care	Borg rating scale		Alarm - light response latency	
Merry, 2011 [182]	Multimodal system designed to reduce errors in recording and administration of drugs in anaesthesia: prospective randomised clinical evaluation	Borg rating scale		Alarm - light response latency	
Merry, 2017 [183]	Retesting the Hypothesis of a Clinical Randomized Controlled Trial in a Simulation Environment to Validate Anesthesia Simulation in Error Research (the VASER Study).	Borg rating scale		Alarm - light response latency	
Martin, 2016 [184]	Linear and non-linear heart rate metrics for the assessment of anaesthetists' workload during general anaesthesia	Borg rating scale, NASA - Task Load Index			Heart rate and heart rate variability

Sato, 2016 [185]	Influence of Mental Workload on the Performance of Anesthesiologists during Induction of General Anesthesia: A Patient Simulator Study.		Secondary tasks		
Prottengeier, 2016 [186]	The effect of a standardised source of divided attention in airway management: a randomised, crossover, interventional Manikin study	NASA - Task Load Index			
Garden, 2012 [187]	Fifteen - hour day shifts have little effect on the performance of taskwork by anaesthesia trainees during uncomplicated clinical simulation.	Tasks			
Man, 2014 [188]	The effect of audible alarms on anaesthesiologists' response times to adverse events in a simulated anaesthesia environment: a randomised trial	NASA - Task Load Index		Alarm - sound response latency	
Vredenburgh, 2000 [189]	Developing a technique to measure anesthesiologists' real-time workload. in Proceedings of the Human Factors and Ergonomics Society Annual Meeting.		Primary tasks		

Cao, 2008 [190]	Differences in day and night shift clinical performance in anesthesiology.		Secondary tasks	Alarm - light response latency	
❖ Byrne, 2014; used data from Davis study [174] ❖ Schulz, 2011; used data from Schulz [175] + Routine cases used expected differences in workload between induction, maintenance and emergence as a self-generating variation in workload.					

4.4 Discussion

Four techniques of measuring mental workload were found in this review; scoring, task performance, response time capabilities and physiological changes measures. The Borg rating scales measuring method was the most commonly used method and showed consistent association with expected variations in workload. Correlation between self-reported and observed rating was moderate to good.

Areas with increased workload such as emergency department, intensive care unit and operating room are associated with a significantly higher rate of medical errors compared to other departments [198]. While less well studied compared with other high risk industries, mental workload among anaesthetists is presumably related to incidents and recovery from human error [199]. Observed results support the concept that anaesthesia is similar to other high-risk industries such as aviation and nuclear power where human behaviour has positive and negative impacts on safety and performance. Workload is believed to be a key contributing factor for human error [47]. In the context of anaesthesia, the main target of evaluating such matter is through monitoring the cognitive demands of the anaesthetist and for predicting capacity for extra tasks. Clinically, it may be crucial to the recovery from human mistakes and increased the level of safety for both system and patients.

4.4.1 Subjective measurements

The efficacy of subjective measurement in evaluation and measure workload has been well documented, however, little evidence can be found in the literature about subjective management in anaesthesia. They include several scales, some of them are usually utilised such as Borg Rating scales and NASA-TLX. It has been reported that these kinds of measurements have a long history for assessing feelings of workload, effort, mood and fatigue. They involve asking the operators to deliver their decision of the mental effort needed to complete a task after it has been done.

Cain 2007 [167] points out that it seems suitable that workload be measured by such a method as it is a psychological construct. Results obtained from Cain's study [167] are in agreement with those obtained by others which indicate that subjective measurements are significantly sensitive measurement tools [184, 188].

Borg rating scales and NASA-TLX mental workload measurements are subjective cognitive workload measures that can be performed with a paper and a pencil and are easily available, readily accessible, and only take a few minutes to complete [165]. They have been widely studied and used in other settings [167].

The Borg rating scale was the single most common measure used in the identified studies. It consistently demonstrates discriminant ability between expected contexts of varying workload: phases of anaesthesia, routine versus and non - routine simulated scenarios. The NASA-TLX questionnaire has been extensively validated in the aviation and nuclear industries. It has been found to have diagnostic capability for subjective overload [200]. It does not interfere with primary tasks and affords opportunity for operators' individual perception of workload to be explored in depth.

The interpretation and ability of these scores to quantify performance is uncertain. Subjectivity is integral to the approach [160] and it is unclear whether they are measuring mental workload or 'stress' [201]. All of the studies reported individual NASA-TLX subscales as well as the weighted summary score, though formal analysis was less commonly carried out. Qualitatively, the temporal and mental domains were consistently associated with workload and physical domains not. Inconsistent for the frustration and performance domains, suggested that NASA-TLX should be reported at domains level.

4.4.2 Task performance

Tasks performance are generally preferable in measurement of performance in human factor ergonomic. Previous research [179, 202, 203] identified that performance based

measures focus on the people workload from capacity to task performance. The two main tasks of essential based measures, described in the literature, are the primary task measures and the secondary task measurements [204].

Primary task measurement has been determined as the capability of the operators to implement the primary task (directly related to anaesthesia care). This method is usually measured through the speed for finishing the task such as during induction and recovery of anaesthesia or number of errors that have been occurred [199].

It is accepted that the increased workload in operators who have limited processing information, which will lead to a breakdown in the performance of the primary task. However, Julien Cegarra [202] argued that the main task has not always been reliable and care is needed when explaining such measures of mental workload. Julien Cegarra could be right, as it is important to understand the variation between low level of performance that is associated with high level of mental workload and that has been related to the quality of the facts currently offered. These findings seem to be consistent with other research [169, 172] which noted that primary task performance is crucial because it measures what the system has achieved rather than the estimation of what operators have achieved. Further, Weinger et al [205] claims that dissociation between mental workload and primary task is usually observed.

Alternatively, secondary task measurement determines the ability of the individual to do the primary task alongside an additional or secondary task [203]. In other words, it means that the capacity that is not being utilised to carry out the primary task can be utilised to carry out an additional task. For instance, someone drives while holds a conversation on mobile phone. Workload rating scale measures used in the identified studies in association with secondary task measurements reported high levels of workload.

Furthermore, arithmetic questions were used as a secondary task for measuring performance workload. From the literature, I have found that arithmetic questions have

taken longer to carry out when used as a secondary task. In addition, the literature shows that there were conversations between staff about using arithmetic questions to test workload. Gaba et al [96] stated that repeated verbalisation during their use could disturb other clinicians, this may impact patient care and increase the risk of incidents due to distraction.

Leedal et al [199] assert that operators can use secondary task as a component assessment but they have to be familiar with the task such as stimuli, number of concurrent tasks and it must be match with mental resources. This means that its main target proved an indicator of workload, it is not likely to show that as workload increase, this may lead to deterioration of performance.

In a summary, although some methods, e.g., anaesthetic record and arithmetic questions have been described as being the way to measure performance mental workload, measuring performance in context of anaesthesia is quite difficult. It can be difficult in observe the increase or decrease of workload. There is also the possibility that the overlap with the primary task measurement.

4.4.3 Vigilance (response latency)

Vigilance (response latency) is an objective method that requires a more technical involvement, considerable time for the investigator, and is moderately expensive. With advances in technology, equipment is becoming much more portable, capable and acceptable [167]. The Vibrotactile device is unobtrusive, allows operators to move easily, and can be freely used in different clinical practice settings without interfere with normal working practice.

For all the included studies in this review, only one study [173] reported a reliability for the Vibrotactile device as workload measurement tool in anaesthesia. This objective method is sensitive and provides an index of variation in load across a variety of operator

information processing functions [167]. It is not affected by inter-observer bias that has been observed across rating scales. Its placement on the arm does not reduce or impair mobility and is not affected by difference in light latency like the Eye-tracking. However, the definition of delay or threshold varies between studies, which hampers interpretation.

In addition, the alarm light was placed on the anaesthetic machine, which has been described as a measurement tool for evaluation performance mental workload. It could be used as a procedural workload measurement, since it can be a secondary task representation. It can also be considered for measurement of spare capacity.

Previous studies [179, 205] supported this technique as they suggested that clinicians have already absorbed in other tasks, in other words they already have high level of workload and they are less likely to release the lights illumination. Whereas, Weinger et al [97] disagree as they noted that pressing a button in response to a light can impact physical movement of the operators.

The present writer considered that it is quite hard to use this technique, if the response has been delayed it is hard to differentiate whether it was due to failed perception, lack of recognition or failed response. It might be suggested that this technique must be utilised carefully within the consideration of clinical context.

4.4.4 Physiological measurement

Physiological measurement includes heart rate (HR), heart rate variability (HRV), and pupil responses indicators of workload [206]. Physiological measurement is commonly regarded as distinguished rate of workload measurement and is based on the change in such matter result in changes to the body. It can be a very sensitive method as it seems to influence the body state rather than task demands. The included studies in this review showed that it appears to be inconsistent in its ability to discriminate workload, though

more advanced metrics of autonomic function (derived from heart rate variability) showed better discriminative ability in one study [184].

Eye - tracking provides objective surrogate measures of physiological responses (pupil diameter) and other behaviours. Eye - tracking can be considered a reliable method, as it seems to influence the body state rather than task demands. Pupil measurement can be used easily and several high risk industry might already be in a place to support this assessment [167].

Schulz et al [175] proposed that pupil measurement is likely to be an appropriate variable to measure or evaluate development of mental workload. However, pupil diameter is different among participants, it is impacted by light intensity, daytime, and caffeine, all of which are relevant to anaesthetists. Sirevaag et al [207] claimed that pupil measurement needs a suitable sensor to detect any small movements, therefore it is considered to be difficult to achieve this within the anaesthetic field.

Aviation research provides similar results and found that the influence of mental effort on eye movement measurement is highly reliant on specific task characteristic [208]. Therefore, it is not suitable to use as a method to assess workload in aviation. Currently, sensors are placed on the head, which may result in measurement error as they move due to body movements. Thus, the connection between eye movement measurement and increased level of workload seems to be tenuous [167].

Cain [167], reported that heart rate and heart rate variables are effectively utilised in measuring workload in anaesthesia. His result seems to be questionable as heart rate sometimes interacts with respiration, physical work and with psychological circumstances. Moreover, in the workplace, inter-individual variability, therapeutic drug use, caffeine and physical workload all potentially act as confounders.

Changes within a low-physical load situation may be reflective of mental workload, but this ideal may not exist in most scenarios where mental workload coincides with increased movement.

The BioharnessTM (version 1, Zephyr Technology, MD, USA), is a new applied research system [209]. It is a physiological measuring tool, measuring heart rate, respiratory rate, skin temperature and activity through an unobtrusive chest strap. Johnstone et al [210] reported that this multi-variable technology was demonstrated to be reliable and valid in a laboratory setting. However, several aspects have to be considered on heart rate measurement as a variable for mental workload; individuals have different basal and maximal heart rate. It sometimes interacts with respiratory and physical work and it is sensitive to task complexity.

In the nuclear power field, they used heart rate measurement to calculate workload and concluded that heart rate is unobtrusive and objective [211]. This result is in agreement with the aviation field as some researchers argue that using heart rate to assess level of workload can be reliable physiological method in other areas but not reliable in aviation.

Pilot workload during routine flight requires a relatively low physical load whereas the nonphysical content of pilot workload may be a relatively high [211]. Correlation between heart rate and pilot workload has been observed [211]. Therefore, this means that the structure of workload itself could be the main issue.

These results seem to be consistent with other research in clinical field which found that this technique has some problems in that it is less resource specific [113, 179]. For instance, increased heart rate of operators performing chest compression through resuscitation is questionable as to whether it is entirely due to increased level of physical workload. Further, anaesthetists move between rooms and often use range of equipment in different locations and this will probably lead to increased heart rate.

To summarise, these measurements might have some benefits of being continuously monitored, however drawbacks include the lack of sensitivity to environmental interference, heart rate can be increased due to a rise in respiratory and physical work. For a sensitive workload measurement, it needs to be able to measure physiological workload in different tasks. Physiological workload measurement, therefore may prove useful in the future for mental workload measurement.

4.5 Study strengths and limitations

A strength of the study is that I conducted comprehensive search strategies following systematic review guidance. Data extraction and quality assessment were independently implemented by myself and findings were confirmed by the team. All the studies involved had the same measurement outcome.

The review has some limitations; presentation of results and the methods used to generate or infer differences in workload differed across the studies, making direct comparisons difficult. There were also limited data comparing tools in the same setting.

Despite the advantages of using an objective measurement, some approaches directly interfere with clinical practice making their widespread use questionable.

Despite the criticism of self-reported measures including subjectivity; lack of clarity of what is actually being measured; and time delay, the evidence presented in this review supports their use and validity for measuring workload. They are sensitive to changes in workload in a variety of contexts and seem acceptable to users.

4.6 Conclusion

The measurement of workload in anaesthesia is an emerging field - supporting patient and anaesthetist safety. The findings from this review highlight the currently applied measurement tools and found self-reported measures have the best evidence base. The Borg rating scale was the most commonly used method and showed consistent

association with expected variations in workload. Correlation between self-reported and observed rating was moderate to good. In addition, the NASA-TLX were comparable with the Borg rating scale and/or physiological monitoring tools, where both tools were used.

Subjective methods have focused on task demands, which could be a sensitive measurement of complexity and time pressure. Such findings can supply diagnostic information where the level of workload is increasing in the system. In addition, the reliability of alarm-response latency (using either a light or Vibrotactile device) methods requires proper context, significance, simplification and time-on-task training. Heart rate alone has an inconsistent relationship with workload with marked inter-individual variability. More advanced metrics of autonomic function (derived from heart rate variability) showed better discriminative ability in one study [184]. Pupil changes were inconsistent relationship with workload with marked inter-individual variability.

To sum up, there is a greater necessity for further studies to validate Borg rating scale in other specialised clinical areas. In addition, meta-analysis should be carried out in order to assist comparison between Borg rating scale and other tools. These will provide reliable validation of this tool and be of clinical value for future research

CHAPTER 5

An Observation Study of Feasibility of a Novel Drug Storage Tray In Anaesthesia Practice

5.1 Introduction

Drug preparation and administration in the operating theatre is seen as a particular challenge, unlike other hospital settings [32]. Anaesthetists routinely choose, prepare, administer, and record several potent intravenous drugs in a relatively short period on their own, sometimes while stressed or fatigued [212]. Most developed countries have attempted to improve the prescription, preparation, and administration of medications to help reduce the inherent difficulty of this process [24], but it remains a serious cause of iatrogenic harm [212, 213].

The most recent prospective observational study examined the rate of medication errors and adverse drug events [32], finding that approximately 1 out of every 20 preoperative drug administrations and every second operation resulted in drug errors or adverse drug events. More than one third of these incidents led to observed patient harm, while the other two thirds had the possibility of patient harm. This is markedly higher than the rates observed in past literature, wherein the incidence of drug errors ranged from 1:131 to 1:5475 ‘pre-operative anaesthetic administrations’ [214-217]. The lower incidence observed in the past is perhaps because of operators’ unwillingness to self-report errors or the lack of awareness that an error has occurred [32].

Several of these errors have been reported due to slips or lapses in the focusing that happen in the multitasked area in which anaesthetists perform [43]. The physical appearance of syringes containing, similar label, and similar drug packaging reported as the main factors of incidents and accidents.

The responsibility for relevant anaesthetic organisation should be appear here, as they should work with the relevant industry to find out a proper solution of the problems of similar drug syringes, packaging and presentation.

There are several practices employed within the anaesthesia specialty that help mitigate the risk of drug error. International colour coding on drug labels ensures that drug labels

used by anaesthetists follow a standard colour design, reduce the risk of selecting the wrong class of drug. There are restriction on the contents of the anaesthetic room drug cupboard to only those drugs that are frequently used or must be administered on an urgent basis. Prefilled syringes to reduce the risk of the wrong drug being drawn up. Some hospitals use a double-checking system (either two-person double check or a machine checking the preparation) [218, 219]. Nevertheless, several researchers have argued that the types of medication errors made, the most common drug errors, and the main factors contributing to drug errors in anaesthesia have remained relatively unchanged for more than 20 years [32, 214, 220, 221].

Current UK practice is for anaesthetists to draw up drugs and then collect them together on one or more disposable trays. However, this method can lead to selecting wrong drug or syringes swaps and these have linked to potential or actual patient harm. It is therefore crucial to detect whether even obviously small or simple alterations in practice are actually of possible advantage.

Novel drug trays were designed for use in theatre, to support the International colour-coding system. Aiming to reinforce the visual attention of the required medications and provides for reducing issues related to infection control using a single-use of disposable internal tray. They have a particular tray for local and emergency anaesthetic medications which can be prepared, stored and placed individually to prevent avoidable errors [222]. In general, Rainbow trays broadly focus on the patient safety and problems that has been reported in the healthcare system in the UK.

The original motivation for developing Rainbow trays resulted from anaesthetic (LS) and pharmaceutic (SG) dissatisfaction with current practice, in the context of serious drug errors and their consequences [223] and the frequency of clinical distractions [49, 224]. Syringe swaps have consistently been cited as a major contributor to medication errors, with the potential and actual serious adverse consequences [216, 225].

The present study aimed to explore the potential impact of a simple adjunct to drug preparation and storage on safe drug administration during anaesthesia in three NHS Hospital Trusts in England. The study aimed to investigate both the praxis of novel drug tray, and the perceived barriers and drivers to its use in daily practice.

5.2 Methods

5.2.1 Study design and participants

This was a multi-centre qualitative study, adopting an interpretive paradigm, utilising observation and semi-structured interviews. A pragmatic approach of convenience sampling within three NHS Trusts in England was used. Approval for this study was obtained from the NHS Research Ethics Committee (O14072015 15057 SoM AIC CN, 23rd July 2015) and local research governance approval, and local research governance approval was gained at all sites. Twenty different anaesthetists participated in the study. Each participant was sent a letter of invitation and information sheet and signed a consent form prior to taking part.

5.2.1.1 Primary objective

To determine how drugs are currently used and stored and how a novel drug storage system influences normal practice.

5.2.1.2 Inclusion Criteria:

All anaesthetists who were working at one of the Trusts at the time of the study and who worked in operating theatres were asked to participate.

5.2.1.3 Exclusion criteria

Any anaesthetists who did not wish to participate in the observations or be involved for any reason.

5.2.2 Data Collection

5.2.2.1 Observations

The observations were conducted at three NHS Trusts by three different trained researchers to permit comparisons and ensure the validity of the data collection.

Over a six-month period, the three investigators observed 30 cases, 10 of which involved the standard trays in 'normal' practice and 20 cases wherein new Rainbow trays were used. The sample size of the observation was achieved through theoretical sampling saturation [123].

Standard practice at all three institutions is for anaesthetists to collect and transport their prepared drugs in one or more disposable, single-colour, unicompartmental paper trays. In comparison, the Rainbow trays include three separate trays: one for non-emergency drugs, one for emergency drugs, and the other for local anaesthetic drugs (**Figure 5**). Each one has a specific disposable insert with rounded edges to aid syringe retrieval and has a colour-coded base, matching ISO 26825:2008 [226] in drug separation.

I introduced the Rainbow trays after completing the initial observation (with the standard trays) with each anaesthetist; then, at least two weeks later, a second observation was carried out where the Rainbow trays were used. This allowed for comparison between the two types of trays and ensured the anaesthetists were familiar with the Rainbow trays prior to the second observation period.

Data were collected utilising a specially designed pre-tested observation schedule across all three sites to promote reliability (Chapter 2). I also recorded any additional comments provided by anaesthetists, trainees, or operating department practitioners (ODPs). This helped us clarify the content of the observations. I observed and recorded our observations in real time, focusing on the drug preparation, administration, and use of the

trays from the beginning until the end of the case. All observations and detailed notes taken during the observation period were typed up immediately afterwards. The key themes of the observation are summarised in **Figure 6**.



Figure 5: Photos of Rainbow tray

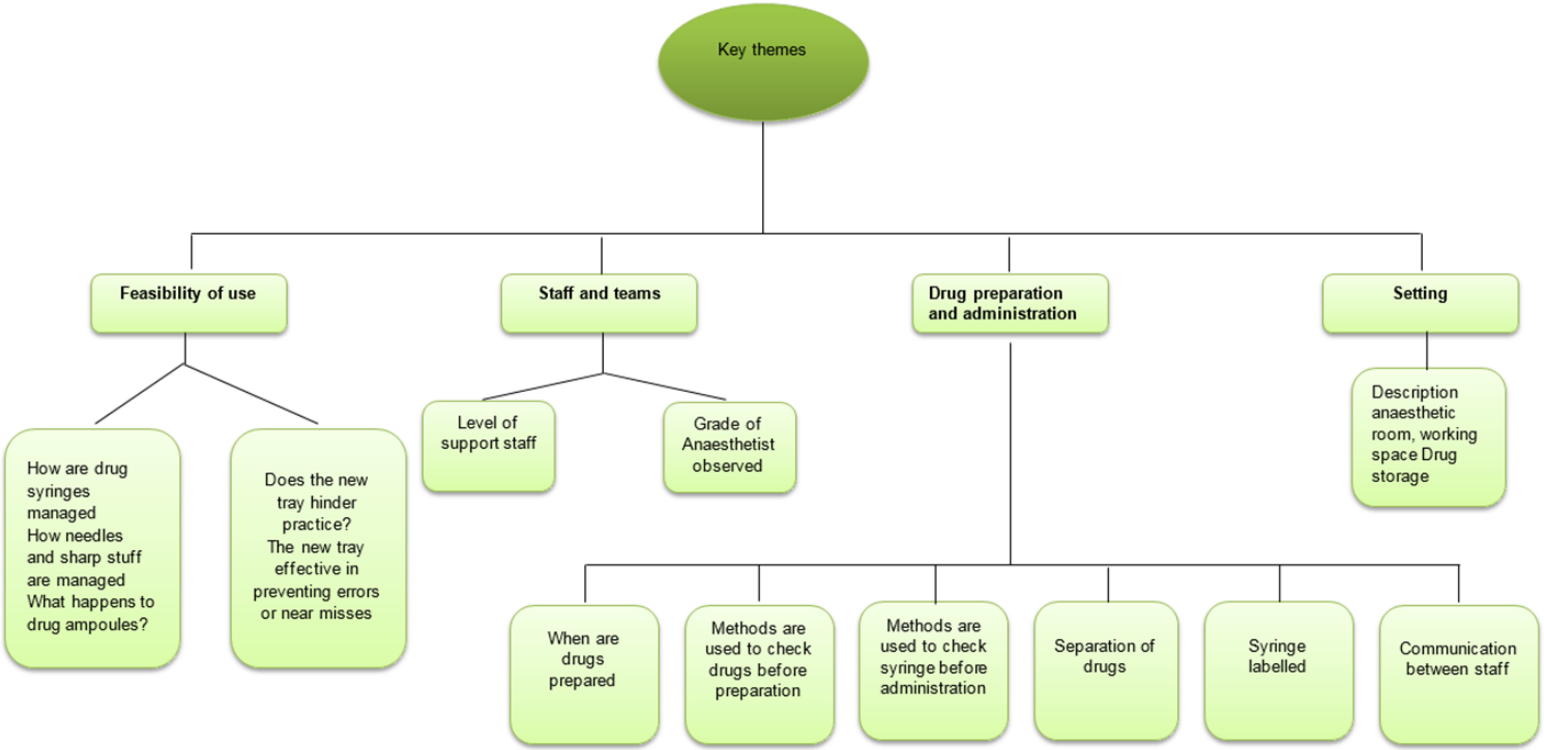


Figure 6: Key theme of the observation

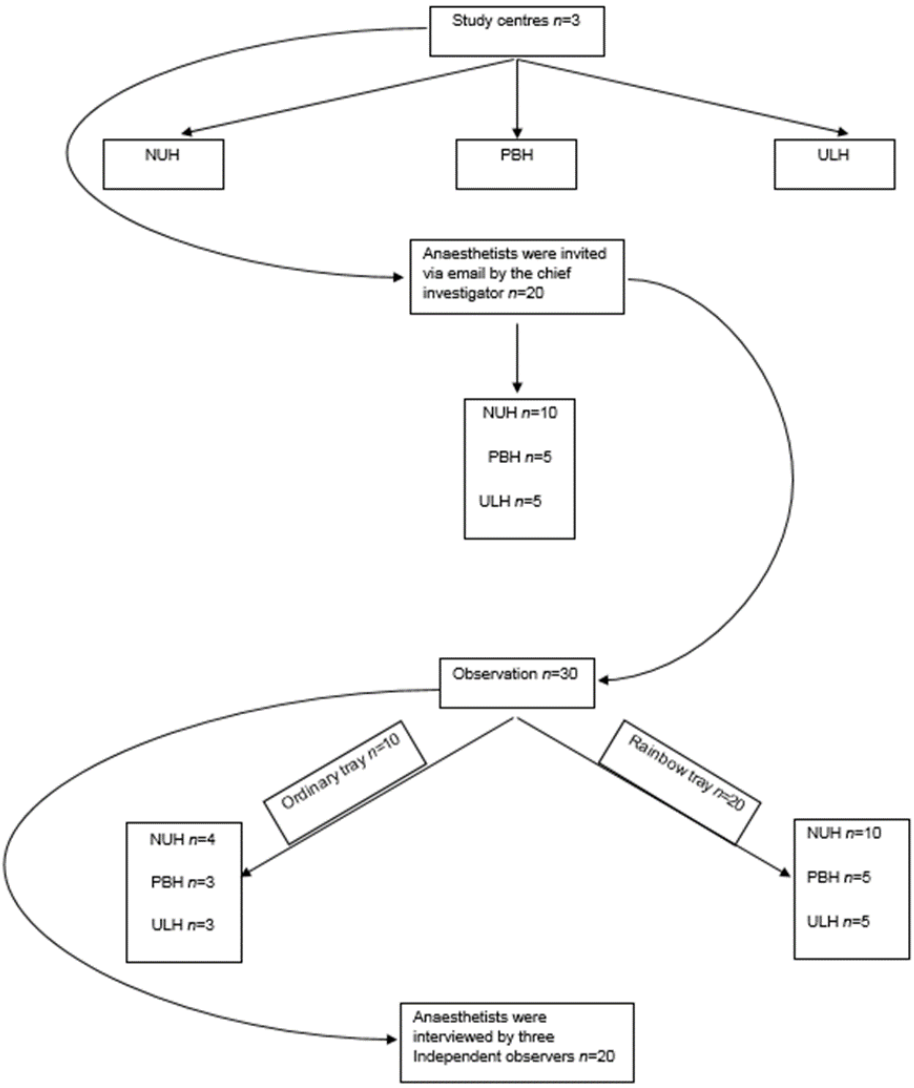


Figure 7: Study process flowchart

5.2.2.2 Interviews

A total of 20 semi-structured interviews were performed immediately upon completing the second observation with the involved anaesthetists, in order to reach theoretical saturation [227]. Each interview was face to face and took place in a location convenient to the interviewee. Each interview lasted between 20 and 30 minutes. I used an interview guide as a prompt for each interview to ensure key questions were asked to all participants. The interview questions focused on the participants' opinions of current practice for drug preparation and storage, and how novel drug storage systems interact with normal practice in **[Appendix 10**]. After obtaining participants' permission, all of the interviews were audio recorded. This allowed me to follow up on any interesting points raised during the interviews and avoid the distraction of attempting to take notes during the interviews. This also allowed for easier data analysis.

During the interviews, discussions were supplemented using the observation notes to help elaborate topics that arose. Before beginning the interviews, a brief outline of the format of the questions was given to ensure that all questions were understandable to participants and to mitigate any possible anxiety. The final transcripts were independently read through by DA and double-checked alongside the original records by the investigators (DA, RE, IM) for reliability and integrity. Any additional comments were included at this phase.

5.3 Analysis

Data from both the observations and interviews were analysed using thematic analysis to identify themes and subthemes. The interview and observation data were sufficiently in-depth to be coded line by line as described by Charmaz [134]. Charmaz [228] mentioned that qualitative methodology was approved to produce elaborate descriptions and categories, as guided by the data, aiming to explain the phenomenon under exploration. The analysis of the data used the constant comparative technique and therefore was

iterative rather than sequential (Chapter 2) [229]. Grounded theory methodology was also used (Chapter 2).

Initial analysis and coding was carried out by DA independently. DA and RE then met to discuss the coding and to agree or revise the thematic categories before discussing the results with the IM. Open coding generated 98 codes; these codes were then synthesised using focused coding into three theoretical categories; two of these categories were then further broken down into three subcategories.

The organisation and management of the data was assisted by the software package NVivo-11 (QSR International Pty Ltd.; Melbourne, Australia) [230]. The observation notes and transcripts were repetitively revisited to compare categories, to explore for 'negative' or inconsistent themes, and triangulation of data from interviews and observations. These themes could then be examined further during the research period throughout gathering additional purposive data until no new themes emerge [125], and no new examples of existing categories appear which known as data saturation (Chapter 2). When completing categories process, memos about every thematic category were written to describe them and confirm reliability between investigators. Memo-writing provided the ability to detail each category, identify its properties, outline any relationships observed between categories or found gaps in the data gathered.

5.4 Result

The two main thematic categories that emerged from the data were 1) standard practice with subcategories; preparation, benefits and risks and 2) Rainbow trays with subcategories; preparation, benefits and disadvantages. A third category that emerged was syringe labelling.

5.4.1 Standard Practice - *Preparation*

Anaesthetic induction was routinely carried out in an anaesthetic room at all three Trusts; I observed no cases of induction within the operating room. In Trust A and C I found that drugs were prepared sequentially prior to the patient arriving in the anaesthetic room, whereas at Trust B drugs were prepared in advance for the whole operation list.

Standard practice in all three sites was to keep prepared syringes on a grey, disposable, compressed paper tray.

In all three NHS Trusts, the drugs were prepared before the patient entered the anaesthetic room by the anaesthetist. Several reasons were given for this practice; one reason was as a way of mitigating distractions or mistakes,

"*I like to draw up my drugs before the patient enters the anaesthetic room, so that I am not being distracted when I am doing it"* [Trust C, A1];

"*Normally I would like to prepare anticipate drugs before patient arrived because it takes reasons to avoid having wrong drug and to reduce risk of mistakes"* [Trust C, A4].

Other reasons given were to ease patient anxiety and reduce the time spent in the anaesthetic room;

"I can g*ive my undivided attention to the patient, and not delay the time before induction to minimise the anxiety levels of the patient"* [Trust B, A2];

"*I think once the patient is in the anaesthetic room, [making sure] the drugs [are] ready at that point means the patient is waiting for less time"* [Trust A, A9].

In all three Trusts, 10 out of 20 anaesthetists read aloud the drug label, including the name of the drug, its concentration, and the expiry date, before the drug was drawn up. Once the drug was drawn up I found all anaesthetists labelled the syringe, however I did not

observe any occasions where the anaesthetist reconfirmed the drug in the syringe corresponded to the drug in the ampoule.

I observed that when drugs were checked by another individual after preparation, this was always by an anaesthetist, not an ODP or nurse. At Trust C I did not observe any second person double-check being performed, including when emergency drugs were prepared.

At Trust C emergency drugs were prepared on an individual patient basis, whereas at Trusts A and B emergency drugs were prepared in advance for the whole theatre list. I also found differences in whether ampoules were discarded or kept after drug preparation. In Trusts A and C empty ampoules were kept until the end of the operation, however in Trust B they were discarded immediately after drawing up.

Across all three trusts, during induction, multiple drugs were held in the hand by the anaesthetist at the same time and I did not observe any two-person double check prior to administration. It was not possible by observation to determine how deeply the anaesthetist checked the syringe prior to administration; for instance, whether only colour was checked, or whether the label was read and checked internally and explicitly against the mental model of the correct drug.

Prepared drug syringes were placed in grey trays at all three Trusts (**Figure 8**). I did observe that anaesthetists sometimes used more than one grey tray to separate the syringes containing ‘emergency drugs’ (typically metaraminol and / or ephedrine), from induction drugs. I found that the grey trays containing the induction drugs were routinely placed on the anaesthetic machine during induction, while the grey tray containing the emergency drugs were left where they had been prepared.

On transfer to the operating room, the emergency drug tray (if used) was generally placed on top of the anaesthetic machine, while the induction drug tray was placed on the anaesthetic machine work surface. At Trust B, both drug trays were routinely placed on

top of the anaesthetic machine with an anaesthetic drug trolley moved to the operating room and placed behind the patient.

5.4.2 Standard Practice - *Benefits*

A frequent perceived benefit of the grey trays was ease of use, size and cost. "*A very cheap method of drug trays"* [Trust C: A1, Trust A: A5],

"They are simple, cheap, and ecological, and are quick and easy to use" [Trust B: A2],

"*It doesn't take up as much room on the anaesthetic machine work surface; the space is limited at the anaesthetic workstation"* [Trust B: A3].

Another benefit was the ability to separate the multiple drugs used during the anaesthetic pathway,

"*I can use a number of trays…my practice uses a lot of local anaesthetic drugs…to separate the local drugs from the other drugs I use"* [Trust A: A7],

"It is useful and just keeps drugs together, and if a couple of different types of drugs are used it is helpful, as I do not confuse my emergency drugs with other drugs" [Trust A: A9].

I observed that grey trays were used to collect the empty ampoules, this finding was supported within the interviews a reason given for retaining ampoules was to mitigate distraction and prevent wrong drug administration

"*We use the grey tray to collect some other discarded ampules"* [Trust A, A9], *"It is easy for me to find my drugs when I am distracted"* [Trust A, A2]

5.4.3 Standard Practice - *Risks*

The main perceived risk of the grey trays was size. Our observations found that when only one tray was used the tray was full of syringes and it was difficult to read the labels. Within our interviews this theme emerged on more than one occasion

"Drug error is a risk and [it] is not big enough, and all drugs are mixed up" [Trust C: A1],

"*It is easy to fail and choose the wrong drugs"* [Trust A: A4],

"Drugs may still fall out if tilted" [Trust B: A3].

There was a uniform acknowledgement that the crowded tray could lead to error, "*Drug error is a risk"* [Trust B: A1],

"Obviously, in terms of the syringes all going together in the tray, we do have to be careful to pick up the right drug before we give it" [Trust A: A7].

5.4.4 Standard Practice - *Summary*

There is no 'standard' practice with considerable variation in timing of drug preparation, the process of drug – syringe checking and the separation of emergency drugs. There are perceived benefits of current practice – cheap and simple, and risks – insufficient size, intermingling of syringes.



Figure 8: Photo of Grey tray

5.4.5 Novel drug storage - *Preparation*

The introduction of the Rainbow trays (**Figure 5**) did not change the way drugs were prepared for the anaesthetic pathway. However, it did impact on the storage of the syringes while in use, consistent with its intended purpose. I observed that all anaesthetists cleaned the main body of the Rainbow tray with sanitising wipes prior to use even though the tray includes a disposable insert as part of its design.

Once the drug was drawn up into the syringe and labelled, it was placed into the individual compartment that corresponded to the appropriate drug class within the Rainbow tray. This was observed for both the induction drugs and the emergency drugs.

I observed no difference in where the Rainbow trays were placed during use compared to the grey trays in anaesthetic room, however I did observe a change in practice during induction. Anaesthetists no longer held multiple syringes at the same time, instead each syringe was individually removed from the tray and the label rechecked prior to administration. The syringes were subsequently returned to their specific sections in the tray.

Similarly, anaesthetists placed Rainbow trays on the anaesthetic machine work surface in the operating room. At the end of the operation, the Rainbow trays were taken from the operating theatre back to the anaesthetic room; inserts were discarded and the trays cleaned and prepared for the next case.

5.4.6 Novel drug storage - *Benefits*

From both our observations and interviews the Rainbow trays were found to be easy to use

"*I did like it; it does not come with a lot of problems"* [Trust A: A4, Trust C: A5], "*I like it, it is straightforward; I like the colour code and how it's organised, and it is easy to use"* [Trust A: A8],

"*I like using Rainbow trays. I find it a good way of storing drugs; I think they are safer than the cardboard trays if used properly"* [Trust B: A4].

The Rainbow trays appeared to aid drug identification through colour-coded compartmentalisation, which reinforced individual syringe labelling. Another frequently cited benefit was the sequential ordering of syringes in line with anaesthetic practice.

"*I liked that they were tidy and they follow the normal order we use in the theatre"* [Trust A: A1],

"It is easy to find drugs and follow the normal sequences" [Trust A: A2],

Additionally, participants liked the way that different classes of drugs were clearly separated

"*I like the way that local anaesthetic drugs are separate from the emergency drugs",* [Trust A: A1].

In an emergency situation, the coloured sections within the Rainbow tray were seen as particularly advantageous, the majority of anaesthetists I interviewed felt it would aide in quick identification of the correct drug

"I can see there is a benefit for [them] in [an] emergency" [Trust A: A7]

"*It is easy to identify syringes, especially in emergency situations"* [Trust B: A2].

Finally, I found that the introduction of the Rainbow trays appeared to increase awareness of the potential for drug errors within anaesthesia

"I like the way they ensure that you think about which drugs you might need and the way of separating drugs very carefully, although syringes in colour coded trays does not mean that the right syringe will get to the patient. Still, it is good and does add additional safety" [Trust A: A4],

"*It adds to the safety, as it is less likely to pick up the wrong syringe and the more likely to put the right drug in the syringe in the right compartment"* [Trust A: A8],

"*I would think that the risk of administering the wrong drug is reduced"* [Trust B: A3].

5.4.7 Novel drug storage - *Disadvantages*

The main disadvantages I found were around the size of the tray and the compartments. There were several comments on the size of the individual compartments being too small

"There are a number of drugs that go in the white compartment so I think that means you could potentially have a collection of drugs in that space that are potentially mixed up" [Trust A: A9],

"In terms of layout of the tray, some compartments needed to be slightly larger, such as the 'other agents' compartment coloured white, as the variety of different drugs that would be placed in it" [Trust C: A5].

However, I observed that the overall size of the tray could be problematic when placed on the anaesthetic machine as it took up a reasonable amount of space. Tray size was also mentioned by several of the participants

"*The size again was a drawback when regular drugs went to the patient, while the core trainee managed the airway"* [Trust B: A2],

"Once you have used most of the drugs in the tray, it takes up a lot of room on the anaesthetic machine table and made it more awkward to complete the anaesthetic chart" [Trust B: A2].

"It is a very bulky container that does not fit on the anaesthetic machine if everything is in the tray" [Trust B: A1].

An identified barrier of the Rainbow tray was the latent risk of syringe swap. If the syringe is initially placed in the wrong compartment there is the potential to rely on the tray placement over the syringe label and administer the wrong drug. This risk was acknowledged by several anaesthetists

"*There is potential for making the mistake of putting drugs in the wrong compartment"* [Trust A: A2],

"You might suddenly put drugs in the wrong compartment and pick them up without reading the label" [Trust A: A8].

Finally, most of the participants were concerns about the cost effectiveness of the Rainbow trays on NHS finances.

5.4.8 Summary

Rainbow trays did not change the way drugs were prepared for anaesthesia. However, consistent with its intended purpose, it did impact on the storage of the syringes while in use. There are perceived benefits of ease of use and increased awareness of the potential of drug errors. Limitations to the feasibility of use were around design and placement.

5.4.9 Syringes labelled

14 out of 20 of the participants labelled syringes around the barrel at the neck of the syringe, predominantly to permit the accurate reading of syringe markings. One anaesthetist reported:

"*By labelling around the syringes, you can obviously see the label whichever way the syringe lays*" [Trust A, A7].

This was supported by another anaesthetist, who also said that a label,

"*Around the barrel at the end does not cover any gradations"* [Trust A, A4].

An additional benefit of labelling syringes was that the colour was more visible. This made anaesthetists more attentive and ensured that they avoided picking up the wrong syringe. Some participants mentioned:

"*I like be able to see the ml gradation and the labelling at the same time, and I think the advantage is that the colour is visible"* [Trust A, A8]

"If the label is around the base of the syringe, you normally see some part of it, even if it's only a bit of the colour, to help indicate what drug it is".[Trust B, A4]

"Generally, I prefer labelling the syringe around the barrel because if it is upside down it still clear what the label says or at least shows the colour of what class of drug it is" [Trust C,A2].

However, some anaesthetists labelled syringes in this way because of manufacturing issues:

"*The biggest problem was that the labelling stickers did not stick very well along the barrel, so around it is the only way to make them stick"* [Trust A, A5]

"My practice is around the barrel. I found it easy to stick them if they are around the barrel because some stickers have lost their glue and do not stick very well" [Trust C, A1].

5.5 Informal post-publication commentary from Twitter.

As we published our final results we wanted to gauge the attitude of key stakeholders toward this change in routine: we shared the trays with colleagues via Twitter which attracted widespread note with more than 200 "likes", 117 "retweets and 43 "comments". Whilst the majority of those who replied were supportive, a few concerns were raised, chief among these was the potential increase in wastage by using plastic insert and caps. Whilst

we recognise this concern, we would also point out that in current practice the cardboard tray is usually disposed and not recycled. Rainbow tray inserts are made of recyclable plastic, while they are single use to ensure appropriate infection control, making sure they are recycled rather than disposed of would reduce waste within the NHS.

Others raised the thought that some colour-blind individuals might encounter problems while using this innovation. Colour-blindness is a really important and interesting point to think about it in the context of medication errors. The rainbow tray is based on the colour coding of the drug labels and so there could already be potential problems which have not been highlighted with the colours chosen within the standards for syringe labelling [231]. As part of our research in the future, we are looking for ergonometric solutions to this potential problem.

5.6 Discussion

This study was designed to clarify how drugs are currently used and stored in anaesthetic practice and if it is feasible to introduce a novel drug storage system within three NHS Trusts.

The main finding of this study was that the current drug storage system was easy to use, low cost and portable, it did however have the latent potential for syringe swap errors. The novel Rainbow tray was readily accepted into clinical practice, was generally preferred to the standard grey tray by the participants and was perceived to have the potential to reduce drug errors.

We developed this ergonomic study to conceptualise how the Rainbow trays might work (or not), rather than to demonstrate any impact on the prevalence of drug errors *per se*. Ergonomics is concerned with the interaction between humans and their (working) environment. Understanding both how work is actually done (as opposed to how work is imagined to occur) and the impact of change on behaviour and attitude is the key to changing practice successfully [49]. The Rainbow trays are simple and linear, designed in

line with Reason's recommendation for reducing complexity [59, 232] and 13.42 NAP5 recommendation for the formal organisation of the anaesthetic workplace and handling of drugs [43].

The literature describes drug preparation as a potentially high risk activity and several factors should be mitigated to reduce the potential for error [43, 47, 213, 233], however, there is still no definitive consensus on the best method for preparing drugs. In my study, I have found the most common practice for preparation of drugs was to initially read the drug ampoule then draw up the drug and label the syringe. This integrity of this process could however be impaired by an interruption or a distraction. Orser [217] recommends pre-labelling the syringe before the drug is drawn up but this method does not prevent the a drug being drawn up in to the wrong syringe. Conversely, Jayasuriya [234] argued that the best method is to check the drug ampules first, draw up the drugs, and then recheck the drug ampules before labelling the syringe, which reflected the practice I found.

Syringe swaps have consistently been cited as a major factor leading to medication errors. Reported consequences of syringe swaps have included awake paralysis and tachycardia; awake paralysis has been found to lead to post traumatic stress disorder (PTSD) and a high rate of psychological sequelae [235]. From my observations I found the potential for syringe swaps is still a risk, too many syringes in a single tray not larger enough to hold them could inadvertently lead to the wrong syringe being selected. The new Rainbow trays are larger to accommodate all the syringes needed within the single anaesthetic, the trays also aid easy identification of the correct syringe as each drug is now placed in its own colour coded compartment, it is anticipated this will lead to a reduction in the selection of the wrong syringe.

The workplace in which anaesthetists prepare and administer drugs has also been cited as a contributing factor to medication errors [215, 236, 237]. To address environmental factors of drug error, standardisation has been advocated. One of the domains within the

productive operating theatre programme [238] focused on the ‘well organised theatre’, this programme encompassed standardisation within the anaesthetic environment. The Institute of Medicine’s report, ‘Crossing the Quality Chasm: A New Health System for the 21st Century’ advocated the standardisation of workspaces to improve patient safety, this is also supported within the literature [237, 239, 240]. From my observations, I found that all three Trusts had standardised their anaesthetic room and theatre layouts, as well as the drug cupboards and fridges across the theatre complex.

Distractions have been implicated as a cause of medication error previously in the literature. Westbrook and colleagues found that the greater the number of interruptions, within a single drug administration, the more severe the error [223]. A consequence of being distracted while drawing up intravenous drugs is the potential to miss-label, NAP5 data [43] reported that six out of seven cases of drug preparation errors were related to labelling errors, which led to awake paralysis and severe psychological sequelae. The Guidelines for Provision of Anaesthesia Services for Intra-operative care 2017 [241] states that 'all drug-containing infusions and syringes should be clearly labelled’, this is in line with the document ‘Syringe Labelling in Critical Care Areas’ [231].

My interview data found that anaesthetists believed preparing the drugs prior to the patient entering the anaesthetic room could help to mitigate errors, however I did find there were issues with the pre-printed labels in that they did not stick very well to the syringe, which in turn could potentially lead to selection of the wrong drug. From my observations I recognised that most anaesthetists found the colour of the Rainbow tray corresponding to the label colour a noticeable benefit, there still however remains the risk of a syringe being placed in the wrong compartment and leading to the wrong drug being unwittingly selected.

Participants felt that the best practice would be to use prefilled syringes, a systematic review by Wahr and colleagues found ‘using prefilled syringes whenever possible’ as one

of the top recommendations [237]. In our experience the use of prefilled syringes within the NHS varies from Trust to Trust, at the three trusts involved in this study non used prefilled syringes as standard. There are potential problems with using prefilled syringes, only certain drugs can be prepared in advance, the shelf life of drugs differs depending on manufacturing process, prefilled syringes have previously been found to have labels that do not meet the international syringe labelling standards, and the cost of preparing prefilled syringes can be prohibitive [242, 243].

Merry et al. have designed an integrated drug administration system in which anaesthetic drug trolleys are arranged to complement the process of anaesthesia. The bases of each drawer are divided into colour-coded sections that match the class of drug stored in each compartment [244]. Evley et al. examined the feasibility of introducing either two-person or bar-coded drug confirmation in 7 UK hospitals [218], but identified workarounds and other concerns that might limit the efficacy of each approach. The Rainbow trays may represent a pragmatic approach to introducing Merry's system into UK practice, where drugs are typically stored in locked cupboards rather than in trolleys. Pragmatic approaches to safety are common in anaesthetic practice. Pin index systems on gas cylinders, colour coding and universal connectors, for example, have all been introduced after considered discussion between anaesthetists, manufacturers and regulators. This often requires an iterative process, to overcome design imperfections identified during development [245].

With the introduction of any new technique or piece of equipment there is the potential for resistance, I did not observe any opposition to the Rainbow trays within our study and participants appeared to uniformly accept them into clinical practice. I did however find a wide range of opinions on the prevalence and consequences of drug errors and acknowledge this could influence the acceptance of any method designed to prevent drug error. As previously noted in the literature [218] it is crucial that the introduction of any new

system is accompanied by activities to promote awareness of drug errors, at a local and national level [246].

5.7 Limitations

During this study I collected a large amount of data from several sources, I also utilised trained observers across all sites. The relationship between observers and participants was a source of potential bias, but I attempted to mitigate any effect through adhering to basic rules for interviewers' conduct and using multiple methods of collecting data. The risk of different observers placing greater importance onto one aspect of the process was mitigated through the use of an observation schedule. The potential for causing a Hawthorne effect [247] was also not apparent in this study and I aimed to limit any potential effect through repeated observations. Finally, although I achieved thematic saturation within the interviews, the issue of waste (insert and plastic caps) articulated strongly on Twitter did not appear.

5.8 Summary

In summary, I have demonstrated that it is feasible to introduce the Rainbow tray into clinical practice at three NHS Trusts in England. I found that the Rainbow trays were readily accepted and facilitated drug identification as intended. Use of the Rainbow trays also appeared to heighten awareness of the potential for drug error and the need to check the syringe prior to drug administration. Further research is now needed to determine both the best strategies for ensuring continued use of the Rainbow trays, and their effect on the prevalence of drug error. Ultimately, introduction to other hospitals will inevitably depend on drivers such as national recommendations [231, 248], institutional policies, education [249-251], and cost, and I intend to report on how these challenges can be overcome in future papers.

CHAPTER 6

Modelling Airway Management using System Reliability Assessment Tools

6.1 Introduction

Every year approximately 230 million major surgical procedures are carried out globally [251]. In the UK an estimated 3 million general anaesthetics are administered per year in the National Health Service (NHS) alone [18]. Safe and reliable airway management remains one of the most crucial responsibilities in anaesthesia, critical care, emergency medicine and related specialities.

Despite its importance, the UK NAP4 [18] has repeatedly shown that the process of airway management is neither '*completely safe'* nor *'reliable'*. This applied to both routine and non-routine settings. 'Minor Process errors' were very common, such as failing to intubate in the first time or failing to use the intended tube. 'Catastrophic failures' as described in NAP4 [18], although rare, can result in serious outcomes such as brain damage, death and high cost [250, 252]. Catastrophic failures therefore indicate a high risk to patient safety. NAP4 and the Difficult Airway Society (DAS) calculated the occurrence of serious airway complications during general anaesthesia to be 1 in 22,000 general anaesthetics, and of death and brain damage to be 7 per million general anaesthetics in the UK [250, 252]. These analyses have added useful information about some critical incidents but are likely to miss a considerable proportion of major events [252]. Knowledge about such complications should be a crucial part of clinical decision-making and risk management.

Human factors thinking utilises conceptual frameworks to describe the NTS, around communication skills, situation awareness , teamwork, and decision making, to facilitate safe and effective performance of tasks [18]. In addition, Gaba and colleagues [253, 254] have used these conceptual frameworks to explore how anaesthetists understand their role. Klemola and colleagues [255] studied the presence or absence of the recognition of the uncertainty and unpredictability of anaesthesia. Of note, success at tracheal intubation was viewed as related not to uncertainty, but to the skill of the practitioner. It is impossible to test or predict every possible combination of events which might occur

when managing a patient's airway, even when using a simulated environment. Clinical practice, especially anaesthesia, is too complicated and unpredictable to be amenable to more standard methods of analysis. It is therefore quite difficult to determine how these processes could be improved in ways which go beyond expert opinion.

Airway management can be considered as a complex engineering process which includes of a series actions (e.g., tasks or decisions) that might occur sequentially or simultaneously utilising different resources such as time, people, equipment and medications. For a long time engineers have had mechanisms and techniques [156] that enable them to analyse complex processes. These have recently become more developed and might be useful for analysing clinical behaviour. The author of this study believe that these may allow systematic analysis of the airway management process if supported by robust, clinically credible data. This can be later applied to other processes carried out in operating theatres and in healthcare systems in general.

Therefore the aim of this study was to explore the actions and decision making during the process of airway management in both routine and complicated cases, to develop a model of routine airway management and decision making using system reliability assessment tools.

6.2 Methods

6.2.1 Study design and participants

This was a single centre qualitative study, adopting an interpretive paradigm, using observation methods (video and audio recordings). Approval for this study was obtained from the London –Surrey Borders Research Ethics Committee, References number 14/LO/1239, 26 January 2016. In total, 6 anaesthetists, 8 operating department practitioners (ODP's) and 20 patients participated in the study. Each participant was sent by a trained researcher a letter of invitation, an information sheet and consent form to sign prior to taking part. Consent was received from all participants, including patients,

who were informed that the data from the recordings would be kept securely confidential in accordance with the Data Protection Act 2017 [256] prior to taking part and that they could withdraw from the study at any point.

6.2.2 Observations (Recording)

A total of 20 multiple channel video and audio recordings of routine induction and airway management were completed in this study. The sample size of the observation was achieved through theoretical sampling saturation [227] (chapter 2). Observations were focused on actions and decisions involved in routine and complicated airway management.

6.2.2.1 The Direction of filming cameras in the anaesthetic room.

For all video recording, there were three cameras used. One camera was a head mounted video worn by the lead anaesthetist. The second camera was lateral to the patient airway looking at the lead anaesthetist and head of the patient. The third camera was on the other side of the room, again on the lateral side of the patient focusing on the monitoring screen **Figure 9**.

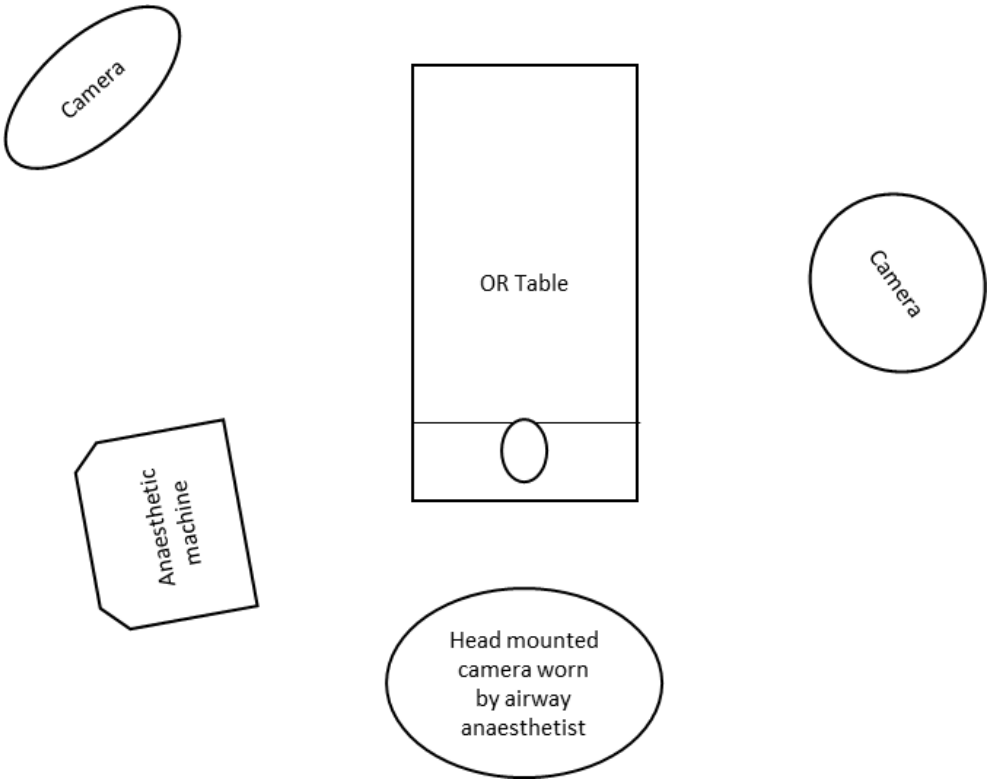


Figure 9: Camera positions in relation to the anaesthetic room

6.3 Analysis

6.3.1 Review of recordings

All recorded cases were given a code number to ensure anonymity. One of the recordings was unable to be included in the analysis due to technical problems. A trained researcher (DA) reviewed all video footage and deconstructed the normal induction and airway management into basic steps based on the work of Phipps [154] (chapter 3). This method of analysis was also based on the application of a series of questions developed from the Critical Decision Method (CDM) [257], with the aim of producing an understanding of the cognitive strategies applied and the influences on strategy selection.

The process of deconstruction was achieved through creating a flow chart of normal induction and airway management; this included resource needs, action, cues, and decision points. The video footage was reviewed again, by the same researcher, to refine both the process map and timings such as start, completion and duration.

For data analysis, each video was subdivided into three periods: 1) patient preparation and application of monitoring, 2) induction of general anaesthesia, and 3) intubation process. The patient preparation and application of monitoring period was defined as the point at which the World Health Organisation (WHO) checklist finished to when the face mask was applied. The induction period was defined from the point of administration of the intravenous induction agent to the administration of the neuromuscular-blocking agent (NMBA). The intubation process period was defined from when the ODP hands the laryngoscope to the lead anaesthetist and ended at the point of confirmation of correct tube position and successful ventilation.

Median and interquartile range (IQR) were used to describe variation in the amount of time spent on different tasks.

6.3.2 Reviewing airway incidents

Before meeting with the participants (predominantly consultant anaesthetists), DA explored and assessed decision making by looking at the available literature and all video footage, during normal induction, airway crises and failure scenarios of the process, equipment and team (as it was unlikely that such failure would occur in the recording period).

Then, the same researcher met with each anaesthetist individually, according to the CDM [257] to prompt information from them and to provide the basis for design of decision support. The CDM is a type of cognitive task analysis. It is usually used by researchers to explain the mental process to implement a task, and contains knowledge deriving, data analysis and knowledge demonstration [257]. Its main target is to perform explicit the information, decisions and approaches underlying observable behaviour.

DA went through the recording with each consultant anaesthetist focussing on the following key areas:

- What actions occurred during the process and how long they took;
- What cues or decisions were involved in determining these actions;
- What resources (knowledge, people, equipment) and communication between the team were required for successful completion of the process,
- What failures and/or delays of the procedure and equipment can sometimes occur,
- What alternative actions exist in the process

DA also asked about any additional comments provided by consultant anaesthetists, trainees, or ODPs during reviewing videos and with the participants. This helped clarify the content of the record and we came up with 3 outputs overall;

1. Full description of tasks that were undertaken through routine induction of anaesthesia and airway management.
2. A description of the decision-making process during routine induction of anaesthesia and airway management
3. A description of decision making processes through difficult or unplanned airway management.

DA met with a trained researcher in airway management to discuss these outputs and to agree or revise them before discussing the results with IM, the results of this phase were fed into the next stage of analysis.

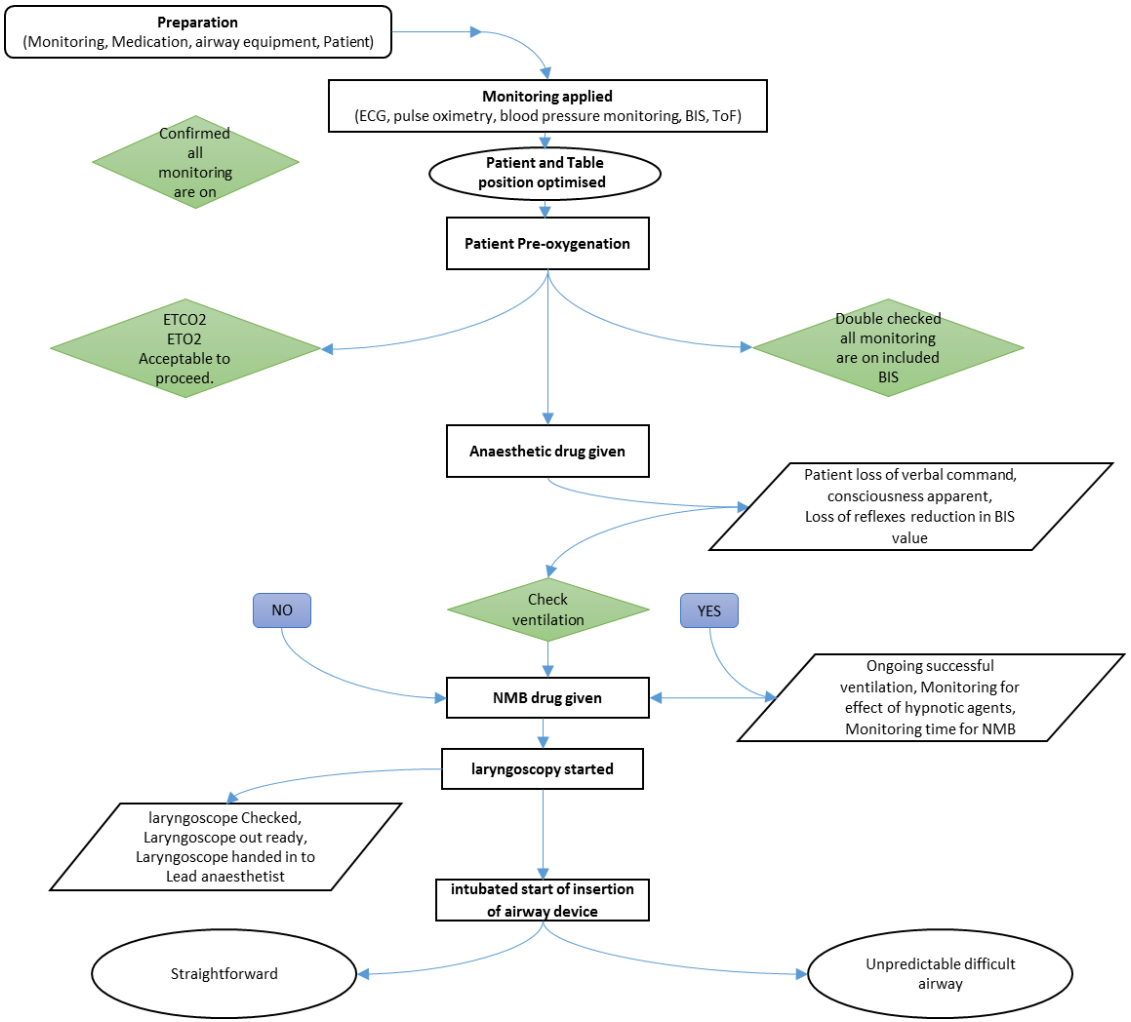
6.3.3 Modification of hierarchical task analysis (HTA) into coherent process

As discussed in chapter 3, HTA was initially defined by Annett and Duncan [152] , it's a method used in order to assess and reduce human error. It helps researchers to ensure a full coverage of tasks in a hierarchical construction of goals, sub-tasks and plans; this process was followed to refine HTA in this study.

The task analysis covered anaesthetic team main performances from the patient preparation and application of monitoring to the end point of confirmation of correct tube position. Data for the HTA was gathered from published data (DAS [258], NAP4 [252], and the AAGBI guidelines on preoperative machine and checking anaesthetic equipment [259]), observations (the processes observed in the video and audio recording and embedded the decision making and cues identified in reviewing airway incidents), and technical expert advice from a consultant anaesthetist (IM).

6.3.3.1 Applying HTA to airway process

HTA of the airway process was drawn up by DA and reviewed by IM. The top level of the HTA was to maintain and secure the airway in the anaesthetised patient. The task steps necessary to achieve this are outlined as plans 0, 1, 2, 2A, and 3 and 4 on the next level of the hierarchy. Plans were applied to prescribe how tasks interrelate to meet the overall goals. In addition, plans usually included ordering information. Plan 0 was outlined as preoperative assessment, which was carried out in the pre-op department before the recording started. Then subordinate sub-tasks were indicated to achieve the goal (preparation, action of anaesthesia, maintenance of airway, ventilation and action of paralysing and intubation). These subordinate subtasks were broken down further at the lower levels. Each goal, task and sub-task was assigned a hierarchical number and represented by using a flow chart diagram and demonstrated in **Figure 10**.


Preparation
(Monitoring, Medication, airway equipment, Patient)
Monitoring applied
(ECG, pulse oximetry, blood pressure monitoring, BIS, ToF)
Confirmed all monitoring are on
Patient and Table position optimised
Patient Pre-oxygenation
ETCO2
ETO2
Acceptable to proceed.
Double checked all monitoring are on included BIS
Anaesthetic drug given
Patient loss of verbal command, consciousness apparent, Loss of reflexes reduction in BIS value
NO
Check ventilation
YES
Ongoing successful ventilation, Monitoring for effect of hypnotic agents, Monitoring time for NMB
NMB drug given
laryngoscopy started
laryngoscope Checked, Laryngoscope out ready, Laryngoscope handed in to Lead anaesthetist
intubated start of insertion of airway device
Straightforward
Unpredictable difficult airway

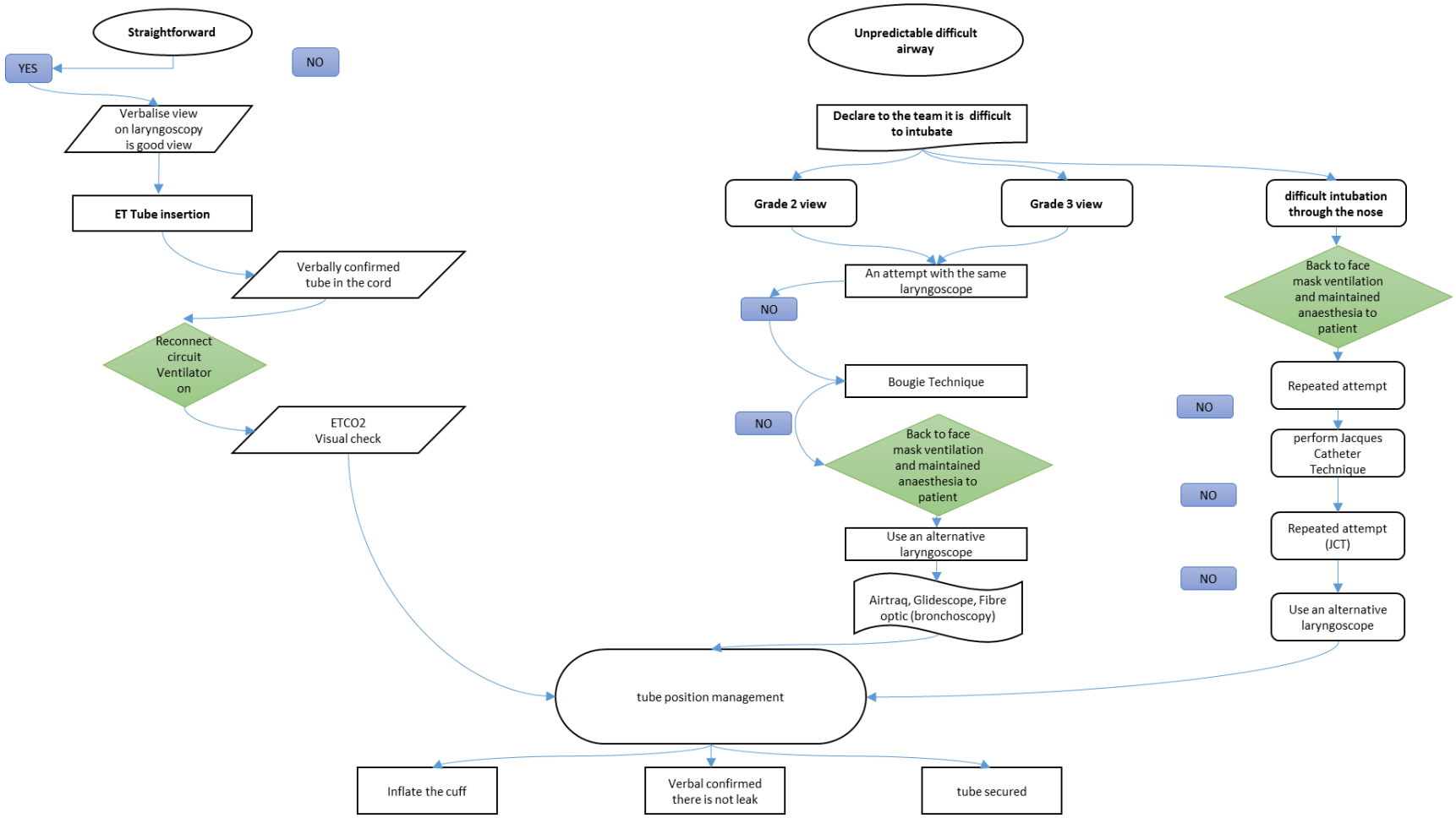


Figure 10: Process of Airway Management

6.3.4 Systematic human error reduction and prediction approaches (SHERPA)

I chose the systematic human error reduction and prediction approaches (SHERPA) [156] to examine the task steps at the lowest level of HTA in more detail. SHERPA was used because it can be employed to analyse tasks at several levels. The combination of HTA and SHERPA was to enable identification of errors that might occur and in which part of the task they might occur. The kinds of error that may occur within airway management come into one of the four behaviour sections: action (preparation, drug given); checking (monitoring and procedure); information communication (non-task communication); and selection (choosing wrong alternative process). Both the HTA and SHERPA were subsequently reviewed by DA and IM.

6.4 Results

In the present study, the results were presented according to HTA three broad themes and eleven sub-themes from the analysis of the data are summarised in **Figure 11.** Individual themes are presented below with detailed supporting extracts from individual participants and observed recordings.

6.4.1 Airway process

This theme broadly encompasses order of actions during the process of airway management, and then subdivided into duration of each actions and verbal communication during airway management.

6.4.1.1 Actions

The review of the video recordings and interviews showed that the order of actions during the process of airway management were found to be: patient position preparation and monitoring applied; administration of induction agent /NMB and intubation process.

Preparation of patient position and application of monitoring.

In all the video recordings, all anaesthetists preferred to put the patient's head flatter with the patient's head positioned very close to the end of the table ('sniffing position'). The reasons given were to avoid stretching, provided better pharyngeal airway patency and less force for laryngoscopy. In 13 out of 19 of observed cases, the patient's pillow was folded by the anaesthetist before they started pre-oxygenation; this appears to help them to get a good view for direct laryngoscope insertion. However, variation between individuals themselves was also observed, for example one anaesthetist always folded the patient's pillow, another anaesthetist sometimes folded the patient's pillow and other times he did not. Other anaesthetists did not fold the patient's pillow at all.

The results also showed that while the table height is required for helping airway procedure, in only 6 out of 19 cases did the anaesthetist make an adjustment to height of the table. It was not possible by observation to determine whether the table in the rest of the cases was adjusted or not.

Patient positioning of the observations are summarised in **Table 5**

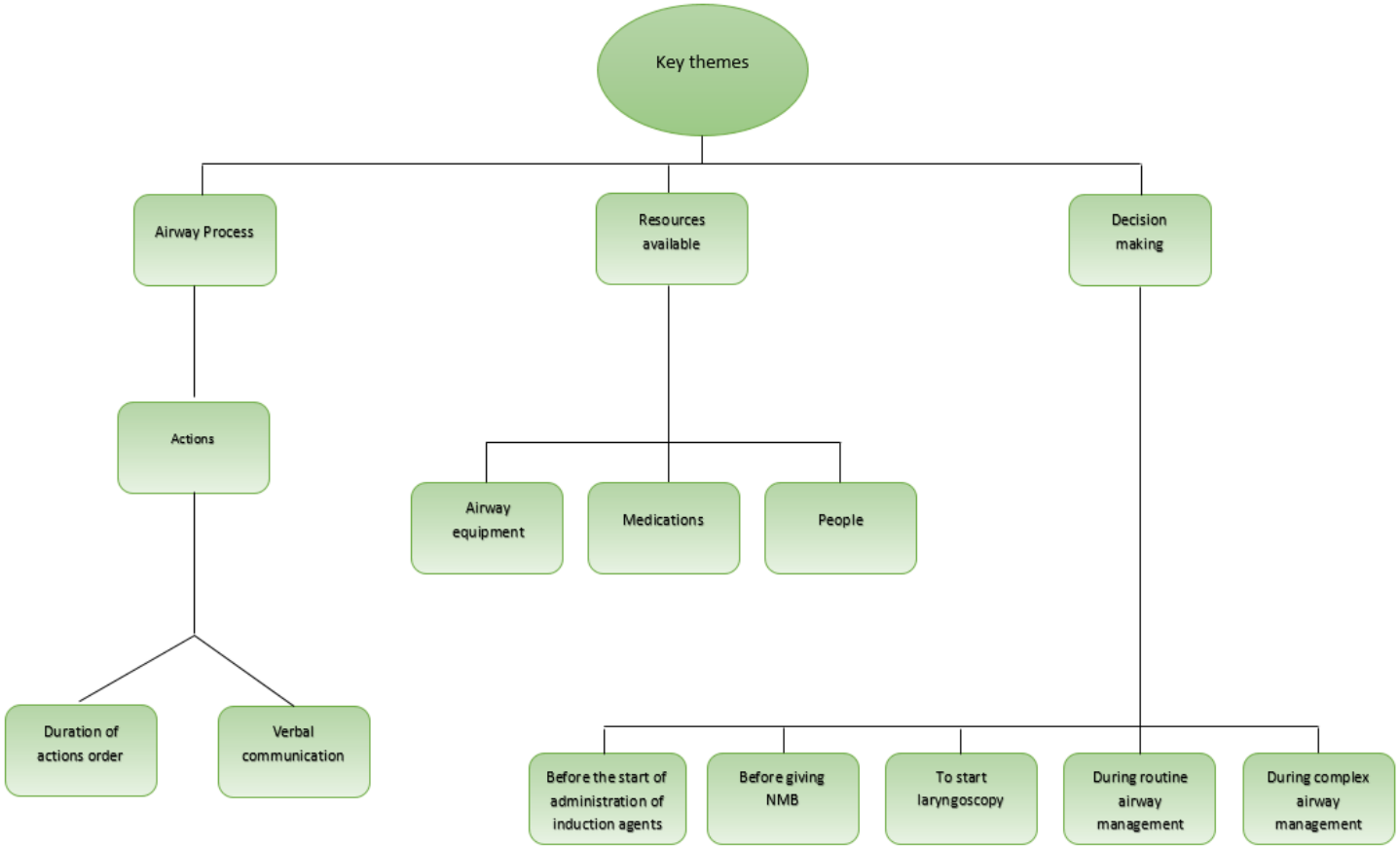
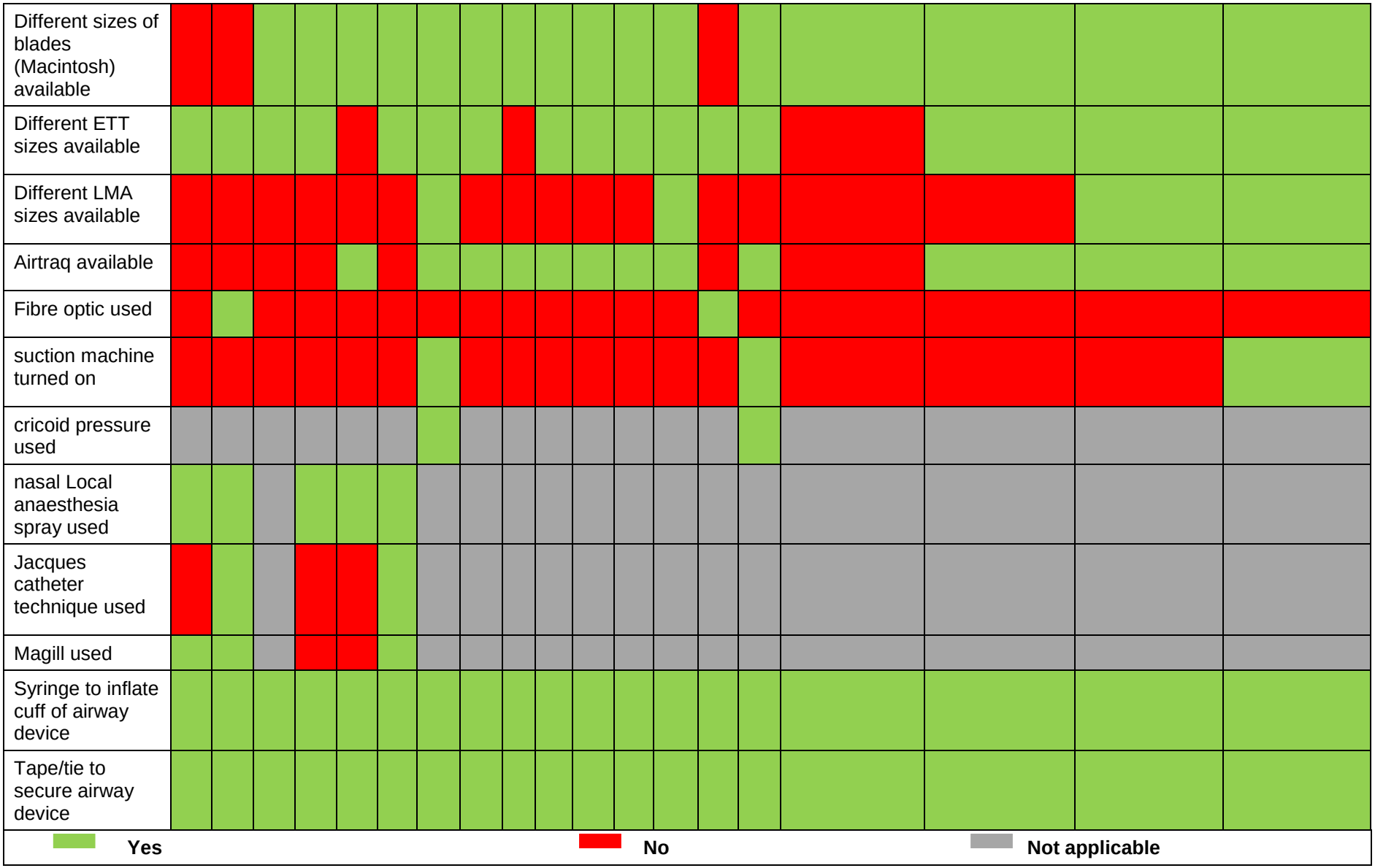


Figure 11: Identified themes

Table 5: Positioning and Airway preparation

	First consultant						Second consultant									Third consultant	Forth Consultant	Fifth Consultant	Sixth Consultant
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
Folded Pillow position																			
Remove of Denture(s) if present																			
Spectacles off if there is																			
Neck extension for pre-oxygenation																			
Bed head flat																			
Adjustment of table height																			
checking airway equipment's and monitoring																			
Different sizes of oropharyngeal airway out ready																			
Bougie available																			


Different sizes of blades (Macintosh) available
Different ETT sizes available
Different LMA sizes available
Airtraq available
Fibre optic used
suction machine turned on
cricoid pressure used
nasal Local anaesthesia spray used
Jacques catheter technique used
Magill used
Syringe to inflate cuff of airway device
Tape/tie to secure airway device
Yes
No
Not applicable

Patient monitoring

Patient monitoring includes electrocardiogram (ECG), capnography, pulse oximetry, blood pressure monitoring, gas analysis, Bispectral index (BIS) machine, and neuromuscular blockade monitoring (train-of-four (TOF)). BIS and neuromuscular monitoring were used in 50% of observed cases. This finding was likely due to the case mix in our sample: the anaesthetists involved explained that BIS is primarily used in conjunction with total intravenous anaesthesia (TIVA), and assessment of neuromuscular function prior to intubation is indicated for certain neurosurgical pathologies.

Administration of induction agent

The lead anaesthetist usually started with opioids and then with an administration of rapidly –acting IV induction agents either by direct IV bolus or via TIVA target controlled infusion (TCI) at pre-set speed. The author of this study observed that once anaesthesia was maintained, the main activities of the anaesthetic team focused on maintaining vigilance of the patient's physiological status.

Following the IV induction agent and once the patient had lost verbal command and reflexes, the patient's head position was optimised and airway patency maintained. Subsequently, the anaesthetists' deepened anaesthesia with O_2 and volatile agent (+/- N_2O) via face mask or TIVA. It has noted that over half (4/6) of the lead anaesthetists did not ensure manual ventilation was possible before giving NMB. Moreover, in contradiction to NAP4 and NAP5 [18, 43] it was found some anaesthetists administrated NMB too early and did not leave patient until adequately sleep.

Intubation process

It was noted that the intubation process started once the anaesthetists managing the airway confirmed the patient was adequately anaesthetised and paralysed (either through monitoring or clinical assessment, see below) and the ODP handed them the

laryngoscope. The process ended once anaesthetists were reconnected the circuit, turned the ventilator on and visually checked $ETCO_2$ as well as tube position fixed.

6.4.1.2 Duration of actions order

From my observations the process of patient preparation and applying physiological monitoring took up the largest proportion of time within the induction (**Table 6**). The cases where the anaesthetist spent the largest proportion of time on patient preparation were often when intravenous cannulation was more challenging or additional time was spent optimising the patient's position (**Table 6**).

The current author also observed other tasks which occupied a large amount of time, these included cases where TIVA was used for induction and maintenance of anaesthesia and where the BIS machine was applied. Conversely, some cases were associated with a short period of time, in these cases, lead anaesthetists did not use the BIS machine or TIVA, and the cases were uncomplicated. On reviewing the observation data, one participant was surprised how long it took for the induction process during TIVA but did comment that it was difficult to predict.

Table 6: Duration of actions order (minutes)

Process	**Median (IQR)**
Patient preparation and monitoring applied	3:41 minutes (2:02-7:50 m)
Administration of induction agent	1:01minutes (0:54-1:15 m)
Intubation process	1:39 minutes (1:12-2:40 m)
cases when TIVA and BIS	4:33 minutes (2:13-8:17 m)
Cases when did not use BIS and TIVA, and uncomplicated cases	2:05 minutes (0:53-4:58 m)

6.4.1.3 Verbal communication during airway management

6.4.1.3.1 Patient communication

During the induction process, there was direct conversation between the patients and the anaesthetist, such as task communication and reassurance conversation. These types of communication were also observed to be used as methods of communicating to the team via the patient.

Task communication included explanatory communication around what tasks they were performing at a particular time or more generally. Task communication was more about patient preparation and positioning: *"I will put you a bit flatter"* [Anaesthetist 1-6], *"I will put you extra monitoring across your chest*" [Anaesthetist 2 and 5], *"This is brain monitoring"* [Anaesthetist 2, 3, 4 and 6], *"Here's some O_2 for you coming through this mask"* [Anaesthetist 1-6], *"I will get you off to sleep"* [Anaesthetist 1-6]

Another frequently cited task communication between the patients and the anaesthetist, was explaining the medication given and their effect: *"This is a sleeping medicine and you may will get some tingling in your forearm"* [Anaesthetist 1], *"This is sleeping medicine, you might feel a bit achy in your forearm, it is normal"* [Anaesthetist 2 and 3].

Task communication between anaesthetist and patient before starting the process of airway management acted as prompts to the ODP that the process is about to start and the situation was well controlled.

Other direct conversation to the patients, aimed at the team, were reassurance conversation. Anaesthetists routinely asked the patient: *"How you doing dear?"* [Anaesthetist 2] *"You doing grand"* [Anaesthetist 1], *"Doing well"* [Anaesthetist 4], *"Are you warm enough?"* [Anaesthetist 3].

These were used as signals to let the ODP know that the patient was adequately asleep and be ready to proceed to the next step, it was also a cue for the trainee to pick-up the NMB syringe.

Quotes about communication between the anaesthetist and the patient during airway process are shown in **Table 7.**

Figure 12 below shows frequency of these type of communications during the airway process across all observed cases. Task communication was observed to be the most common communication used by all participants, following by reassurance communication and communication addressing both needs.

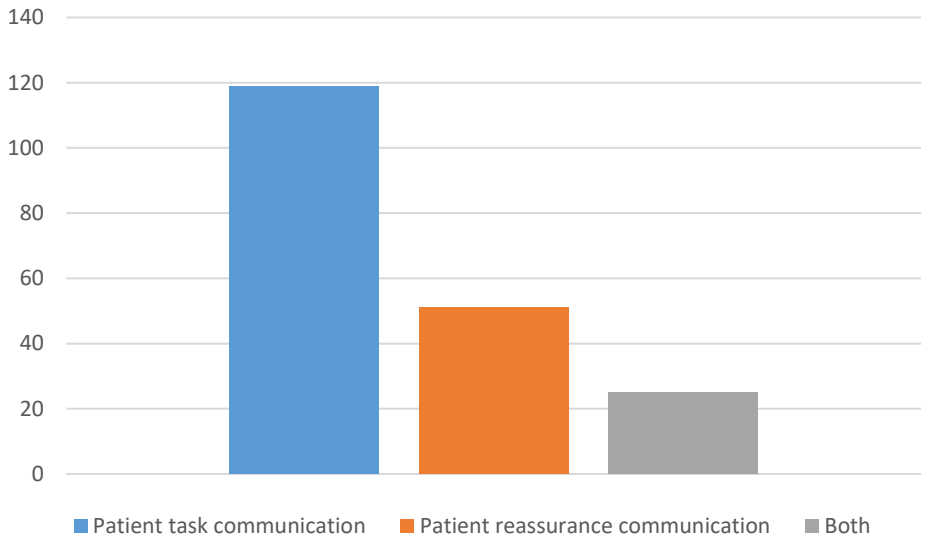


Figure 12: Frequency of communication to team via patient during the airway process

Table 7: Communication to team via patient during the airway process

Process	Task communication	Reassurance communication
Preparation/positioning	• What I need to do, laying you flatter and then double your pillow, to put you in better position. • We need to put in a cannula. • I will put you extra monitoring across your chest. • We use brain monitoring as well show us how sleep you are. • Give you fresh air to breath and then get you off to sleep.	• What I need to do, laying you flatter and then double your pillow, to put you in better position. • We use brain monitoring as well show us how sleep you are.
Before induction	• I will get you off to sleep. • Here's some oxygen for you coming through this mask. • Some of the medicine might make your forearm tingling ok? • Keep your eyes open as much as you can please.	• Alright. • All is fine. • Well done you doing really well. • Very good. • Going off to sleep.
NMBA	• This medicine will feel sore. • This is a strong painkiller. • Open your eyes for me? • Take deep breath for me. • A big breath in and out, please. • Can you take deep breath for me?	• How you doing dear? • You doing grand? • Doing well. • Are you warm enough? • That is great well done you doing well. • You doing great.
Laryngoscopy	No communication observed	No communication observed

6.4.1.3.2 Team communication

Once the patient was asleep, communication between the team started to include social communication, teaching and task communication.

Social communication and teaching conversations were observed between the team in several cases. The usual focus of teaching conversations between the anaesthetist, ODP and/or trainee were around airway device operation and drug effects.

Four types of task communication between the team were found during the process of airway management. These included Closed-Specific (closed-loop communication), Open-Specific (non-specific language dependent on the context), Open-General (ambiguous language) and Closed-General (double-checking).

Before administration of induction agents, task communication between anaesthetists and ODPs used closed-specific questions and closed-general questions, such as, *"Is there a bougie?"* or *"Do we have video laryngoscope?"* or *"You happy?" or "You ready?*

All of these questions were directed by anaesthetists to the ODP which confirmed that they were ready.

When the ventilation was successful, common words used were open-general statements such as "*well done", "all is fine", "that's great",* and closed-specific open-general statements like *"airway equipment double checking*". These statements were directed to both trainee and ODP. The appeared to be a prompt for the trainee checked the NMB to be given and ODP to prepare for intubation.

At the laryngoscopy stage, some of the anaesthetists used open-specific statements that described the view of the airway, like "*grade 2 view"* or *"grade 3 view"* or *"good", and "nice view*". Furthermore, they sometimes used open-general statements, like *"I am happy", and "all good".* All of these terms were observed to be a message to the team

that they had a clear view. The ODP always responded by handing in the tube and/or an alternative laryngoscope.

Finally, there are view statements anaesthetists always said like *"well controlled", "everything is fine"* and *"sounds good*". The meaning of these statements were dependent on the context.

Subcategories, and quotes for team communication during airway process is shown in **Table 8** and **Table 9**.

Figure 13 demonstrates rates of types of conversations between team during the airway process. From the figure, it can be seen that by far the greatest user of conversation between the anaesthetic team is for open-general conversation, followed by Open-specific, closed-general and closed-specific.

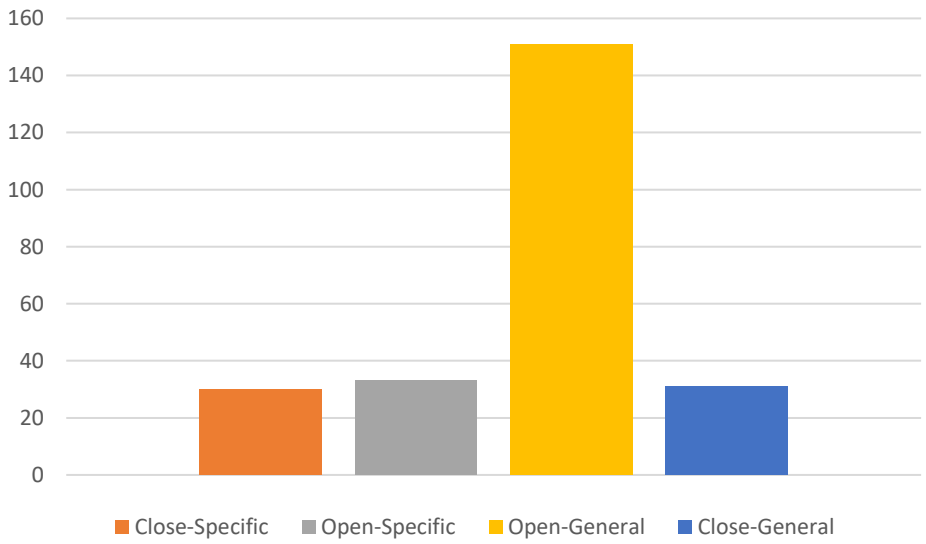


Figure 13: Type and frequency of communication between team during airway process

Table 8: Communication between team during the airway process

Process	Closed-Specific	Open-Specific	Open-General	Closed-General
Before induction	• Is there a bougie? • Do we have Airtraq? • Do we have video laryngoscope? • Do we have a different sizes of LMA?		• Great, • Excellent, • Very good, • Ready? • Happy? • Ok.	• Let's go.
NMB	• Double checking *(i.e. Do we have orange Guedel*?)	• Well controlled. • Everything is fine. (*i.e. able to ventilate, ongoing successful mask ventilation, patient adequately a sleep, patient adequately paralysed*)	• Well done • All is fine. • Very good. • Ok that's better.	• You happy? • You ready? • You Ok? • You alright?
Laryngoscopy	• Do we have a different sizes of LMA? • Is there a bougie? • Do we have Airtraq? • Do we have video laryngoscope?	• Nice view, • Grade 2 view, • Grade 3 view, • Difficult view, • Stiff neck, • View ok, • Good view	• Good, • That's good, • That's perfect, • Everything is fine, • Beautiful, • It is not easy, • Cool, • I am happy • I am alright • It is in cool • Well it is ok, • Looks good • Sounds good (*i.e. Verbal confirmed there is not leak, Visual check $ETCO_2$*).	• You happy? • You ready? • You Ok?

Table 9: Response by ODP during the process of airway management

Anaesthetists	ODPs
• You happy?	• Yes I am happy
• You ready?	• Yes I am ready
• You Ok?	• Yeah I am ok
• You alright?	• Yeah
• Do we have a different sizes of LMA?	• Yes We have, all ready
• Is there a bougie?	• There is
• Do we have Airtraq?	• We got it
• Do we have video laryngoscope?	• It is here

6.4.2 Airway process – Summary

Overall, the results showed that there was variation between individuals themselves in patient positioning and sequence of application of. From reviewing videos and interviews with anaesthetists, there was a general consensus that it made no difference to the order in which physiological monitoring was utilised, as long as all the leads were connected correctly to the monitor and the patient and they were recording.

Furthermore, the choice of induction agent was selected according to the clinical condition of the patient. The most striking result to emerge from the data was the different practices of the anaesthetists when giving NMB drugs; checking the ability of the patient to self-ventilate prior to administration of the NMB compared to those who did not. Neither group started intubation until they had ensured that the patient was adequately anaesthetised and paralysed.

During observations, it was found the time spent on patient preparation and connecting physiological monitoring took a significant proportion of the induction period. This was more pronounced when TIVA and BIS were used. In addition, verbal communication during airway management was used by the anaesthetists as a clear message to the ODP that the process was about to start.

6.4.3 Resources available

In general this theme includes resource needs during the process of airway management. It is further classified into three subcategories: airway equipment, medications and people.

6.4.3.1 Airway equipment

We found variation between how each anaesthetist checked the availability of airway equipment prior to intubation. Reviewing the recordings and interviews, each anaesthetist had their own routine of airway equipment preparation. In 7 out of the 19 observed inductions, the presence of a bougie was checked by the anaesthetist during WHO Surgical Safety Checklist sign in. It was not possible by observation to determine whether other members of the anaesthetic team present had checked the availability of the bougie or not. In addition, in nearly half (9/19) of observed cases, the availability of the Airtraq optical laryngoscope was checked, while in 15 cases the lead anaesthetist checked if they had different sizes of oropharyngeal airways ready. Only in 4 out of 19 observed cases was the presence of different LMA sizes checked by the lead anaesthetist during WHO sign in. in addition, a fiberoptic bronchoscope was used by only two of the lead anaesthetists; in one case there was no evidence of checking for the availability of the bronchoscope during the WHO sign in which led to the ODP leaving the operating theatre to source it.

When reviewing the video observations with the individual anaesthetist at interview it became clear there was a discrepancy between what the individual perceived they checked routinely and what actually happened. Participants were surprised that on some occasions they did not carry out the checks. The reason they gave was that they had presumed, when they asked the ODP about readiness for all airway equipment, this meant everything they would need was available and ready.

Airway equipment preparation of the observations are summarised in (**Table 5**).

6.4.3.2 Medications

Another important resources found was medications. Across all observed cases, the medications that are required for safe airway intubation were observed to be induction agent, volatile agent +/- nitrous oxide (+/-N_2O), Opioid.

6.4.3.3 People

In each recording, there was usually a consultant anaesthetist, one or two trainees and ODPs, and a patient.

During the period of induction of general anaesthesia, participants (anaesthetists, trainees and ODP's) spent the majority of their time performing six tasks: observing monitors; adjusting monitoring; observing time; mask ventilation; task communication; checking and preparing airway equipment. However, in the period of intubation process, the anaesthetic team spent their time performing laryngoscopy, manipulating the airway and securing the tube.

Before each induction a plan was made by the lead anaesthetist and the supporting team. The supporting team were important in establishing situation awareness during the process of induction specifically around oxygenation of the patient. For instance, the most frequently observed cue relating to airway equipment was that when the lead anaesthetist was facilitating ventilation, the ODP observed and listened to check whether there was a leak from the face mask or not. If there was, they directly handed the oral airway (Guedel) to the lead anaesthetist. In addition, in situations where the bougie was difficult to pass through, the ODP usually decided to do external laryngeal manipulation or suggested an alternative airway equipment.

6.4.4 Resources available – Summary

I found variation between how each anaesthetist checked the availability of airway equipment prior to intubation. However, the medication preparation and administration of

induction agent was relatively standardised for each case and in every case there was a spare trainee anaesthetist and ODP and they were found to be performing different tasks such as, double checking medications and airway equipment.

6.4.5 Decision making

Decision making appeared to be based on cues received from different parts of the anaesthetic environment, such as teamwork, monitoring, and patients. The following decision points were determined from the observation video recordings during the semi-structured interviews with the 6 lead anaesthetists.

6.4.5.1 Decision to start laryngoscopy before administration of induction agents

There were 6 distinct cues identified in the period of time between making the decision to start laryngoscopy and proceeding to start administration of induction agents:

1. The appropriate airway technique was chosen during WHO sign in
2. All necessary monitoring was applied and working, including gas analysis ($ETCO_2$ and ETO_2)
3. NIBP, ECG and BIS machine where in used
4. Patient position was optimised and readiness of all airway equipment anticipated for the case was double checked with ODPs
5. It was confirmed that the patient was sufficiently pre-oxygenated (had good $ETCO_2$).
6. Anticipated drugs were double-checked with the trainees.

The majority of cues were comparable across all lead anaesthetists except for two which were concerned checking of drugs and pre-oxygenation. All of the six cues influenced the anaesthetist's decision on when to commence administration of induction agents.

6.4.5.2 Decision before administration of NMB

A variety of cues were perceived as significant by the lead anaesthetists before they decided to start giving NMB.

The anaesthetists, on the whole, confirmed that administration of NMB depended on the availability of NMB. However, half of them (3/6) confirmed with ODPs if they were ready or not and that all the airway equipment anticipated for the case was ready before administration of NMB. 4 out of the 6 lead anaesthetists checked whether successful ventilation was possible before giving the NMB. In addition, 2 out of the 6 anaesthetists only administered the NMB if the patient was adequately anaesthetised with the loss of verbal command, consciousness and reflexes.

Those anaesthetists who used a BIS machine looked for a predefined reduction in the BIS number to administer NMB. Two lead anaesthetists who used BIS, usually gave NMB early and gave 'minimising pre-intubation apnoea' as the reason for early administration. Furthermore, in one case the administration of NMB depended on the expectation of a difficult intubation. All of these observational and technical cues were used by lead anaesthetists to make the decision to give NMB.

6.4.5.3 Decision to start laryngoscopy

There were a variety of cues relating to decision making before starting the process of laryngoscopy: with all anaesthetists agreeing that time was the most common indication to make the laryngoscopy start, "if time is more than enough for NMB to work, then we can start laryngoscopy". The observations however showed that this wasn't happening in practice during assessing NMB. Another important cue was observing the physiological monitoring: there was a significant difference between each of the lead anaesthetists on what observations and monitoring they used prior to the start of laryngoscopy. Four out of the six anaesthetists used a BIS machine and looked for a suitable reduction-in BIS number, three confirmed that the patient was adequately paralysed by using the train-of-

four (TOF), and two of them monitored the systemic effects of hypnotic agents, such as reduction in heart rate.

On reviewing the video observations the majority of anaesthetists agreed that what they imagined they did routinely varied from what they actually did. Some of the participants were surprised to find they did check the ventilation before giving NMB while others were surprised about the length of time they took for patient ventilation.

6.4.5.4 Decision during routine airway management

The most significant decisions during routine airway management were found to be analogous for all lead anaesthetists and their supporting teams. They made decisions based on cues observed during visual view through the laryngoscope, tracheal confirmation and cuff management.

The decision that they could pass the tube through was based on a simple visual cue by looking through the laryngoscope to check that the view was good. In addition, ET tube intubation position was verbally confirmed by commenting that the tube had been visualised going into the trachea. The decisions were supported by different methods; the detection of $ETCO_2$ through capnography to confirm the tube was in the right place; confirmed misting of the ET tube and visual assessment of chest movement.

Further cues utilised during routine airway management were in relation to ET tube cuff management, which focused on confirmation by all ODPs that there was no leak once the cuff of the ET tube was inflated.

The overall decision making during routine intubation was found to be similar among all anaesthetists. The teamwork was verbal in this situation and also based on body language cues and observation of patient physiological monitoring demonstrating situational awareness.

6.4.5.5 Decision points during complex airway management

There were 3 situational assessment cues when airway land marks (the Cormack & Lehane grade) were difficult to visualize: grade 2 views and grade 3 views, and when the ETT would not pass through during nasal intubation. In addition, it was noted that there was considerable variation between grade views in both time and equipment required.

In situations where difficult intubation was observed, the participants in this study appeared to follow recommended guidelines. Their decision points arising from management of difficult airways were perceived to be fairly common.

- Declare the airway view to the attending ODP and trainee, for example grade 2 or grade 3 view.
- Return back to oral airway and face mask ventilation
- Anaesthetist asked for a bougie or Jacques Catheter Technique
- Anaesthetist asked for an alternative laryngoscope
- Increasing the dose of hypnotic and NMB with the aim of keeping the patient safe, stable and asleep.
- Alerted the surgeon to the difficult airway in order to share the decision making
- Repeating the process of laryngoscopy with an alternative laryngoscope

Appendix 11, Appendix 12 , Appendix 13, Appendix 14, Appendix 15, Appendix 16 are outlined the process of decision making during complex airway management.

In a summary, in difficult intubation cases, it was noted that there was effective teamwork and communication among the operating theatre team to achieve successful intubation. In addition, it was common for the plan to change rapidly during this situation. Difficult intubation cases found to require different types of airway equipment and the length of time they took varied on the grade view. Cues related to decision-making observed and discussed with the participants are summarized in **Figure 14**.

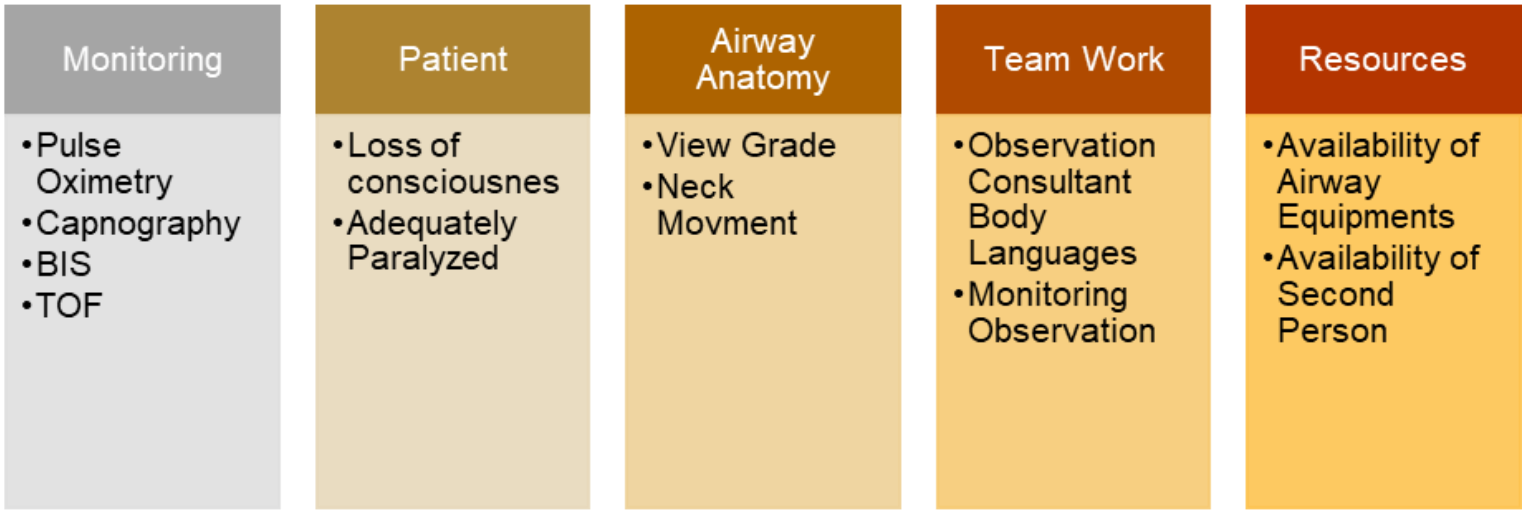


Figure 14: Cues related to decision-making observed and discussed with the consultant

6.5 Discussion

The purpose of this study was to explore the process (i.e., actions and decision-making procedures) of airway management in routine and complicated airway management cases. It is hoped that these results will lead to the development of a systematic model of routine airway management and decision-making.

The results of this study revealed clear variations in the intubation process. Specifically, anaesthetists varied in terms of how they utilised patient monitoring and how they checked the availability of airway equipment prior to intubation. Furthermore, results revealed that patient preparation and the connecting of the physiological monitoring equipment consumed a significant proportion of the induction period, and this was more pronounced when TIVA and BIS were used.

Effective team communication was observed during the process of airway management, and the teams used check-back techniques and abbreviated communication. Most decisions were made by the lead consultant anaesthetist. The lead trainees and ODPs engaged in specific behaviours in support of these decisions, but they were not active decision makers. Instead, they contributed to the main decisions made by lead anaesthetists through situational monitoring (i.e., attending to the lead consultant anaesthetist's body language and observing the physiological monitoring equipment).

Some decisions were based on novel approaches (e.g., a fiberoptic bronchoscope or Airtraq optical laryngoscope), and almost all situations had been previously experienced by the lead consultant anaesthetists and their supporting team, thereby allowing for effective collaborative behaviour. In some cases, decisions could only be reached after considerable negotiation, the use of novel techniques, and through different forms of support (e.g., the support of surgeons). Most decisions by the supporting team concerned the preparation of airway equipment.

Human factors play a role in the interaction between individuals and their working settings. The data suggest that it is important for the anaesthetists and their supporting team to understand the real-time process of their work, instead of focusing on how they imagine the processes will occur. Furthermore, to successfully change practices, there needs to be a focus on changing performances and attitudes.

It is crucial to clarify the role of the anaesthetic team in ensuring airway management safety. Effective airway management requires the cooperation of all members of the operating theatre team, particularly between the anaesthetists and other team members (i.e., trainees, ODPs, and the surgeon). Teamwork can occur when the healthcare system employs ergonomic techniques to extract specific information about the process of anaesthesia and risks to safety. In addition, operators must be appropriately skilled in dealing with the complex demands of the operating room [260].

6.5.1 Non-technical skills (NTS)

The NAP4 [18] highlighted the importance of human factors and training in achieving success in complex airway management. These results are consistent with the findings of other studies that have found that the complexity of patient care in an anaesthetic environment calls for anaesthetists to possess a range of skills and attributes such as communication, decision-making, and teamwork [260]. Accordingly, greater comprehension of skills related to human factors are required to improve the overall outcome of airway management.

Ensuring this comprehension and utilisation of human factors will require more effective training. This training should focus on a unique set of skills, including communication, situational awareness, teamwork, and decision-making [261], which are collectively referred to as ‘non-technical skills’ (NTS) [261] under the umbrella of human factors [260]. These skills are also believed to be crucial for improving operators’ technical skills and minimising avoidable errors in the operation setting [262]. In this regard, an understanding

of the NTS are necessary for safe and effective performance in the operating theatre environment during both routine and non-routine airway management.

The need for these skills is further emphasised by how the introduction of guidelines, and professionals' adherence to these guidelines, is insufficient for avoiding complications in airway management during anaesthesia. It is clear that all the events stated in the NAP4 occurred in spite of extensive dissemination of the original Difficult Airway Society (DAS) guidelines [258].

This finding suggests that the inherent complexity of airway management cannot be resolved through guidelines or reliance on past experience alone. The modern operating theatre environment is often stressful and anaesthetists must use a multitude of skills and knowledge, all of which are dependent on time pressure, task demands, available options, and the decision-maker's existing resources [78].

6.5.2 Team work

Decision-makers in safety-critical environments hardly ever work alone; as such, it is especially important to consider the dynamics of team decision-making. Participants in the current study worked as a team and correctly noted that group work can decrease the likelihood of errors and accidents.

The literature on patient safety has broadly acknowledged the importance of teamwork for providing safe patient care [92]. The current study also suggests that supporting team members play a crucial role in the process of airway management, and they often use non-verbal cues with other team members, potentially allowing for more efficient work.

Compared with individuals working in other high-risk environments, medical teams who work in operating theatres often work under pressure and constantly changing conditions. The challenges faced by teams are pronounced during unpredictable and difficult airway management procedures. Weller and colleagues [263] reported that anaesthetists do not

work in isolation, and that trained assistants are crucial for improving the outcome of difficult airway management.

The findings from Weller and colleagues [263] are in line with the recommendations of the AAGBI standards of monitoring during anaesthesia and recovery [264]. They recommended that at least one extra anaesthetist and ODP be present in the theatre. This is not only to provide the anaesthetist and ODPs with opportunities for breaks, but also to provide help when needed.

The current study suggests that teams are more efficient when completing tasks in defined sequences. The current study also suggests that the supporting team members are important for completing the process of airway management, particularly in that they were familiar with the cues used by various team members. In the context of research, cues are defined as non-verbal cognitive processes that feature in situation diagnosis and depend on situational awareness. Klein and colleagues. [265] reported that cues are vital to 'recognition-primed decision-making'.

As mentioned earlier, the team used a number of non-verbal cues to aid in effective communication during the procedures. The current study found that these cues were rule-based and context-specific. In other words, cues were based on past successful experiences. The cues used by these teams can be reviewed (**Figure 14**). Schnittker and colleagues [266] suggested cues provided by ODPs or trainees are important for making key decisions during the airway management process. Furthermore, Klein and colleagues [267] argued cue analysis is important to produce actions, assess situations, and help make decisions in complex work environments.

In addition to cues, the current study found that verbal communication was also a hallmark of well-functioning teams and verbal communication increased the speed and efficacy of task completion. In the present study, check-back communication was used to verify the accuracy of information during procedures. The current study revealed communication by

anaesthetists to the team to reassure the team and to let them know when the process was about to commence. This finding aligns with past research, which links teamwork and communication with healthcare outcomes [268]. Communication between team members is crucial, but communication with the patient is also necessary. During the process of induction, anaesthetists explain what will be occurring to the patient.

Task communication was also used by teams in the study. Task communication can be conceptualized as "short-cuts" that communicate a lot of information but require members of the team to have a throughout understanding of each other and of the process. For instance, anaesthetists asked, *"you happy?"* or *"you ready?"* or *"yes"* or *"I am happy"* or *"brilliant"* or *"let's go on"* or *"grand job"*. These short phrases were meant to convey information between team members (i.e., that the face mask was applied, that the drug and airway equipment were ready and checked, and that the process was about to start).

Closed-loop communication was also used during routine and difficult procedures to confirm and certify information exchange [269]. It originated from military radio communication and eventually came to be used in anaesthesia [269]. The results of this study revealed that closed-specific, specific-open, general-open, general-closed are the formal types of communications that occurred in the study **(Figure 13)**. General-open communication was found to be the most commonly used in airway process.

6.5.3 Airway equipment

Importantly, there appears to be no clear 'standard' practice for patient and airway equipment preparation and handling, despite this being a fundamental component of safe airway practice. The lead consultant anaesthetists and their assistants did state that adequate availability of resources was essential for successful airway management. Prior to induction of anaesthesia, all lead anaesthetists discussed the availability of resources with their trained assistant, which aligns with the recommended guidelines [258, 270]. Furthermore, they ensured that team members were familiar with the equipment and

techniques described. Their practices in this regard also aligns well with the effective team check proposed by NAP5 [43]. However, the current study did reveal considerable variation in checking the availability of airway equipment between anaesthetists during the WHO sign-in **(Table 5)**.

It was evident that there was a discrepancy between what the anaesthetists perceived they checked routinely and what actually happened. This represents a mismatch between work-as-done and work-as-disclosed [119], and highlights an area for further education. ODPs always checked the availability of absolute resources needed (i.e., syringe to inflate cuff of airway device and tape/tie to secure airway device), which represented work-as-prescribed [119].

The current study revealed that the lack of airway equipment had a direct impact on team performance and the quality of support for anaesthetists. The specific equipment-related factors included non-availability, lack of training in the use of specific equipment, and failure to consider whether the correct equipment was being operated. Checking the availability of airway equipment a key factor in airway management, and having the correct equipment is key for reducing unwanted incidents [18]. Indeed, the NAP4 reported that equipment-related factors either caused, or contributed to, more than one-quarter of the total number of incidents [252].

Data from several studies suggest that checking anaesthetic airway equipment to ensure their correct function is exceedingly important for patient safety and harm reduction [250, 252, 259, 271]. The AAGBI guideline Checking Anaesthetic Equipment 2012 [259] recommended that anaesthetists take responsibility for checking equipment before use (either directly or via delegation). In addition, they must follow any specific checking procedures recommended by the individual manufacturers. The results of this study showed that all airway equipment was checked before use by ODPs and then confirmed by the lead consultant anaesthetist, according to the manufacturer's instructions during

preparation. Furthermore, the equipment was again checked after anaesthetic induction and again before the intubation process by the anaesthetic team.

6.5.4 Anaesthesia Monitoring

The anaesthetists in this study reported that appropriate monitoring to detect incidents, and having equipment to manage these incidents are essential. During anaesthesia, patients' physiological parameters and the sufficiency of the anaesthesia require continual assessment, and this requires clinical observation and monitoring devices.

Patient monitoring in the operating theatre cannot prevent all adverse events or accidents, but it can decrease risks [272-275]. For these reasons, monitoring standards have arisen as a necessary consideration for patient safety and risk management. The AAGBI has devised several recommendations for monitoring equipment, particularly that monitoring devices should be attached before the induction of anaesthesia [270]. In the present study, the sequence of attaching the monitoring equipment varied with individual anaesthetists' and ODPs' practice.

In reviewing the observation videos, and when probed further within the semi-structured interviews, there was a general consensus among participants there was no difference in the effectiveness of the monitoring based on which device was connected first, so long as the devices were all connected to a source of electricity and were recording. The minimal acceptable standard for monitoring equipment in this study was ECG, non-invasive arterial pressure, pulse oximetry, capnography, and gas analysis.

These monitoring devices are included in the recommendations for monitoring standards by the American Society of Anaesthesiologists (ASA) and the AAGBI [18, 270]. The AAGBI recommendations noted that monitoring is deemed necessary when using total intravenous anaesthetic (TIVA) techniques with NMB [270]. This is consistent with data obtained from the recommendations of the NAP5 [43]. Our results appear to concur with

these recommendations. Including the above-mentioned monitoring devices, participants also used depth of anaesthesia monitors (BIS and TOF) in circumstances where patients were undergoing TIVA.

6.5.5 Patients' position

Evidence shows that optimal patient positioning maximizes the chance of successful laryngoscopy and tracheal intubation [258]. Correct positioning of the patient also appears to be important for maintaining adequate oxygenation while managing the airway. The present results reveal that patient positioning is important step for the commencement of anaesthesia.

There was uniform acknowledgement among the participants that the sniffing position would lead to a better glottis view when using the direct laryngoscope, and this allowed for comparable glottis visualization in the general patient population. Participants also mentioned that this position helped increase the pharyngeal space and improved mask ventilation. These results align with those reported in earlier studies [276-279].

6.5.6 Neuromuscular-blocking drug (NMB)

Current guidelines explicitly stress that anaesthetists should begin ventilation with 100% oxygen as soon as possible after the induction of anaesthesia and pre-oxygenation [280]. However, the guidelines further state that NMB can make mask ventilation easier, and that insufficient NMB can make it somewhat more complicated [280]. In their editorial, Calder and colleagues reported that there is no guaranteed way of making an airway technique work [281], but they noted that NMBs tend to offer more benefits than risks.

They further suggested that NMBs should be administered early, before checking whether ventilation is possible. This result is consistent with a substantial number of studies showing that normal or complex facemask ventilation either remains unaffected or improves, but never worsens, after NMBs [282-285]. They also note that NMBs can

facilitate tracheal intubation when it is impossible to perform facemask ventilation. Checking facemask ventilation before or after the NMB drug is given was a controversial topic among participants in the current study. However, it was noted that over half (4 out of 6) of the lead consultant anaesthetists gave NMBs before checking whether the patient could be ventilated.

The interview data showed that some of the participants were surprised with their working practice (i.e., they thought they had not checked the ventilation before giving NMB although they actually had). Interestingly, one participant gave the NMB early in order to avoid intubation apnoea. However, this contradicts the reports of NAP4 and NAP5 [18, 43].

It was also found that distraction caused one of the lead consultant anaesthetists to forget to give NMB, even though it had been prepared. Distraction by the team, conversation, and equipment issues were noted by the NAP5 to be major contributors to incidents of AAGA [43]. In addition, Campbell and colleagues [224] found that team member distractions are the most prevalent, and they are related to negative outcomes.

Past literature has shown that there is considerable variance in both the onset and duration of NMB effects and that clinical assessment of the effects is currently inadequate [264]. The vast majority (97%) of the reported incidents in the NAP5 were related to NMBs [43]. Another study noted that less than 20% of United Kingdom anaesthetists usually monitored NMBs. In the present study, participants agreed that one of the main methods of assessing NMB was time (watching o'clock) but our observations showed this is not happening in practice. This represents a discrepancy between 'work-as-imagined' and 'work-as-done'. Other important assessment methods were clinical judgment and the use of devices such as TOF and/or BIS.

Some researchers recommend the use of quantitative monitoring to control NMBs. For instance, Baillard and colleagues [286] suggested using a quantitative peripheral nerve

stimulator (e.g., TOF) during all stages of anaesthesia to monitor NMB. They also recommended that the device be activated after the induction period and before the NMB is given, with the goal of ensuring its correct location and functioning.

The participants of this study also used these types of monitors in situations when the patient had undergone TIVA, and attached the devices after the induction period and before the NMB. Cook and colleagues [252] reported that the benefit of using and monitoring NMB was optimising difficult airway management, while Patel [287] noted that it helped ensure effective use of NMBs and aided in mask ventilation. However, there are some barriers to using these devices, such as cost effectiveness and the need to train anaesthetists in their use.

6.5.7 Intubation process

Study participants also reported that the type of laryngoscope used can influence the chance of successful intubation. Past literature has demonstrated that direct laryngoscopy with a Macintosh blade remains the preferred method, except in situations where a difficult airway is anticipated [18]. On the other hand, several studies [288-290] have reported that video laryngoscopes should be the preferred method, where the process is not blind.

Participants in this study used a Macintosh blade device as the first choice in most of the observed cases, along with the Airtraq; however, this might be because of participant bias. From the literature, the benefit of video laryngoscopes in managing airways is unclear [18]. The participants noted that advanced devices can enhance the larynx view to some degree, but the ETT might not pass the larynx. In addition, they are similar to other specialist devices that can cause without an anaesthetist that has been trained to employ them effectively. Further research is required to clarify the benefits of these devices [18].

The DAS guidelines stress the importance of employing various methods for overcoming failed intubation, rather than depending on repeated attempts with the same device [291].

The guidelines also note that repeated use of direct laryngoscopy is best performed only when a different type of laryngoscope is available after the first attempt [18]. These points are consistent with the results of this study.

The participants identified that the first attempt offers the best opportunity for securing the airway without adverse events, and therefore the chances of success should be maximised by optimising the patient's position, the surrounding facilities, and the environment before beginning the airway management process. This finding is supported by Henderson and colleagues' work [291].

Cook and colleagues. [292] suggests that intubation sometimes becomes impossible when several attempts to intubate are made using the same device. These attempts typically involve blind operation, and can lead to progressive airway trauma or oedema. Accordingly, it is crucial for the anaesthetist to have a plan for every intubation situation, which includes utilising the best suited devices on the first attempt.

During observations in the current study, several strategies for handling unexpectedly difficult intubation -- in particular, alternative methods of securing the airway -- were prepared while the anaesthetic team completed the WHO checklist. In all but two cases, this alternative method required brining in equipment from outside the theatre room. There was consensus among the lead anaesthetists and their supporting team that in cases where intubation was difficult or impossible, priority should be given to maintaining oxygenation and increasing the dose of hypnotics and NMB, with the aim of keeping the patient safe, stable, and asleep.

In the current study, the more experienced the anaesthetist the bigger the influence 'work as done' had on the choice of airway device used. This, in turn, led to greater surprise when intubation failed. One reason for this may be a reliance on previous experiences and task knowledge. This, however, can increase the risk of failure due to lack of awareness. This may also have a negative influence on the standard of practice of the team as a

whole, particularly on trainees. This highlights the importance of continual refreshment of airway management risk assessment training.

In the current study, several different approaches for managing complex airways, including the use of bougie techniques, were utilised. Bougies are important aids for intubating patients of viewing grade 2 or above, and they can make the difference between a successful or a failed intubation attempt [293]. Bougies are, by nature, stiff devices and sometimes require considerable force at the tips. Accordingly, when directed against soft tissue (whether tracheal or oesophageal), this force can lead to trauma. In 30% of the observed inductions during this study, the presence of a bougie was checked by the anaesthetist during the WHO sign in.

In some cases – particularly when the passage for the tracheal tube could not be clearly visualised – a primary decision was made to use a bougie with the same laryngoscope. In this situation, lead anaesthetists reported that the bougie was inserted blindly, and that great care had to be taken not to use excessive force. They also stated that, in this situation, the ODP usually provided aid by using the External Laryngeal Manipulation technique. This, in turn, helped improve the view of the laryngoscope. A red rubber catheter (the Jacques Catheter Technique) was also used during complex nasal endotracheal intubation. It can guide nasal endotracheal tubes during difficult intubation. The literature indicates that the use of this technique is correlated with a lower rate of epistaxis and airway trauma [294].

Correct placement of the ETT was confirmed by all participants. End-tidal CO_2 is an important indicator of the correct placement of the ETT, and it is a precise way of confirming or refuting whether the intra-tracheal position of the ETT is suitable [295]. In the operating theatre, continuous capnography is a primary choice for confirming the position of the ETT. Participants also relied on the observation of chest movement and direct visualization. However, as noted by MacLeod and colleagues [295], these

techniques are clearly fallible and therefore cannot be relied upon. Furthermore, when tube management was conducted, the ODP verified the ETT location by checking for leaks when they inflated the ETT cuff and looking for condensation in the tube.

6.6 Limitations

There were a number of limitations in this study. First, it was a single-centre study and it was not blinded, meaning that the results are not particularly generalizable. Second, as with the study in chapter 5, the sample was purposive and one of convenience [227]. Finally, the technical issues with the video recording in this study introduced inconsistency (i.e., in one video recording, one of the camera was not correctly synced with the other cameras, and in another recording the camera focus was not correct and the recording was blurred). These issues made the analysis more difficult.

6.7 Conclusion

In summary, this study revealed differences in airway practice and preparation. Furthermore, lead consultant anaesthetists and their supporting teams made numerous decisions in order to limit potential variability in the airway management process. A lot of the team communication used code language, but the teams worked well together and this did not appear to cause any problems. The decisions were primarily made by the lead consultant anaesthetist, with the trainees and ODPs supporting these decisions. In addition, the more experienced anaesthetists were more likely to rely on their past knowledge (their 'work as done') and their airway risk assessment was inferior to that of their more junior colleagues. The more experiences anaesthetists tended to pre-emptively assume the type of airway they were going to find. This highlighted a training need for the whole team.

The data supports the importance of observational cues used by the supporting team to support decisions in difficult airway management situations (whether that difficulty is expected or not). In addition, the current study also supports the way of communication

between team via patient and communication in general between team during the airway process. Finally, the results from this study illustrated that human factor, non-technical, skills are important for airway management and for ensuring safe, high-quality intraoperative care. Further research is needed to determine how these skills work in conjunction and how they impact anaesthetic performance.

CHAPTER 7

Conflict resolution in anaesthesia- systematic review

7.1 Introduction

Perioperative care is complex, and is delivered by teams and individuals with diverse training, experience and personality. Successful outcomes in healthcare are increasingly understood to be the product of the team as a whole rather than any single member [296]. Healthcare is almost exclusively delivered by teams comprising two or more actors of differing specialties. Team members have to cooperate in an effective way and to share their knowledge to achieve a common goal [296], but to do so, they require an environment with an atmosphere of open and clear speaking up.

Ensuring patient safety in such settings can be challenging, particularly when clinical work is unpredictable and requires rapid assessment and decision making, urgent intervention, and effective speaking up [297]. Inevitably conflicts arise between team members; these may be straightforward such as one individual not having the same information as another, or more complex such as differing interpretations of the same information, conflicting goals or ‘personality clashes’.

Unresolved conflict is detrimental to patient safety in both the short term – through impaired teamwork, and longer term through effects on staff morale and turnover [298]. However, healthcare professionals have little, if any, formal training in conflict resolution, and there is an increasing body of evidence asserting that poor conflict resolution skills can have an adverse influence on patient outcomes (patient safety) and job satisfaction [296, 297] and team performance.

Conflict has been defined as ‘a state of disharmony between incompatible persons, ideas, or interests’, and has been observed to be a significant and recurrent problem in most modern healthcare systems [297]. There are various types of conflict, with the most common being interpersonal conflict.

The General Medical Council (GMC) [299] and the Accreditation Council for Graduate Medical Education (ACGME) have highlighted the importance of conflict resolution skills

and other speaking up skills in resident training [300]. Such skills are taught in other industries such as aviation and business [297], wherein conflict resolution and teamwork principles have been shown to be the bases of teaching and improving safety outcomes [297].

There are a number of potential interventions that can be undertaken in operative settings to improve conflict resolution. To our knowledge, there has been no systematic review of interventions that can improve the outcomes of staff conflict resolution in healthcare settings, such as the operating theatre. This review focuses on conflict resolution interventions and strategies and their impact on educational, behavioural and patient-level outcomes.

7.2 Methods

To allow relevant formulation of search strategy and application of the identified key concepts, we used the population, intervention, comparator, and outcome (PICO) model as an outline for our study [301]. A PRISMA checklist [302] is in **Appendix *17***

- **Population:** Healthcare professionals (anaesthetists, surgeons and trainees, anaesthesia assistants, nurses- anaesthetists) in any theatre setting.
- **Intervention:** Undergoing one or more speaking up training and conflict resolution programs or the use of a professional / social context to influence conflict / speaking up behaviours.
- **Comparator:** Healthcare professionals who have not undergone any specific speaking up training during the study period.
- **Outcomes:** Any measured speaking up /conflict resolution outcomes. The Kirkpatrick categories of outcome following learning [303], which promptly provides identifiable and easy to measure outcomes in learners, [304] was used as the underlying framework. This approach provides a hierarchy of potential outcomes

from learner reaction through to ‘real-world’ changes in patient or organisational outcomes.

In this study, speaking up was defined as ‘speaking up with one’s, and/or other team members’ doubts, differing opinions or potential problems about decision or course of action in medical care’ [305]. This definition includes non-verbal communication.

7.2.1 Search methods for identification of studies

A systematic literature search was performed across six databases;

EMBASE (via Ovid platform), (1960 to 30th February 2018)

MEDLINE (via Ovid platform), (1960 to 30th February 2018)

SCOPUS utilising Ovid platform

Web of Science. (1899 to 30th February 2018)

Clinical Trials.gov

Cochrane Database via Cochrane Library

The search strategy was piloted and tailored to the individual databases. A combination of Medical Subject Headings (MeSH) and free text terms was used to increase sensitivity for identification of potential studies. Search terms used (operating room* OR anaesthesia* OR anaesthetist* OR trainee* OR operating theatre* OR theatre intensive care*) AND (communication* OR communication barrier* OR communication failure* OR team work* OR decision making* OR teaching* OR education* OR authority* OR superior* OR safety*) AND (conflict* OR challenge* OR speak* OR speak up* OR and speak out* OR resolution*). They were initially run individually and then were combined in each database. No limits (publication date, journal of publication or language) were applied. All search outcomes are discussed in detail in the results section.

7.2.2 Hand searching of reference lists

Hand searches were also conducted manually by searching the reference list in studies identified for inclusion through electronic record search. Manual searching of reference list for eligible articles was limited only to first generation full text as this is more likely to offer relevant studies [306]. This review was based on published studies only. The key concern with unreported research studies is that the results of such studies could be viewed as less likely to be reliable since they have not been through a peer review process. The rigorous process of peer review has been highlighted as an imperative means of quality assessment [307]. The search was updated in March 2018.

7.2.3 Hand searching of journals

Journal of Patient Safety, The Joint Commission Journal on Quality and Patient Safety, BMJ Quality & Safety, Journal of Quality Management in Health Care, Journal of Nursing Management, and Journal of Organisational Behaviour. Both forward (using citations recorded in PubMed, journal webpages, and Google Scholar) were checked for further data.

7.2.4 Citation tracking

The Web of Science (Science Citation Index) was tracked frequently checking for relevant updates, monitoring and finding new published studies.

7.2.5 Types of Studies

I included primary published research papers focusing on conflict resolution and techniques or contexts to improve staff members' ability to voice their concerns and patient safety in the operating theatre February 2018. Studies in other languages were considered if an English translation version was available. I excluded reviews, descriptive articles, letters to the editor and opinions. In addition, I excluded studies that did not investigate

any intervention (e.g. teaching programme or social context) and that investigated the effects of conflict resolution and speaking up in general medical practice (i.e. not the operating theatre).

7.2.6 Data Extraction

One reviewer (DA) performed the search strategy and as an initial step, DA independently screened titles of all related studies against eligibility criteria. DA and second reviewer (TM) independently identified potential studies for inclusion at abstract stage. Data extraction was performed individually with disagreements resolved by the discussion and involvement of a third researcher (IM). Data extracted from individual studies included: sample size, type of conflict, factors influencing conflict, barriers contributing to speaking-up, and data on the training programme, period of training, and outcomes.

7.2.7 Risk of Bias assessment

As discussed in the chapter 2, methodology assessment for a risk of bias of included studies was assessed using the criteria defined in the “Cochrane Handbook for Systematic Reviews of Interventions” [139] for randomized control trials (RCT) studies, based on the subsequent factors:

- the method of generation of the randomisation sequence;
- method of allocation concealment;
- blinding of participants, clinicians and outcome assessors;
- loss of participants to follow-up and if analysis was on an intention-to-treat basis

In addition, the Quality Assessment Tool for Before-After (Pre-Post) Studies With No Control Group (BAQA) was used to assess the observational studies [140]. This tool has questions that will help reviewers concentrating on the main ideas for assessing the internal validity of a study and the questions not proposed to make a list from which to add up items to critic a study’s quality.

Overall, all studies were observed to be of moderate to good quality and the outcomes were summarised in **Appendix 18**.

7.3 Result

7.3.1 Overview

The initial online search produced 3,830 papers; after removal of duplicates, we screened 1,485 studies by title yielding 11 potential eligible studies; for full text assessment. Six studies with a total sample size of 286 participants were deemed eligible for inclusion in this review [308-313], five were from the initial online search and one was from reference lists hand search of included papers. No additional papers were obtained through forward searching. All of the studies in this review were conducted in the USA and Canada. The flow chart of study selection is shown in detail in **Figure 15**.

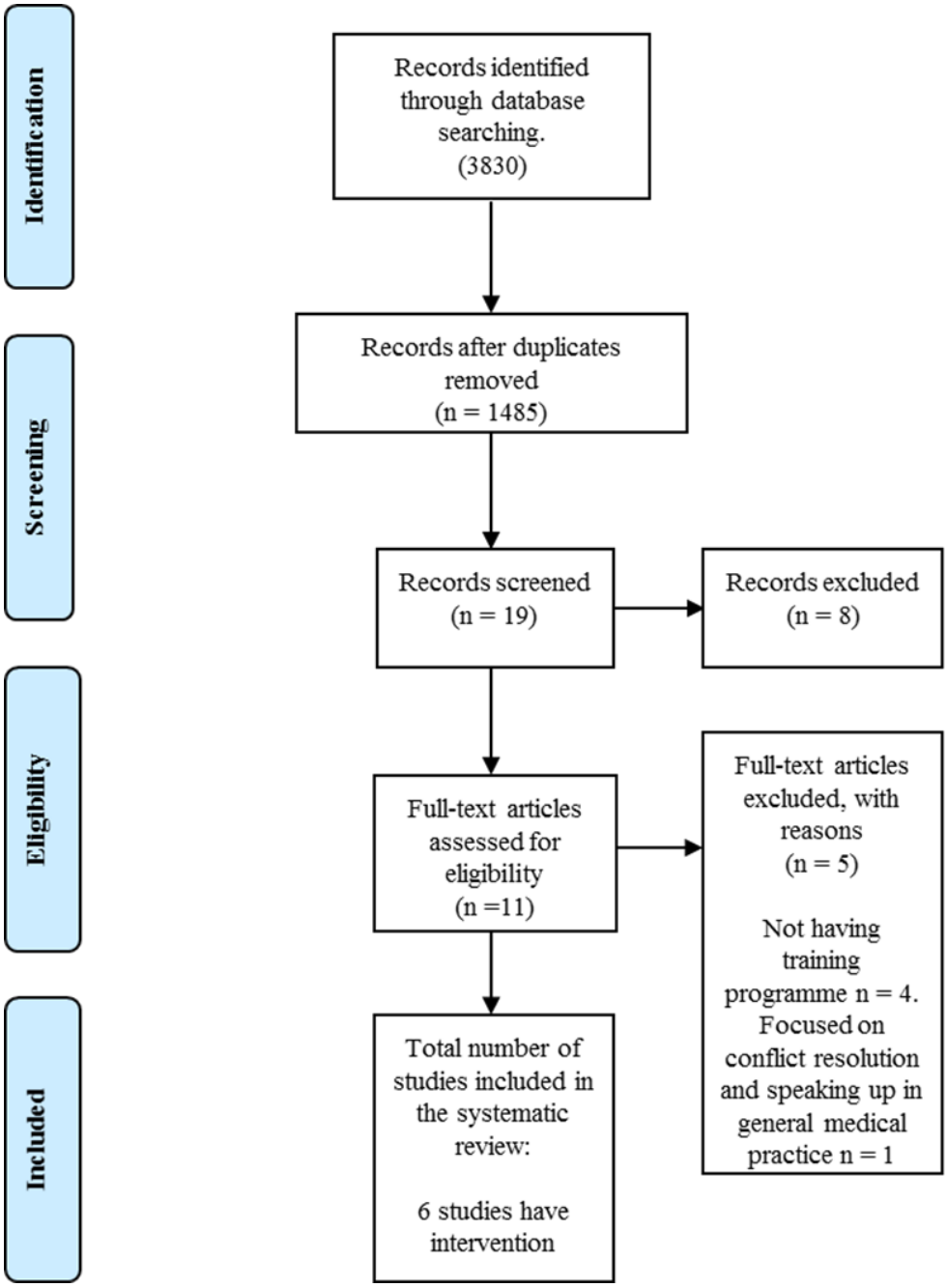


Figure 15: Flow diagram of included and excluded studies

7.3.2 Training programmes

Three distinct training programmes were identified among the included studies; **a)** Crisis resource management (CRM) training [308], **b)** the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) training [309], and **c)** the two - challenge rule [310, 311] which is a component of TeamSTEPPS. Two study used a social construct (behaviour of a senior clinician) as a potential modifying mechanism [312, 313]. Key outcome measures across all programmes included improvement in speaking up, patient safety and positive assertiveness in challenging hierarchy. Characteristics of the included studies are outlined in **Table 10**, and the main outcomes of each training programme are outlined in **Table 11**.

7.3.3 Excluded studies

Five studies [305, 314-317] (**Appendix 19**) were excluded at full text screening stage for the following reason: a) no intervention related to speaking up training (n = 3); b) focused on conflict resolution and speaking up in general medical practice (n = 2). No studies were excluded due to overall high risk of bias [**Appendix 18**].

7.3.4 Context and duration of intervention

Variation in the duration of study intervention were observed, ranging from part-day training [309], short 30 - 45 and 50 minute workshops [310, 311], to one hour session [308]. Outcomes were generally assessed by subjective methods rather than objective methods. Interventions were delivered through various contextual settings – classroom, training sessions and simulation centres.

7.3.5 Intervention outcomes

Friedman et al. [308] assessed if an education training intervention enabled resident anaesthetists to effectively challenge a clear wrong decision-making by their superiors

during crisis in practice. They used a 1 hour interactive lecture which outlined the approaches of CRM and conflict resolution tools in the intervention group and a 1 hour interactive lecture of CRM only in the control group. The performances were randomly assessed by two independent raters using the modified Advocacy-Inquiry Score (mAIS). It includes five scoring levels with the addition of a sixth level when a trainee endeavours to take over management of the case.

Observed results from the short teaching CRM intervention showed a significant improvement in the participant's ability to challenge their superior's wrong decision. The interrater reliability of the mAIS was excellent and mAIS was higher in the intervention group than the control group. The intervention group repeated effective challenge skills.

The results support first and second levels of Kirkpatrick's **(Table 12)** [303] theoretical framework. The course was positively viewed by participants and led to improved learning, which in turn led to behavioural changes. However, reliability might be affected by performance bias as the scenario was created to show very obvious basic clinical mistakes.

Sawyer et al. [309] investigated the TeamSTEPPS training programme including; leadership, situation monitoring, mutual support, communication. They utilised a prospective pre- and post- assessment design, with teamwork skills as the main outcome variable. These outcomes were assessed via writing of scripted medication orders and performance errors. Assessments of group work skills were measured before and after the training course using the previously validated TeamSTEPPS Teamwork Attitudes Questionnaire (T-TAQ) [318] . It includes 22 specific teamwork behaviours broken into the 5 TeamSTEPPS core competencies. Significant improvements in the following factors were observed: team structure, situation monitoring, leadership, and communication ($P < 0.001$), following training programme completion. Furthermore, requests for clarification from nurses on scripted drug order errors doubled between pre- and post-training, from

38% to 77% [16], reflecting an increase in awareness and individual participant confidence. However, there was a potential follow-up bias in this study, as evaluations of the main outcomes were performed by the same researchers who observed the simulation setting in real time and were colleagues of the participants. The study also relied on self-reporting of attitudes and confidence as primary outcomes (Kirkpatrick level 2) which was by definition subjective and often inaccurate; this may be viewed as a major limitation.

The two challenge rule (conversation skills, advocacy and inquiry; a component of the TeamSTEPPS approach) has been investigated in two studies from the same group [310, 311] in two operating room simulation environments. Both studies sought to determine whether the conversational technique of the programme could be effective in enhancing speaking up in practice.

Pian-Smith et al. [310] randomly presented two scenarios to trainees with a 30–45 minutes educational aspect in both cases, while Raemer et al [311] used a 50 minute workshop on speaking up on interventional group and control group, with an 'interactive didactic' presentation of basic patient safety.

Contrasting results were observed. The first study [310] reported an increased frequency in the use of the two challenge rule advocacy-inquiry by participants after programme implementation (16% pre and 72% post). However, the second study [311] observed no improved speaking up behaviours among the intervention compared to the control group ($p = 0.42$). Similarly, Pian-Smith et al. [310] observed that anaesthetists' verbal challenges to nurses did not change ($p = 0.84$). This could be a clinical practice anomaly, where junior doctors might not fully realise the important role that nursing skills can play during a critical event, including managing obtainable resources and providing clinical expertise.

Moreover, findings may be somewhat limited by the fact that the training intervention was immediately before the post-test of communication in a simulated environment. Therefore, the participants could be considered to be primed to "know the answer" to the simulation

scenario and that performance in that scenario may not be applicable in other situations where they had not been primed in that way.

An alternative approach of manipulating the social context in which conflict occurs has been investigated in two studies from the same group [312, 313] in simulated crises.

Sydor et al. [312] randomised scenarios to a hierarchical or non-hierarchical team structure in a simulated combined ethical and life-threatening crisis (administration of blood to Jehovah's Witness). The outcomes were trainee anaesthetists' capability to challenge an unethical decision by their superiors. Friedman, et al. [313] randomised scenarios to a strict exclusive communication dynamic and/or an open inclusive communication dynamic by the consultant anaesthetist in a simulated emergency airway practice. The outcomes were the impact of interpersonal behaviour of consultant anaesthetists on trainee anaesthetists to challenge authority during incorrect clinical decisions. Performances were measured by using mAIS by independent raters [312, 313]. There was a good interrater reliability of mAIS scores in both studies. [312, 313].

The first study [312] did not demonstrate a significant impact of the operating team hierarchy level on trainees ability to challenge their superiors. The checking and administrating of blood between both groups (Hierarchical group and Non-hierarchical) group were not significant. Similarly, Friedman, et al. [313] observed that the interpersonal behaviour of the consultant anaesthetist and the resulting speaking up did not significantly impact on trainee ability to challenge their superiors during airway crisis.

Although, these studies [312, 313] have similar sample sizes to other studies included in this review, they did not demonstrate a positive result. The reason for these insignificant results might be due to a lack of appropriate and effective training in challenging authority. The trainees' lack of training itself in this system could be described as hierarchical.

Table 10: Characteristics of included studies

Study	Country	Department and participants number(n)	Type of study	Intervention	Duration	Kirkpatrick levels outcomes			
						K - 1	K - 2	K - 3	K - 4
Friedman, 2017 [308]	Canada	Anaesthetists residents (50)	Simulation - randomised	CRM	1 – hour session	Kirkpatrick: level 1	Kirkpatrick: level 2		
Sawyer 2013 [309]	USA	Physicians, nurses, and respiratory therapists (42)	Clinical - simulation	TeamSTEPPS	6 hours		Kirkpatrick: level 2		
Smith, 2009 [310]	USA	Trainee anaesthetists (40)	Clinical - simulation	Two - challenge rule	30 to 45 – minute Workshop		Kirkpatrick: level 2		
Raemer, 2015 [311]	USA	Non-trainee anaesthetists (71)	Simulation - randomised	Two - challenge rule	50 minute Workshop	Kirkpatrick: level 1	Kirkpatrick: level 2		
Sydor, 2013 [312]	Canada	Trainee anaesthetists (49)	Simulation - randomised	Team behaviours / team hierarchy	**-**	Kirkpatrick: level 1	Kirkpatrick: level 2	Kirkpatrick: level 3	
Friedman, 2015 [313]	Canada	Trainee anaesthetists (34)	Simulation - randomised	Team behaviours / team hierarchy	**-**	Kirkpatrick: level 1	Kirkpatrick: level 2	Kirkpatrick: level 3	

CRM = crisis resource management, ACRM = anaesthesia resources crisis management, TeamSTEPPS = Team Strategies and Tools to Enhance Performance and Patient Safety, **-** = No data available

Table 11: Summary of main outcomes for each training programme

Training programme	Main assumption	Taught Principles / domains	Strengths	Weaknesses
CRM	Healthcare Practitioners to voice their concern ('speak up') when safety concerns arise. Decision making as a teamwork principle. Emphasis on cross discipline understanding assuring all team members are solving the same problem	Role clarity (leadership) Communication skills (call back of instructions) Management of personnel and resources (requesting help early), Decision-making skills (avoiding fixation errors).	Examined in aviation and military system. Improves performance and reduces errors. Emphasises the role of human factors in high-stress, high-risk environments. ACRM improved patient safety and issues related to resident supervision. Trainees develop an understanding of cognitive errors. Educating individuals about the limitations of human performance	There is no universal CRM training program. No definitive data link CRM to decreased incidents. Few studies utilise a control group. Low cost effectiveness
TeamSTEPPS	Emphasise team work principles for improvement of quality and safety of the healthcare system. Focused outcomes include but not limited to improved communication, effective team work, and reduced error rates	Leadership, Situation Monitoring, Mutual Support, Communication	International use; clinical outcome benefits (mortality); long-standing; rigorous teaching and support framework; conflict resolution taught as part of wider teamwork framework	Lack of time, and the inability to hold an individual accountable. No definitive data link TeamSTEPPS to decreased incidents Lack of control group.

'Two-challenge rule' (advocacy-inquiry)	Assumption of collective responsibility and accountability on patient safety and outcome. Equal responsibilities across both superiors and trainees. Identification of possible risks before they turn into actual issues	The team members voice their concern by advocating and asserting their statement at least twice if the initial assertion is disregarded. These two attempts might come from the same individual or two different team members. The first challenge should be in the form of a question. The second challenge should provide some support for their concern.	Defines roles and responsibilities of the individual with concerns and the individual with whom these are being raised. Requires no specialised language Intended to depersonalise the conflict discussion. Based on aviation cockpit rules. It can be used to bring up certain information that must be addressed. It can be used to resolve conflict. It can be taught effectively, as it relies on a collaborative language of clinical knowledge and procedural skills	Relies on both sender and receiver understanding and 'buying into' the concept. A limited number of studies were identified using this training programme. There was no attempt in studies to demonstrate that this educational intervention improved patient safety in an actual clinical environment
CRM = crisis resource management, ACRM = anaesthesia resources crisis management, TeamSTEPPS = Team Strategies and Tools to Enhance Performance and Patient Safety				

Table 12: Kirkpatrick's hierarchy model [303]

Level 1: Reaction	The degree to which participants find the training favourable, engaging, and relevant to their jobs
Level 2: Learning	The degree to which participants acquire the intended knowledge, skills, attitude, confidence, and commitment based on their participation in the training
Level 3: Behaviour	The degree to which participants apply what they learned during training when they are back on the job
Level 4: Results	The degree to which targeted outcomes occur as a result of the training and the support and accountability package

7.4 Discussion

This study provides a comprehensive review of evidence of impact on outcomes for conflict resolution educational programmes in healthcare systems. The included studies investigated three training programmes: CRM, TeamSTEPPS, and the two-challenge rule (which is itself a part of TeamSTEPPS).

All studies included in this review were conducted in the USA and Canada, possibly because all three training programmes are relatively new and were originally designed for the aviation industry in the USA. Each of these interventions is predicated on the assumption that failure of those further down the hierarchy to challenge those 'higher up' is an underlying problem. The tools and techniques do not seem to directly address the ability of those higher up to 'receive' challenge. A key underlying theme of these programmes is the enhancement of healthcare professionals' frequency of speaking up, thus empowering trainees to assertively challenge their superiors in a positive and effective manner when patient safety is a concern.

Recent studies have indicated that authority differences between team members can contribute to speaking up failures [305, 314]. This may be particularly evident in interactions between consultants and their trainees, given that the consultant has a direct influence on trainees.

A reason for the poor speaking up may be that it is psychologically difficult to challenge directives from an authority figure; in other words, it is hard to speak up to senior anaesthetists or surgeons [310]. This is possibly because of differences in experience, which has been found to be a major factor affecting position in a hierarchy [314].

Additionally, none of the included studies specially focus on speaking up about unprofessional behaviours. A recent study [319] reported that 75% of the respondents observed unprofessional behaviours, however, reported speaking up about unprofessional behaviours was less common.

Marrison's model of employee speaking up supports this assumption. It illustrates that the effect of performance and perception of autonomy were considered to be under the individual's control; these have been reported as influencing factors relating to speaking up in the healthcare system [320]. He found that hospital policy and interdisciplinary policy making are the wider contextual factors that impact on speaking up among professionals.

Interestingly, all the interventions had a predominant focus on the individual at the 'lower' end of speaking up; there appears to be very little emphasis on those at the 'top' listening down, or fostering an environment where this is possible or encouraged. There is a suggestion that speaking up is not only important for people who work in an operating theatre, but is also related to other similar situations in health settings, as it is one part of conflict resolution [320].

The CRM principles focus on interpersonal communication, leadership, and decision making in the workplace. CRM produced positive outcomes in different industries, such as healthcare, aviation, and military [321, 322]. In healthcare in particular, a previous study [322] showed that a CRM programme could effectively improve various CRM skills in a variety of clinical events. Beyond teaching skills, CRM also seeks to improve participants' ability to debrief others or explain critical events, such as medical mistakes.

In line with this, Gaba et al. [323] adapted the CRM model used in aviation into the field of anaesthesia; this was called anaesthesia crises resource management (ACRM). ACRM programme aims to educate anaesthetists' in non-technical skills, particularly group work, by using simulation environments. Most of the outcomes measures were long term, followed up again at a later stage (one year later) to demonstrate that the training had a long term impact. This shows the essence of such a training programme.

A number of researchers reported that such training programme is highly effective in enhancing clinical functioning, and recommend that should be taken yearly [324]. However, the current review found that the strength of evidence reliability might be

influenced by reporting bias as the outcome measurement tools used was self-report of behaviour.

TeamSTEPPS, in contrast, is specially designed for healthcare system to help improve safety culture and teamwork based on CRM principles. Many healthcare centres worldwide have implemented the TeamSTEPPS programme [325]. They have overall concluded that TeamSTEPPS programmes are a positive step towards supporting safety culture and teamwork. Researchers have also indicated that it is an effective method to ensure a safe environment and improve patient outcomes; improvements in outcomes in particular derived from the utilisation of 'handling, briefing, and de-briefing' as communication strategies [325].

These results accord with Sheppard et al.'s [326] findings, which showed that the implementation of such educational programmes in Texas Health Resources and in The North Shore–LIJ Health System in New York led to significant improvements in teamwork, communication, and patient satisfaction. Furthermore, these results seem to be consistent with another study [327] reporting that the TeamSTEPPS led to a 30% reduction in medical incidents and improvements in communication, as well as greater attempts to break down the hierarchy in clinical care.

Recently, Weld et al. [328] reported that after 6 months of implementing TeamSTEPPS in the operating room, patient safety improved, with the average prevalence of incidents decreasing from 16% to 6%, after which it remained relatively stable ($P < 0.001$). They also reported that this programmes encourages discussions of patient safety.

Although there is some evidence to support the effectiveness of TeamSTEPPS, there is still much to learn about its precise impact on safety outcomes [329]. The current review found that there is no a clearly defined control group in the study that applied this programme, and other valid factors limited our ability to make a fundamental relationship from the implementation of TeamSTEPPS. Main outcome measurements were only short

term and the data collection tool used might not have been reliable since as it has not been previously validated.

On the other hand, the two-challenge rule is a technique used in TeamSTEPPS [330]; a group of researchers [331] designed this intervention to support the idea that all team members share the responsibility for a safety outcome and are required to speak up in situations where safety is concerned. For instance, in USA Army aviation, when an aircraft enters an unsafe position, the two pilots in charge must exchange ideas/opinions on how best to resolve the situation and make a joint decision. This process is known as the two-challenge rule [332].

Pain-Smith et al. [310] attempted to implement this rule in the healthcare environment by teaching it to trainee anaesthetists in situations wherein speaking up was required; although they found this to have benefits to speaking up, their results do not accord with the findings of Sydor et al. [312]. Sydor et al. used the same intervention to examine how hierarchal position in the operating theatre team influenced the ability of trainee anaesthetists' to challenge an unsafe decision made by their consultants; they found that the two-challenge rule had no benefit to this ability. Their results were also consistent with Raemer et al. [311] in their recent study.

A possible explanation for the lack of effect in these two studies is that the training was short (30 to 45 minutes and 50 minutes, respectively) [310, 311], while speaking up behaviours are deeply rooted and difficult to alter within this period. Therefore, a longer period observing the impact of the two-challenge rule could be beneficial in demonstrating its effectiveness regarding improving speaking up behaviours. In addition, raising awareness of the key factors that contribute towards the 'hurdles' and 'enablers' in speaking up behaviours may help team leaders and decision makers to develop the quality and safety of healthcare in their settings.

Overall, the two-challenge rule does not have sufficient evidence in supports of its efficacy, therefore its true benefit remains unknown. However, when delivered in the context of the TeamSTEPPS, it appears to have the potential to be effective. This conclusion should not be interpreted as dismissing the evidence of benefit of TeamSTEPPS training per se (beyond the confines of conflict resolution) [325, 329].

The studies exploring the impact of other team members behaviour are worthy of note. They address a potentially more pragmatic and real-world approach. Training programmes (if they are effective at all) are resource intensive, and only directly impact those who attend. Changing the culture of how clinicians work has the potential for far greater reach and with less direct resource costs. Although the studies produced negative results, it is likely that the potential effect size of the intervention was too small to be seen.

Several studies have shown that trainees within a hierarchy are usually unwilling to challenge incorrect decisions made by their superiors [310, 312, 317], even when it is clear that the decision involves unethical practice or might harm patients. The well-known case of Elaine Bromiley, a patient who died from hypoxic brain damage after intubation failure by two consultants, could be viewed as a typical scenario.

Although other team members had the requisite knowledge to correct the problem, they were unable to speak up to the senior members, which in turn directly influenced patient safety [333]. In a similar case, a patient had their wrong kidney extracted despite a trainee member of the teamwork recognising that the healthy kidney was being operated on [334]. These cases indicate that an unwillingness to challenge hierarchy in the operating theatre can be associated with adverse events that threaten patient safety.

7.5 Study strengths and limitations

A strength of the study is that to our knowledge this is the first systematic review on the interventions that can improve the outcomes of staff conflict resolution in healthcare settings, such as the operating theatre.

In addition, comprehensive search strategies were conducted following systematic review guidance. Data extraction and quality assessment were independently implemented by myself and results were confirmed by the team. All the studies involved had the same measurement outcome.

On the other hand, the review has some limitations. These were common to many systematic reviews: only a small number of studies were available. There was also a wide heterogeneity across the included studies and inconsistency in their outcome presentation. This might also have impact our findings.

In addition, although a broad literature search strategy has been done, it is potential that few studies which would have been appropriate for inclusion might have been missed. Several approaches were included to reduce this, however the author acknowledge the possibility that a small number of eligible studies might have been omitted. Finally, each group or researchers has used a different set of measures to define 'success' of their intervention.

Although there is evidence of validity (in its widest sense) for all of these measures, none can be described as completely robust. Detailed reliability and validity aspects of the included studies are beyond the scope of this paper. As with most studies of interventions there are two major limitations of all the studies. First is the limited assessment of 'success' that is these studies – often short term, or surrogates for real patient impact. Second, is that most of the studies used speaking up, and did not address other skills, such as negotiation skills, required for conflict resolution.

7.6 Summary

The overall underlying theme of the above educational programmes is the enhancement of healthcare professionals' ability to speak up and enable trainees to challenge their superiors in a positive and effective manner when patient safety is a concern. There is less focus on seniors' ability to receive this challenge, even though this is identified as a

factor enabling / inhibiting challenge. The published studies generally provide support for level 1 and level 2 outcomes in Kirkpatrick's theoretical framework. There is relatively sparse evidence of longer-term benefit, and studies suffer from a lack of control groups and objective, validated measures.

Future work could consider, all of the proposed training programmes would require continuous examination and validation. Nevertheless, their key aspects should remain unchanged – to identify and develop practical strategies to improve effective communication and minimise mistakes in the clinical environment, thereby optimising patient safety. In addition, future possibilities to find out methods to enhance learner's ability to challenge consultant as a part of team.

CHAPTER 8

Conclusion and implications for practice

8.1 Conclusion and implications for practice

Concerns regarding quality and safety in providing good healthcare rely on team execution [296], and operating room is the best exemplar of this. Therefore, to ensure patient safety in the operating room, understanding workload was found to be important. Ensuring patient safety in the operating room is a challenge because it involves highly demanding tasks, unpredictable events requiring rapid assessment and decision-making, and urgent interventions.

All of these factors influence good communication and decision-making practice because of conflicts among team members. Literature shows that conflicts can lead to reduced team performance [296]. In addition, it shows that the increase in errors and poor performance is correlated with an increase in the level of mental workload [174, 335] and conflicts that result from highly demanding tasks [296].

Therefore, a reliable measurement tool to measure workload and teaching conflict resolution and other speaking up skills are crucial in healthcare, particularly in the field of anaesthesiology. Both are emerging fields supporting patient and anaesthetist safety.

The first (Chapter 4) and fourth (Chapter 7) studies in this thesis were systematic reviews performed to identify the currently available tools to assess workload and conflict resolution interventions and strategies and their impact on educational, behavioural, and patient-level outcomes.

Due to the heterogeneity of the data presented in the included studies in both systematic reviews, I have used qualitative methods to assess the evidence for various workload measures and training programmes for conflict resolution skills and other speaking up skills. In the first systematic review (Chapter 4), I concluded that the existing evidence recommended that the Borg rating scale showed the best validity and sensitivity in measuring workload in anaesthesia. NASA-TLX showed similar outcomes. In addition, they have the best evidence base [335].

The results of the present study support those from previous studies in high risk industries, such as aviation and nuclear power [167], which reported similar observations. It was also found that conducting performance and psychophysiological measures required more technical involvement and substantial time for the investigator, and was expensive [335]. In addition, they are perceived as complex, intrusive, and less likely to be part of daily routine use because of confounders.

In addition, the systematic literature review (Chapter 7) that focused on conflict resolution interventions and strategies and their impact on educational, behavioural, and patient-level outcomes revealed three primary training programmes. Two of the reviewed studies employed a social construct (the behaviour of the senior clinician) as a potential modifying mechanism.

The key outcome measures across all programmes included improvement in speaking up, patient safety, and positive assertiveness in challenging the hierarchy. CRM was developed in the aviation field and then adapted to ACRM, specifically for anaesthesia [323], while TeamSTEPPS training [309], and the two-challenge rule [310, 311] (which is a component of TeamSTEPPS) were developed specifically for the healthcare system.

CRM was found to be highly effective in improving clinical functioning and was recommended by researchers as a yearly course [324], while TeamSTEPPS training was perceived as a positive step towards supporting a safety culture and teamwork; however, there were limited data demonstrating its effectiveness. Though it is a component of the TeamSTEPPS, the two-challenge rule lacks evidence of efficacy on its own, and thus its true benefit remains unknown. Overall, the evidence for training to improve conflict resolution and speaking up in the clinical environment is inconclusive.

According to literature, the current practice of drug preparation and administration so far seems to be linked to potential or actual serious harm. Several practices are employed

within the anaesthesia specialty to help mitigate the risk of drug error, but it is still a serious cause of iatrogenic harm [212, 213].

The objectives of my second study detailed in this thesis (Chapter 5) were to explore the potential impact of a simple adjunct to drug preparation and storage on safe drug administration during anaesthesia in three NHS Hospital Trusts in England. It also aimed to investigate both the praxis of a novel drug tray, and the perceived barriers to and drivers of its use in daily practice.

I found that the current practice within three NHS Trusts in the England showed that anaesthetists draw up drugs and then place them together in one or more disposable grey trays. While being quick, cheap, and portable, this method was directly linked to potential or actual harmful errors including syringe swaps. The Rainbow trays seemed to aid drug identification, allow for drug separation, and act as a prompt to guard against drug errors.

As noted in literature, any attempt to reduce complexity or practice can help to improve safety [59, 232]. The Rainbow trays were designed according to this and by following recommendations about the formal organisation of an anaesthetic workspace and the handling of drugs. Limitations to the feasibility of use were design and placement. Participants felt that some compartments within the Rainbow trays needed to be made larger and there were issues concerning the best place to keep the tray when in use within the operating room.

Literature also shows that the label applied circumferentially to or longitudinally along the syringe barrel is still controversial [336]. The result of this study found that labelling syringes around the barrel at the neck of the syringe was the practice by most of the participants. It helped accurate reading of syringe markings and the more visible colour helped them to avoid picking up the wrong syringe.

In case of high workload demands, like in anaesthesia environment, safe and reliable airway management is fundamental to patient safety. The current literature shows that it

has repeatedly been found that the process of airway management is neither '*completely safe'* nor *'reliable'* [18] and applied to both routine and non-routine settings. It also demonstrates that guidelines and experts' commitment are not enough for minimising or avoiding complications of airway management in anaesthesia [258].

Hence, a qualitative method was used to collect data on actions and decisions involved in routine and complicated airway management with the aim of establishing when and why airway management fails.

The findings presented in chapter 6 show that there was an obvious variation in anaesthetists' practice. In addition, the most key decisions were made by the lead consultant anaesthetists who are very good at making decisions and communicating with their team. However, the risk assessment is sometimes not appropriate. This is because the more experienced the anaesthetist, the more they rely on their past knowledge 'work as done'.

Another finding from this study was that there was an effective team communication using cues or check-back techniques. This has led to increase in the speed and efficacy of task completion. This result supports those from previous studies [269], which reported similar observations.

8.2 Clinical implications and future research

Currently there are no universally agreed mental workload assessment tools in the anaesthetic environment. The Borg rating (6 to 20) scale could be the best tool of choice at present, showed the best evidence of validity and sensitivity tools of workload in anaesthesia [335]. Correlation between self-reported and observed rating was moderate to good. Furthermore, vigilance (response latency) has been observed to have as good discrimination as the workload assessment tools, but requires more technical involvement, considerable time for the investigator, and is moderately expensive.

Physiological measurement methods are perceived as complex, intrusive and less likely to be part of daily routine use.

A key recommendation from my observations is the need to emphasise routine and appropriate use of the currently available mental workload assessment tools. If applied correctly, the current measurement tools could act as a guide for future development and validation of more accurate tools or revalidation of the currently available tools and quality recommendation of scale (s) to be used as a standard tool, or through further investigation of subjective methods in the anaesthesia field incorporating the new objective measurements.

There is no 'outstanding' measurement tool in existence; however better use on current tools is essential for both anaesthetists (in monitoring cognitive demands of the anaesthetist and for predicting capacity of anaesthetists' to undertake extra tasks) and in the clinical field (improved outcomes with recovery from human mistakes and increased levels of safety for both system and patients). In addition, current tools might be used for measurement for drug errors, by way of performance such as numerical rating scales that generate quantitative data that based on self-report.

Further research comparing and evaluating these measurement tools using national data should be conducted to find the best tool. Standardising an assessment tool would be of benefit across the whole healthcare system and NHS Trusts for evaluating cognitive demands of jobs and for predicting operator capacity for extra tasks. In addition, it would improve quality of care and patient safety, and could audit regional patient risk presentation variations.

The study "a Novel Drug Storage Tray in Anaesthetic Practice" recommended that anaesthetists and their supporting team should seriously consider implementing a safe method of drug preparation, administration and storage during anaesthesia. However, if the normal drug tray is being considered as a way of drug storage then adequate

information and resources should be ensured in terms of a second person verbally and visually double-checking drugs during preparation and administration, labelling syringes and keeping empty ampules. In addition, more than one tray should be used. Additionally, another double checking of syringes before drug administration should be done. This is because it was found that although the normal drug storage is quick, cheap, and portable, this method was directly linked to potential or actual harmful errors, such as syringe swaps.

With the introduction of any new technique or piece of equipment there is the potential for resistance. However, I did not observe any resistance to the Rainbow trays within the study and anaesthetists seemed to uniformly receive them into clinical practice. However, a broad range of opinions were found on the prevalence and consequences of drug errors. Therefore, acknowledging this could influence the acceptance of any method designed to prevent drug error and safe drug storage.

The Rainbow trays are designed to prevent drug errors and help drug storage. Mitigating drug errors and improving drug storage during anaesthetic practice are important aspects of daily practice. This helps in addressing any concerns anaesthetists and NHS trusts might have and encourages in improved patient safety greater cost effectiveness and reduce drug errors.

For the Rainbow trays to have any chance of adoption, further research is now required to determine both the best strategies for ensuring continued use of the Rainbow trays, and their effect on the prevalence of drug error and improving drug storage. Furthermore, introduction to other hospitals will inevitably depend on drivers such as national recommendations [231, 248], institutional policies, education[249-251],and cost. The study authors intend to report in future papers on how these challenges can be overcome.

Another important recommendation of this study was that the implementation of the Rainbow tray drug storage during anaesthesia practice should be accompanied by

constant effort to develop the patient safety culture within anaesthetic theatres where a high level of workload is reported.

Education in methods to enhance patient safety, and training in human factors are important for safety culture. In addition, team working, reporting and learning from incidents are also crucial for improving safety culture.

A key recommendation from the study of “Modelling Airway Management using System Reliability Assessment Tools” is the need to emphasise a training need for the whole team in non-technical skills. That is because human factor is crucial component when looking at delivering of high level of workload tasks. The data also recommend that it is vital for the anaesthetists and their assistant team to understand the real-time process of their work, instead of focusing on how they imagine the processes will occur. Furthermore, to successfully change practices, there requests to be a focus on changing performances and attitudes.

The study “Conflict resolution review” recommended that trainees understand that it is their responsibility to advocate for the patient in all situations, and that consultants must support and accept open communication with their trainees. Conflict resolution can only occur when speaking up is open and honest [297]. It is also necessary for superiors or the head of teams to encourage an environment where junior staff are encouraged to speak up, particularly when patient safety is a concern.

Another key recommendation is that future research should consider the fact that all of the proposed educational programmes require continuous examination and validation, as well as a longer period of training. Speaking-up behaviours are deeply rooted in the individual, and as such are difficult to change within a short period. Nevertheless, their key aspects should remain unchanged – namely, that their goal is to identify and develop practical strategies for improving effective communication and minimising mistakes in the clinical environment, thereby optimising patient safety. Another important point to be considered

in future research is the factors that influence individuals' decision to challenge the hierarchy. I noted an interesting recommendation that involves integrating the education and training programmes I found into undergraduate curriculums, in an attempt to instil skills for challenging hierarchy from an early stage. This is also could include the nursing or ODP curriculum, should training be as a team or as a professional group. Finally, it would be interesting to look at approaches to enhance learners' capability to challenge authority as part of a team.

8.3 Conclusion

This thesis has explained various techniques for improving patient safety in an environment characterised by a high workload. I identified that the Borg rating scale as the most appropriate workload assessment tool in anaesthesia, because it showed consistent associations with expected variations in workload. In addition, the correlation between self-reported and observed ratings was moderate to good. However, it needs to be continuously validated for accuracy and precision by performing meta-analysis in order to assist comparison between this scale and others. Likewise, the Rainbow tray was preferred because of its easy of use and effectiveness in aiding drug identification and separation, meaning that it is likely to reduce drug error and increase patient safety.

The thesis also reviewed the efficacy of several educational programmes aimed at improving healthcare professionals' ability to speak up and enable junior professionals to challenge their superiors in a positive and effective manner when patient safety is a concern.

It is necessary to continue exploring the approaches to improve safety in healthcare environments. However, various clarifications of similar approaches arise with different "latent factors, contributing factors, and solution factors" in the system. While there are various methods for improving safety in a high workload environment, developing a culture conducive to safety – by cultivating understanding of the human factors skills – is in

particular necessary for safe and effective performance in the operating theatre environment. These skills include training in communication, situational awareness, teamwork, and decision-making. They are crucial for improving operators' technical skills and minimising avoidable errors in the operation setting.

As with the introduction of any new safety initiative, additional scoping is now necessary to determine the best ways of ensuring compliance. Furthermore, establishing an evaluation programme is essential to ensure the new initiative (Drug Trays, understanding NTS, and Training programmes and supports the importance of observational cues, and "short-cuts" communication) successfully achieves its optimum outcome.

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APPENDICES

Appendix 1: Observation Schedule

The University of Nottingham

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 necessary to record all data for an observational session, and number the 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. Use the key themes below and the table provided to record specific details. Record as fully as possible all talk and all actions by Anaesthetists, Operating Department Practitioners, Theatre Nurses and other members of the theatre team. 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
-

Key themes – these give you an idea of the some of the things that you may want to record. A table is provided so that you can keep a note of these for each session

1. **Setting**
   - Type of Theatre – including type and length of surgery, number of patients per list/day
   - Brief description of anaesthetic room - including drug storage, working space
2. **Staff and teams**
   - Grade of Anaesthetist observed
   - Level of support staff – type and number
3. **Drug Preparation**
   - When are drugs prepared
   - Where are the drug syringes kept when in not in use?
   - Is there any separation of drugs (e.g. local anaesthetics, 'emergency drugs')?
   - What methods are used to check syringe before administration?
4. **Feasibility of use**
   - How are drug syringes managed?
   - What happens to drug ampoules
   - Criticisms by staff
   - Impact on patient
   - Is the new tray effective in preventing errors or near misses?
   - Issues with cleanliness?
   - Does the new tray hinder practice?

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	

TIME	OBSERVATIONS

Reflections

Appendix 2: Ethical, R&D approvals of Drug Trays In Anaesthesia

research & innovation

Nottingham University Hospitals NHS
NHS Trust

Research & Innovation
Nottingham Health Science Partners
C Floor, South Block
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16th September 2015

Dr Iain K Moppett
Academic Department of Anaesthesia
C Floor East Block
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
NG7 2UH

Dear Dr Iain K Moppett

Short Title / Acronym	Drug Trays In Anaesthesia /
CSP Number	
R&I REF	15AN007
Long Title	An Observational Study Of Feasibility Of A Novel Drug Storage Tray In Anaesthesia Practice
PROJECT MILESTONES	
Recruitment Target	30
Date of Valid Submission	14/09/2015
Recruitment End Date	01/04/2016
1st Patient to be Recruited by	23/11/2015

The R&I Department has reviewed the following documents and NHS permission for the above research has been granted on the basis described in the application form, protocol, and supporting documentation. The documents reviewed were:

Document	Version	Date
Drug Trays Study Protocol	1.0	11.06.2015
PIS_Drug_trays_Final final PIS	1.0	24.07.2015
Drug Trays Interviews consent form final Consent form	2.0	08.10.2015
Observation Schedule Trays_ _ final	1.0	24.07.2015

Your study now has NHS permission, on the understanding and provision that you will follow the conditions set out below.

Conditions of Approval

The Principal Investigator is responsible for:

1. **Compliance with all relevant laws, regulations and codes of practice applicable to the trial including but not limited to, the UK Clinical Trials Regulations, Medicines for Human Use (Clinical Trial) Regulations 2004, principles of Good Clinical Practice, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (2013 version), the Human Rights Act 1998, the Data Protection Act 1998, the Medicines Act 1968, and the NHS Research Governance Framework for Health and Social Care (version 2 April 2005). Should any of these be revised and reissued this will apply. Copies of the up-to-date regulations are available from the R&I Office or via the R&I website http://nuhrise.org.**

2. **Submission of study amendments to the Ethics committee and MHRA in accordance with the IRAS guidelines. Amendments and information with regards to changes in study status must be sent to R&I, (this includes changes to the local study team). Within 35 days from the receipt of a valid amendment submission, the R&I department will inform you if the amendment cannot be implemented locally. If no objections are raised NHS permission is valid and the amendment may be implemented.**

   When submitting documents for studies adopted into the NIHR portfolio please send the information to the Clinical Research Network: East Midlands (CRN:EM) (CSP.CRNEastMidlands@NIHR.ac.uk).
   When submitting documents for all other studies please use the email address rdamend@nuh.nhs.uk.

3. **Ensuring all study personnel, not employed by the Nottingham University Hospitals NHS Trust hold either honorary contracts/letters of access with this Trust, before they have access to any patients or staff, their data, tissue or organs or any NUH facilities.**

4. **For initiating and delivering research in accordance with the Department of Health's Plan for Growth. The first patient, first visit should occur within 70 days from the receipt of a valid submission in R&I. This applies to all studies where:**

   i. **The research is classed as a "clinical trial "on the IRAS filter page (first 4 categories)**

5. **Ensuring the research team via an identified individual, collaborates with the department of R&I and the CRN:EM in reporting recruitment data using Documas and the CRN EM Study Tracker.**

6. Ensuring that for GTAC-approved studies, the NHS permission is forwarded to GTAC via the sponsor. GTAC should then issue a site authorisation letter which must be received by each site prior to recruitment commencing. A copy of this letter must be forwarded to R&I.

7. Comply with requests from NUH R&I to allow monitoring of research to comply with the Research Governance Framework and other applicable regulations.

8. Record *all* types of adverse events (including Suspected Unexpected Serious Adverse Drug Reaction - SUSARS) in the patient medical records and study documentation and report to the sponsor as required by the protocol.

9. Report any Serious Breach of the UK Clinical Trial regulations in connection with the trial or Serious Breach of the protocol, immediately after becoming aware of the breach to the study sponsor.

10. Reporting any changes to the study to R&I by letter or e mail. These should not be implemented until agreed with R&I.

For NUH sponsored studies only, the Chief Investigator is responsible for:

i. All duties as detailed in the "Clinical Trial Delegation of Sponsorship responsibilities to Chief Investigator" agreement.

ii. Contacting the sponsor for review of all amendment documentation prior to submission to the HRA and MHRA. Please note that according to HRA and MHRA regulations, all submissions of amendments need to be signed by the authorised sponsor's representative. All relevant documentation should be emailed to rdamend@nuh.nhs.uk.

iii. Sending copies of the completed Annual Progress Reports, Development Safety Update Reports, and End of Study report required by the Ethics Committee and the MHRA (if appropriate) to the sponsor researchsponsor@nuh.nhs.uk.

iv. Notifying NUH R&I of all SAEs by completing and sending the *"Serious Adverse Event reporting form"* to R&I (only via fax, e-mail or by hand), within 24hrs of becoming aware of the event. Further guidance can be found in the R&I Adverse Event SOP (SOP-RES-019).

v. Reporting any Serious Breach of the UK Clinical Trial regulations in connection with the trial or Serious Breach of the protocol, immediately after becoming aware of the breach to NUH R&I as sponsor. Further guidance can be found in the R&I Non Compliance and Serious Breach Reporting SOP (SOP-RES-017).

This approval letter constitutes a favourable Site Specific Assessment (SSA) for this site.

If you have any queries regarding the milestones or points detailed in this letter, please contact the Research Project Manager responsible for managing the performance of the study at NUH. This information is available on http://nuhrise.org.

Please note that the R&I department maintains a database containing study related information, and personal information about individual investigators e.g. name, address, contact details etc. This information will be managed according to the principles established in the Data Protection Act.

Yours sincerely,



Dr Brian Thomson / Dr Maria Koufali
Director of Research and Innovation / Deputy Director Research and Innovation

Appendix 3: Ethical, R&D approval of System Reliability and Airway Management Study

NHS
Health Research Authority
NRES Committee London - Surrey Borders
Research Ethics Committee (REC) London Centre
Ground Floor
Skipton House
80 London Road
London
SE1 6LH

Telephone: 020 797 22561
Fax: 020 797 22592

01 July 2014

Dr Iain Moppett
Associate Professor/Honorary Consultant
University of Nottingham and Nottingham University Hospitals NHS trust
Anaesthesia
Queen's Medical Centre
Nottingham
NG7 2UH

Dear Dr Moppett

Study title:	**System Reliability and Airway Management**
REC reference:	**14/LO/1239**
Protocol number:	**14060**
IRAS project ID:	**158873**

Thank you for your application for ethical review, which was received on 27 June 2014. I can confirm that the application is valid and will be reviewed by the Proportionate Review Sub-Committee on 09 July 2014. To enable the Proportionate Review Sub Committee to provide you with a final opinion within 10 working days your application documentation will be sent by email to Committee members.

One of the REC members is appointed as the lead reviewer for each application reviewed by the Sub-Committee. I will let you know the name of the lead reviewer for your application as soon as this is known.

Please note that the lead reviewer may wish to contact you by phone or email between Thursday 03 July 2014 and Wednesday 09 July 2014 to clarify any points that might be raised by members and assist the Sub-Committee in reaching a decision.

If you will not be available between these dates, you are welcome to nominate another key investigator or a representative of the study sponsor who would be able to respond to the lead reviewer's queries on your behalf. If this is your preferred option, please identify this person to us and ensure we have their contact details.

You are not required to attend a meeting of the Proportionate Review Sub-Committee.

Please do not send any further documentation or revised documentation prior to the review unless requested.

Documents received

The documents to be reviewed are as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Email invitation text]	1.0	17 June 2014
Copies of advertisement materials for research participants [Poster]	1.0	17 June 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of Insurance]		31 July 2013
IRAS Checklist XML [Checklist_27062014]		27 June 2014
Letter from sponsor [Letter from Sponsor]		18 June 2014
Participant consent form [Consent form staff - observation]	1.0	17 June 2014
Participant consent form [Consent form patient - observation]	1.0	17 June 2014
Participant consent form [Consent form staff - focus group]	1.0	17 June 2014
Participant information sheet (PIS) [PIS Staff Observation]	1.0	17 June 2014
Participant information sheet (PIS) [PIS patient observation]	1.0	17 June 2014
Participant information sheet (PIS) [PIS Staff focus group]	1.0	17 June 2014
REC Application Form [REC_Form_27062014]		27 June 2014
Referee's report or other scientific critique report [Reviewers comments]		
Research protocol or project proposal [System reliability in airway management Protocol]	1.0	17 June 2014
Summary CV for Chief Investigator (CI) [Moppett REC CV 2014]		17 June 2014

No changes may be made to the application before the meeting. If you envisage that changes might be required, you are advised to withdraw the application and re-submit it.

Notification of the Sub-Committee's decision

We aim to notify the outcome of the Sub-Committee review to you in writing within 10 working days from the date of receipt of a valid application.

If the Sub-Committee is unable to give an opinion because the application raises material ethical issues requiring further discussion at a full meeting of a Research Ethics Committee, your application will be referred for review to the next available meeting. We will contact you to explain the arrangements for further review and check they are convenient for you. You will be notified of the final decision within 60 days of the date on which we originally received your application. If the first available meeting date offered to you is not suitable, you may request review by another REC. In this case the 60 day clock would be stopped and restarted from the closing date for applications submitted to that REC.

R&D approval

All researchers and local research collaborators who intend to participate in this study at sites in the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland should apply to the R&D office for the relevant care organisation. A copy of the Site-Specific Information (SSI) Form should be included with the application for R&D approval. You should advise researchers and local collaborators accordingly.

The R&D approval process may take place at the same time as the ethical review. Final R&D approval will not be confirmed until after a favourable ethical opinion has been given by this Committee.

For guidance on applying for R&D approval, please contact the NHS R&D office at the lead site in the first instance. Further guidance resources for planning, setting up and conducting research in the NHS are listed at http://www.rdforum.nhs.uk. There is no requirement for separate Site-Specific Assessment as part of the ethical review of this research.

Communication with other bodies

All correspondence from the REC about the application will be copied to the research sponsor and to the R&D office for Nottingham University Hospitals. It will be your responsibility to ensure that other investigators, research collaborators and NHS care organisation(s) involved in the study are kept informed of the progress of the review, as necessary.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/LO/1239	**Please quote this number on all correspondence**

Yours sincerely



Mr Atul Patel
REC Manager

Email: nrescommittee.london-surreyborders@nhs.net

Copy to: *Mrs Angela Shone*
Ms Stacey Harrison, Nottingham University Hospitals

Appendix 4: Consent Forum of Drug Trays In Anaesthesia

Nottingham University Hospitals NHS Trust

The University of Nottingham

University of Nottingham
School of Medicine
Anaesthesia and Critical Care
Queen's Medical Centre
Derby Road
Nottingham

CONSENT FORM
(Version draft: 1st May 2015)

Title of Study:

An Observational Study of Feasibility of a Novel Drug Storage Tray In Anaesthetic Practice

(Staff Participant)

REC ref: A15082013 SoM Anaesthesia
Name of Researchers:
Dr Iain Moppett Miss Dalal Almghairbi
Dr Rachel Evley Ms Shashi Gupta

Name of Participant:

Please initial box

1. I confirm that I have read and understand the information sheet (Version draft dated **01/05/2015**) for the above study and have had the opportunity to ask questions. ☐
2. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐
3. 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 this information may still be used in the project analysis. ☐
4. I understand that relevant sections of 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 my 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. ☐
5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

When completed: - 1 copy for participant, 1 copy for researcher site file
Participant Consent Form. Drug Trays - Interviews.
University of Nottingham. Version draft, 1st May2015

Appendix 5: Consent Forum of System Reliability and Airway Management Study

The University of Nottingham

Nottingham University Hospitals NHS
NHS Trust

CONSENT FORM
(Final version 2.0: 14/07/2014)

Title of Study: System Reliability and Airway Management

REC ref: ***14/LO/1239***

Name of Researcher: Iain Moppett, Andrew Norris, Mark Barley, Rob McCahon, David Evans, Alex Lang, Sarah Sharples

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 2.0 dated 14/07/2014 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of my medical notes and 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 my 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. ☐

4. I understand that the induction of anaesthesia will be recorded (audio and video) and that anonymous direct quotes from this time may be used in the study reports. ☐

5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the project notes; 1 for the medical notes

Appendix 6: Participant Information Sheet of Drug Trays In Anaesthesia

The University of Nottingham

University of Nottingham
School of Medicine
Division of Anaesthesia and Critical Care
Queen's Medical Centre
Derby Road
Nottingham
0115 8231009

Participant Information Sheet
Version draft 1ST May 2015

An investigation exploring the perceptions and understanding of paediatric anaesthetists in relation to standardisation of drug preparation

Name of Researchers: Iain Moppett, Dalal Almghiarbi, Rachel Evley, Shashi Gupta

Introduction
We would like you to take part in our research study. Before you decide it is important that you understand why the research is being done and what it will involve for you. One of our team will go through the information sheet with you and answer any questions you may have. Talk to others about the study if you wish. Please take time to decide whether or not you wish to take part. This study is a part of a PhD student research project.

What is the purpose of the study?
Drug errors occur relatively frequently in anaesthesia, though fortunately serious harm is uncommon.
The last line of defence for drug administration by an anaesthetist is checking that the syringe contents are exactly what the anaesthetist thinks they are. This is clearly a fallible process – anaesthetists are human and make mistakes. Standardisation of drug preparation may be an earlier defence mechanism – if syringes are always in the same place, then the chance of an anaesthetists checking error causing harm may be reduced. Separation may also be beneficial – keeping emergency drugs, local anaesthetics and routine anaesthetic drugs apart has been suggested as a mechanism to reduce the risk of inadvertent maladministration. Conversely, medicine has had its fair share of well-intentioned but unsuccessful attempts to re-engineer individual components which are part of more complex process of care. For example, anaesthetists are well aware of the ongoing issues around the use of non-Luer connections for spinal needles.

This study has two parts. One is to observe how anaesthetists actually prepare and use drugs in clinical practice, both with normal equipment and with a locally-designed 'anaesthetic tray'. The second part is to explore the perceptions and understanding of anaesthetists in relation to standardisation of drug preparation.

Why have I been invited?
You are being asked to participate in this study because you are an anaesthetist working at department of Anaesthesia.
Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights. If you did decide to take part you would be asked to complete either a short interview.

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. If you decide to take part in this study, you will be asked to sign a consent form and participate in one of the following:
Observations
A researcher will observe the actions of the anaesthetist during a theatre case, from initial drug preparation to leaving theatre. They will be recording (on paper) how drugs are prepared, stored and used. They will discuss with you and the team beforehand where the best place is to observe without interfering with the flow / process of the case.

For each individual case, the observations will stop at the end of the case. If time allows, the investigator will ask you some questions about what they have observed to get your perspective on what they observed.

During the observations we would ask that you do not interact with the observer as far as possible unless there is a clinical need (for instance they are in the way).

We may wish to observe more than one case. We will inform the key team members before the start of the ward round or procedure that observations are taking place. Each observation will take the length of a case. The whole study is taking place over 6 months.

One of the theatre pharmacists and a local trainee anaesthetist have designed a new set of anaesthesia-specific drug trays. These are colour coded and have separate trays for local anaesthetics, emergency drugs and routine anaesthetic drugs. We are planning to observe cases where these trays are used and those where normal (cardboard) trays are used. How you use (or don't use) these trays is completely up to you.

Interview
For this study you will be asked to complete a semi-structured interview with one of the researchers at a time and location within the Trust convenient to you.

The interview will be conducted by one of the investigators and the interview will consist of questions on the following themes, specifically designed to explore anaesthetists' perceptions, understanding and attitudes towards potential benefits and risks of standardised practice in preparation of anaesthetic drugs.

1. Current practice for drug preparation
2. Benefits of current practice
3. Risks of current practice
4. How do you feel about using a standardised / colour coded drug tray?
5. Benefits of a standardised / colour coded drug tray
6. Risks of a standardised / colour coded drug tray
7. What do you feel should be best practice?

The interview will be recorded and last approximately 30 minutes. You are free to withdraw at any time without giving a reason. However, if you do so, any recordings made up until that time will continue to be used in the final analysis.

If, during the course of the study, information is disclosed which requires reporting, this will be discussed with you confidentially by the Chief Investigator.

Feedback will be given at anaesthetic meetings at Directorate teaching days.

What are the possible disadvantages of taking part?
There should be no disadvantages of taking part in this study. In the extremely unlikely event of participants sharing sensitive information or discussing upsetting experiences during the interviews, the investigator will be available to offer support and advice or further support if required. A process of mentorship or counselling would also be available should the need arise.

You will need to give your time to the interview, which would be a maximum of half an hour.

What are the possible benefits of taking part?
You will have the opportunity to discuss your experiences and perceptions relating to drug preparation in anaesthesia. This may consequently lead to improvements being made regarding drug preparation in anaesthesia, which may improve patient care and safety.

What will happen if I don't want to carry on with the study?
Your participation in this study is voluntary and you are free to withdraw at any time, without giving any reason. If you withdraw then the data collected may still be used in the project analysis and final write-up.

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 to one of the researchers who will do their best to answer your questions. Their contact numbers are:

Dr Iain Moppett 0115 8230959 Iain.Moppett@nottingham.ac.uk
Dr Rachel Evley 0115 8231004 Rachel.Evley@nottingham.ac.uk
Miss Dalal Almghairbi 011578331006 msxda@nottingham.ac.uk

If you remain unhappy and wish to complain formally, please contact the secretary of the University of Nottingham Medical School Research Ethics Committee, Mrs Louise Sabir, e-mail address: louise.sabir@nottingham.ac.uk

Will my taking part in the study be kept confidential?

If you choose to take part in the study, all information that is collected about you during the course of the research will be kept strictly confidential. Recordings and observations made during this study will only be available to the researchers. Names will not be written on the transcripts created 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 Anesthesia, University of Nottingham and destroyed 7 years after the study is completed. Representatives of regulatory authorities and authorized people from the Trust may inspect the data to check 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 to the results of the study?

The findings of this study may be presented at national or international meetings and may be published in a medical journal. We will present the results, suitably anonymised, at the directorate teaching meetings.

Who is funding the research?

The costs of the trays have been met by funds from the Division of Anaesthesia. There is no external funding.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the ..... Research Ethics Committee

Expenses and payments

No expenses or payments will be made. The interviews will take place at a time convenient to you, for example before or after a shift.

Further information and contact details

You may contact: Dr Iain Moppett
By phone: 0115 924 9924
By email: iain.moppett@nottingham.ac.uk
By post: University Department of Anaesthesia
C floor, East Block
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

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 7: Participant Information Sheet of System Reliability and Airway Management Study

The University of Nottingham

Nottingham University Hospitals NHS Trust

Participant Information Sheet
(Final version 2.0: 14/07/2014)

Title of Study: System Reliability and Airway Management
Name of Researcher(s): Iain Moppett, Andrew Norris, Mark Barley, Rob McCahon, David Evans, Alex Lang, Sarah Sharples

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

We want to use video and audio recordings of the induction of anaesthesia to try to provide a better description of the processes, thoughts and decisions which occur during induction and **routine** airway management. We hope to use these data to help build better quantitative (mathematical) models of how these processes occur in real life (as opposed to textbook teaching). In turn, we hope these data may help us improve the reliability and safety of this process.

Why have I been invited?

You are being invited to take part because you are anaesthetist, ODP or anaesthetic practitioner working at Queen's Medical Centre We are inviting 20 participants like you to take part.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

Your participation in the study will be in two parts: an audio-visual recording of the induction and airway management of a routine general anaesthetic and a review of this recording with a member of the research team. The first part will occur just in the anaesthetic room – about 15-30 minutes depending on the case. The second part will take up to about an hour, though probably less. The whole research project is expected to last one year.

Observation:
We want you to go about the induction of anaesthesia as you would do normally. We will only be doing recordings on with patients who have given consent, and who you (or

the anaesthetist) assess as being routine, ASA 1-2 and without anticipated airway difficulties.

There will be no extra people in the anaesthetic room. The recording will involve fixed mount cameras pointed at the monitor screen, the 'head end of the patient' and a wide angle view of the rest of the anaesthetic room. We will ask the lead anaesthetist to wear an unobtrusive head mounted camera (we will show this to you) which is essentially the head band from a pair of sports sunglasses with a small camera on the bridge. We will also ask the lead anaesthetist and the ODP / anaesthetic practitioner to wear a small lapel microphone.

We will check the recording equipment is working beforehand and start it just before the patient enters the anaesthetic room.
We will stop the recording once the patient leaves the anaesthetic room.

Review of recordings:
Once the recordings have been completed we will edit the different streams into one single video. A researcher will review this with you at a convenient time in the Academic department. The purpose of this review is for the researcher to clarify actions and in particular to gain an understanding of what you were thinking at various times, and what internal or external cues influenced your actions at various points.

Expenses and payments

Participants will not be paid to participate in the study.

What are the possible disadvantages and risks of taking part?

There are no direct risks to you from taking part. However, people involved in recording of clinical practice have voiced some concerns.

'If something goes wrong the recording can be used against me'. As clinicians, the research team actually believe this is wrong – accurate contemporaneous recording allows objective judgement of what happened, rather than relying on subjective memory. However, you will be able to stop the recording at any time. In the very unlikely occasion of a serious adverse event occurring, any access to the recordings by any party will have to be by formal request.

'The research process alters behaviour to the detriment of patient safety.' Although this is commonly raised there is little evidence that it occurs. By using unobtrusive recording equipment we have avoided the problem of having a 'camera man' in the room.

What are the possible benefits of taking part?

There are unlikely to be any direct benefits to taking part in this study but the information we get from this study may help improve reliability and safety of airway management in the future. All participants will have the opportunity to review high quality recordings of their own practice which may have educational benefit.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints. Details can be obtained from your hospital.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (name) will be kept for 6 months after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

The recordings will be reviewed with you offline. In accordance with other observational studies and GMC requirements of Good Medical Practice, if an investigator sees something which he / she believes is an immediate or continuing threat to patient safety this will be discussed with the individuals concerned, and if appropriate with their clinical manager.

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

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study

The results will be published in a peer-reviewed journal. They will also be published in summary form on the website of the National Institute of Academic Anaesthesia. You will not be identified in any report or publication.

Once we have completed the analysis we will invite you to a meeting at QMC to discuss the results.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the Difficult Airway Society.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by NRES Committee London - Surrey Borders Research Ethics Committee.

Further information and contact details

Chief Investigator: Iain Moppett

Anaesthesia and Critical Care Research Group
Queen's Medical Centre
Nottingham University Hospitals

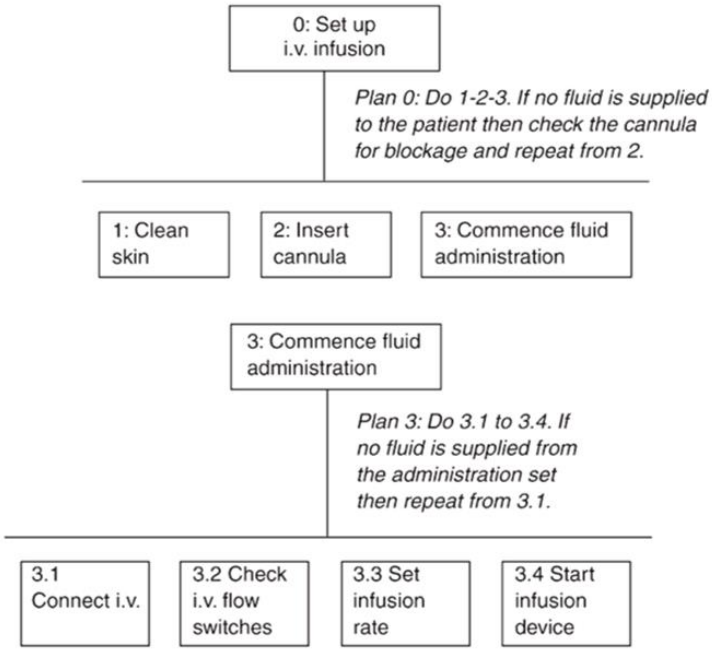
Local anaesthetist investigators: Andrew Norris, Mark Barley, Rob McCahon, David Evans

Can all be contacted through the QMC anaesthetic office (61195).

Dr Chris Gornall (College Tutor) is happy to discuss this study with trainee anaesthetists (66898).

Theatre staff may wish to discuss this study with their team leader or Maria Shallow (Deputy Clinical Lead; 63249).

Appendix 8: Examples of the process of HTA of setting up iv infusion, showing the initial decomposition (top) and then a further decomposing of one of the sub goals (bottom) [154]



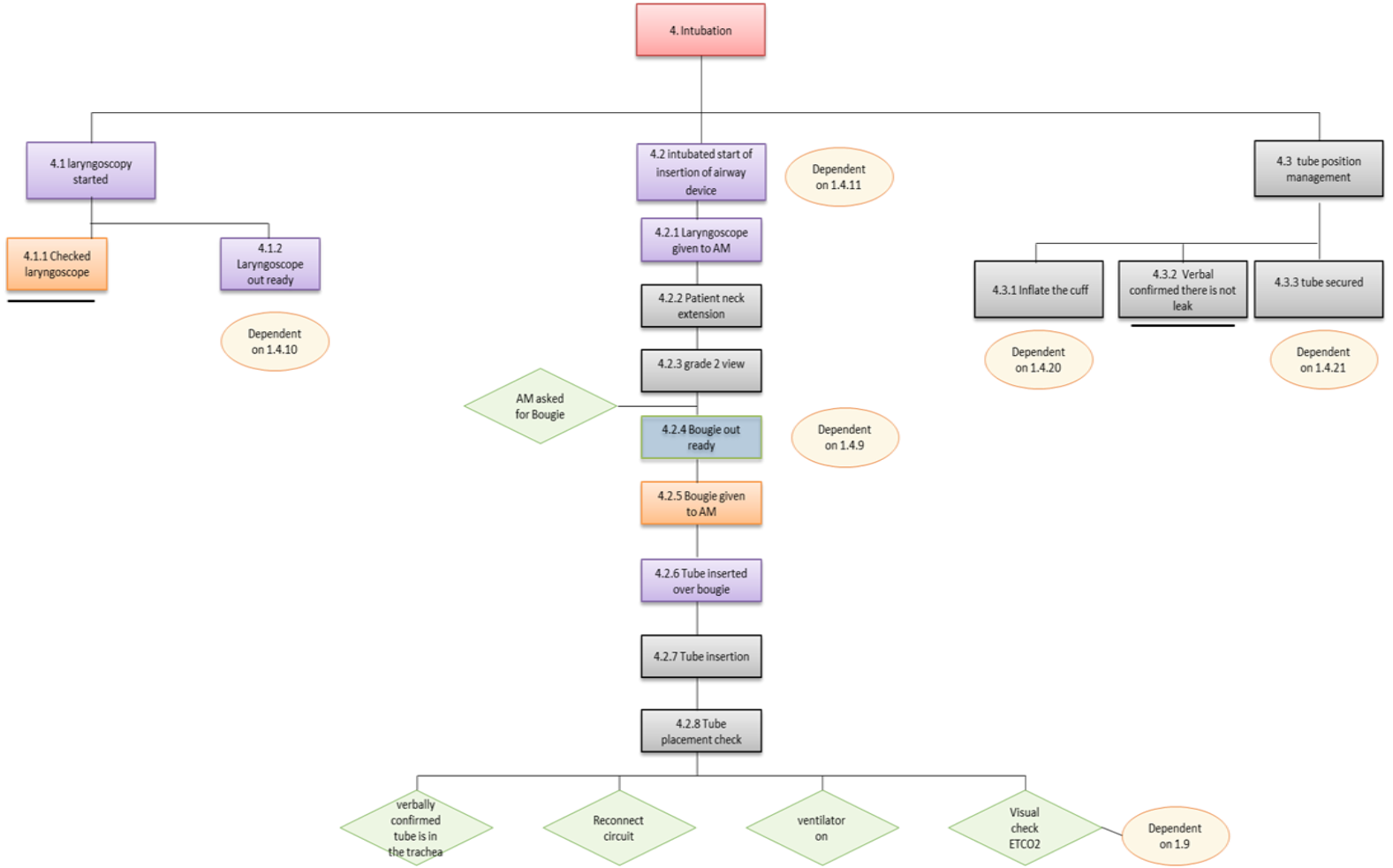
Appendix 9: Example of SHERPA output for each 'phase' of anaesthesia [154].

Task step	Error	Probability	Criticality	Remediation
Preoperative visit				
1.1.1 Identify type of surgery (including incorrect theatre lists or consent forms)	Incorrectly identified	Medium–low	Medium	Ensure sufficient details are provided on the operating list (e.g. 'laparotomy/colectomy' rather than 'laparotomy', if the former is meant)
1.2.4 Ask about previous anaesthetics/complications	Assessment not made	Low	Low–high	Use preoperative checklist
Preoperative equipment check				
1.7.1 Ensure that the vaporizer is filled to the correct level	Vaporizer not checked	Low	Medium–high	Ensure compliance with checklist. Automate this task step
1.9.1 Ensure correct configuration of the ventilator tubing	Incorrect configuration not identified	Low	High	Train operators on the machines that are being used. Standardize the machines being used
1.9.3 Select mode of operation (circle or open)	Controls incorrectly set	Medium–high	High	Make the switch setting more clearly visible. Remove the common gas outlet control
Induction				
2.1 Collect drug	Wrong drug collected	Low	High	Cross-check the label. Use a bar-code checker
2.3 Transfer required amount of drug to syringe	Wrong amount transferred	Low	Medium– high	Cross-check the dose. Use pre-loaded syringes
4.2 Attach arterial pressure monitor	Monitor not correctly positioned	Low	High	Ensure there is a check of signal quality. Use a 'signal quality' alarm
12.3.1 Disconnect pulse oximeter	Monitor not disconnected	Low	Low–medium	Employ single port for all monitor connections. Cross-check monitor disconnections. Telemetry
Maintenance				
13.1.1.1 Monitor inspired agent concentration	Concentration not monitored	Low	High	Improve the display design. Encourage 'standard checking' by manual recording of values. Use agent level alarms
13.1.5 Monitor respiration and respiratory gas traces	Ventilatory frequency not monitored	Low	High	Set context-specific monitors and alarms. Encourage 'standard checking'
13.1.7.2 Monitor urine output	Not read	Medium	Medium– high	Set context-specific monitors and alarms. Encourage 'standard checking'
13.1.9 Record observations on anaesthetic chart	Observations recorded incorrectly	Low	High	Use automated recording device. Encourage 'standard' checking
Emergence				
14.5.1 Remove throat pack	Throat pack not removed	Low	High	Tie the throat pack to the LMA. Ensure end of throat pack is visible at all times. Recovery nurse to check in postoperative care unit
15.4.4 Move patient using movement device	Patient mishandled	Low	High	Manual handling training. Have a member of staff take charge of patient movement
15.7.7 Inform recovery nurse of postoperative care requirements	Nurse not given complete information	Low	High	Use a formal protocol for handover. Use an integrated care pathway. Use a perioperative care practitioner. Use a data link between theatre and postoperative care unit

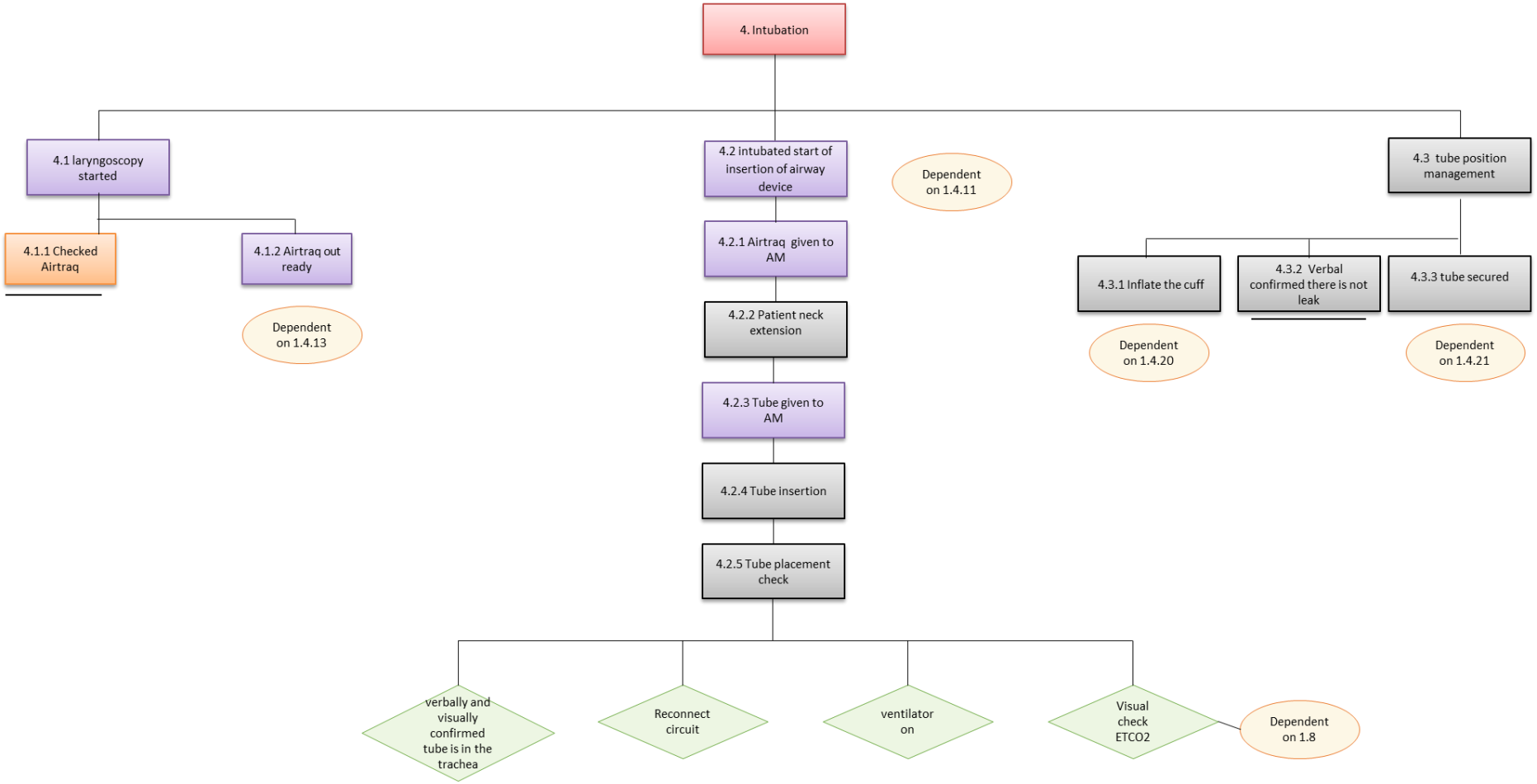
Appendix 10: Interview Questions of Drug Trays Study

1. What is your current practice for drug preparation and storage?
2. Do you find any benefit of current practice?
3. Do you find any risks of current practice?
4. How do you feel about using a standardised / colour coded drug tray?
5. Do you find any benefits of using the new rainbow tray?
6. Do you find any risk of using the new rainbow tray?
7. What do you feel should be best practice?

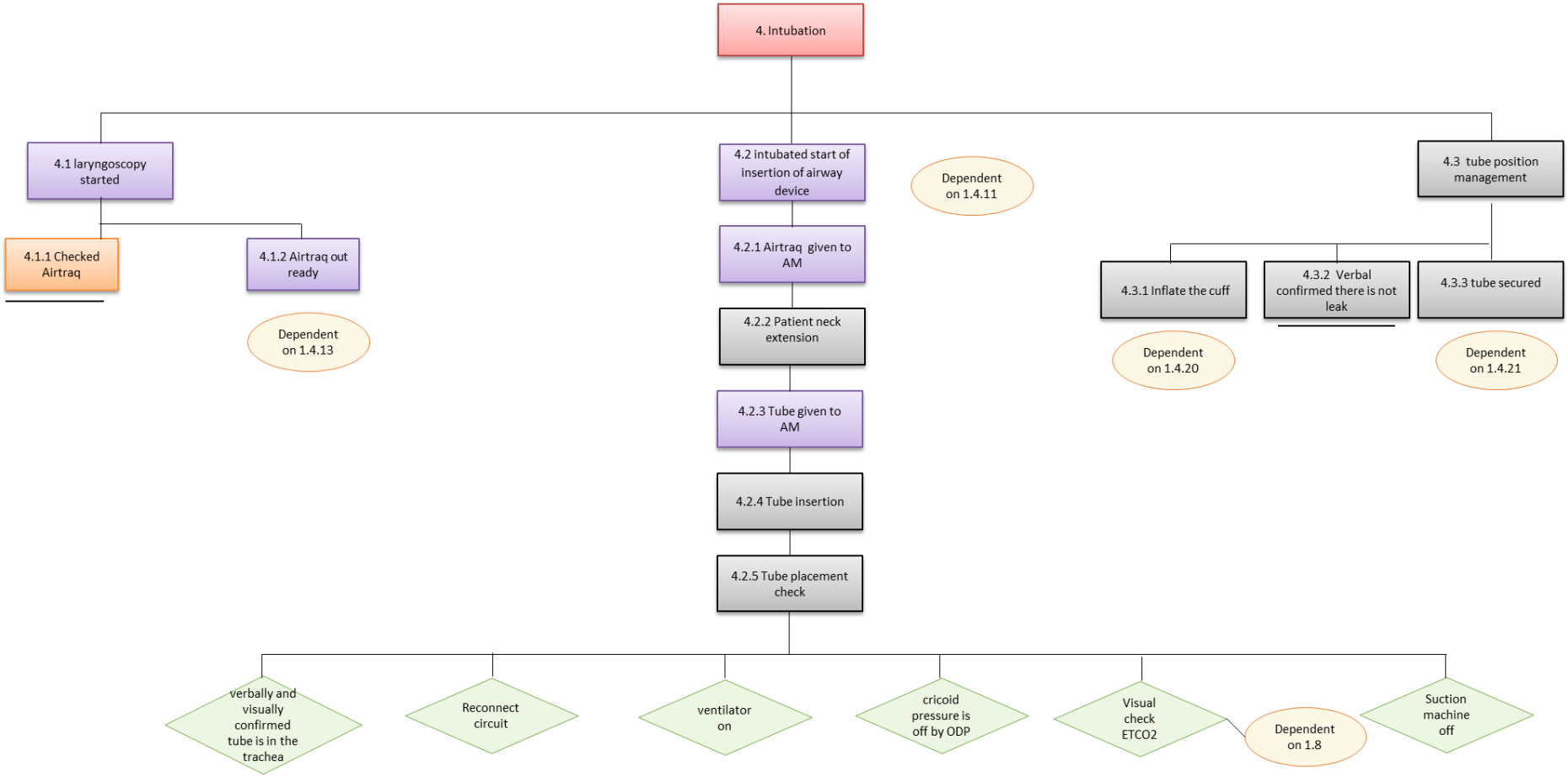
Appendix 11: Intubation process in grade 2 view



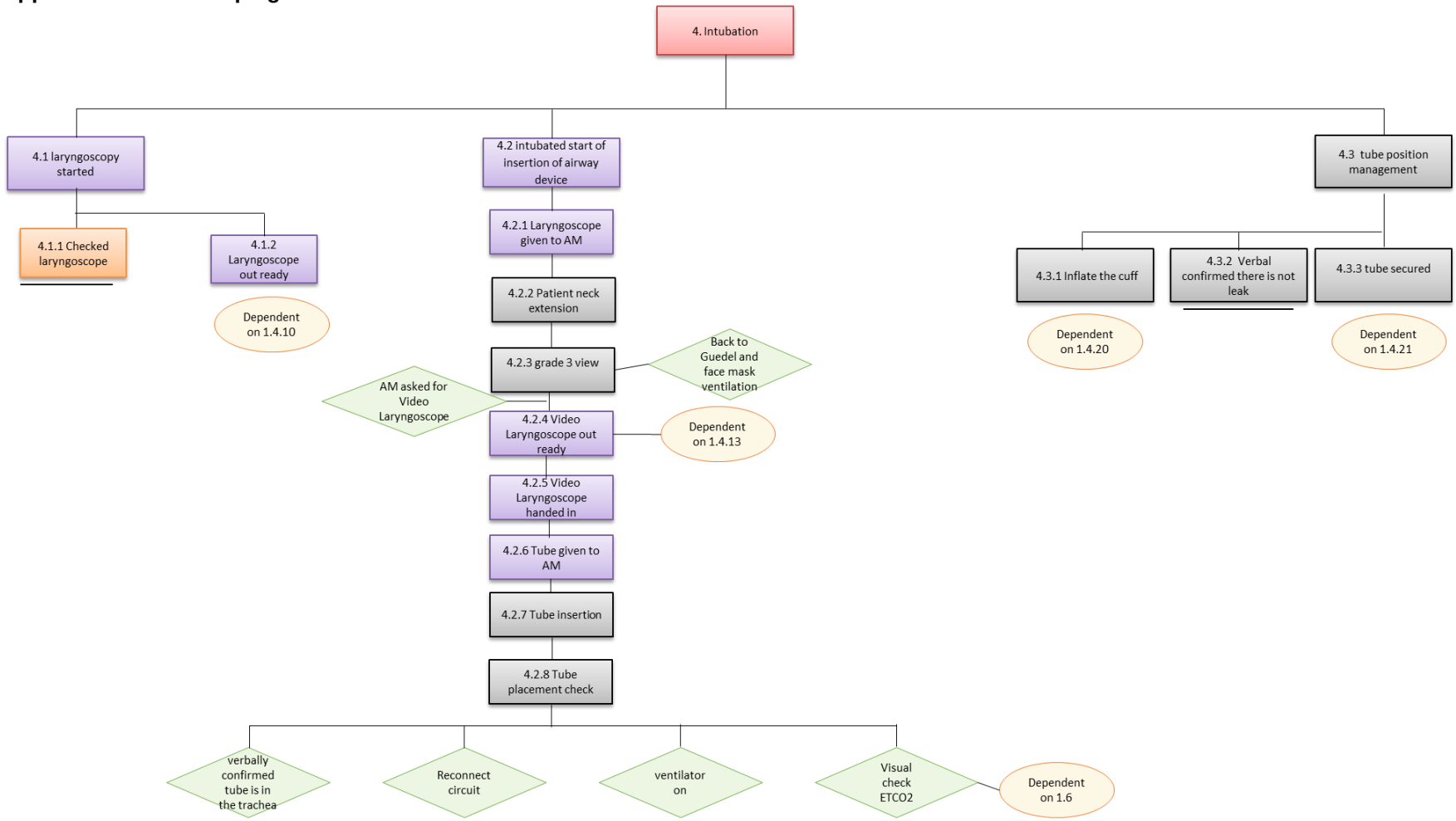
Appendix 12: Intubation process in grade 3 view



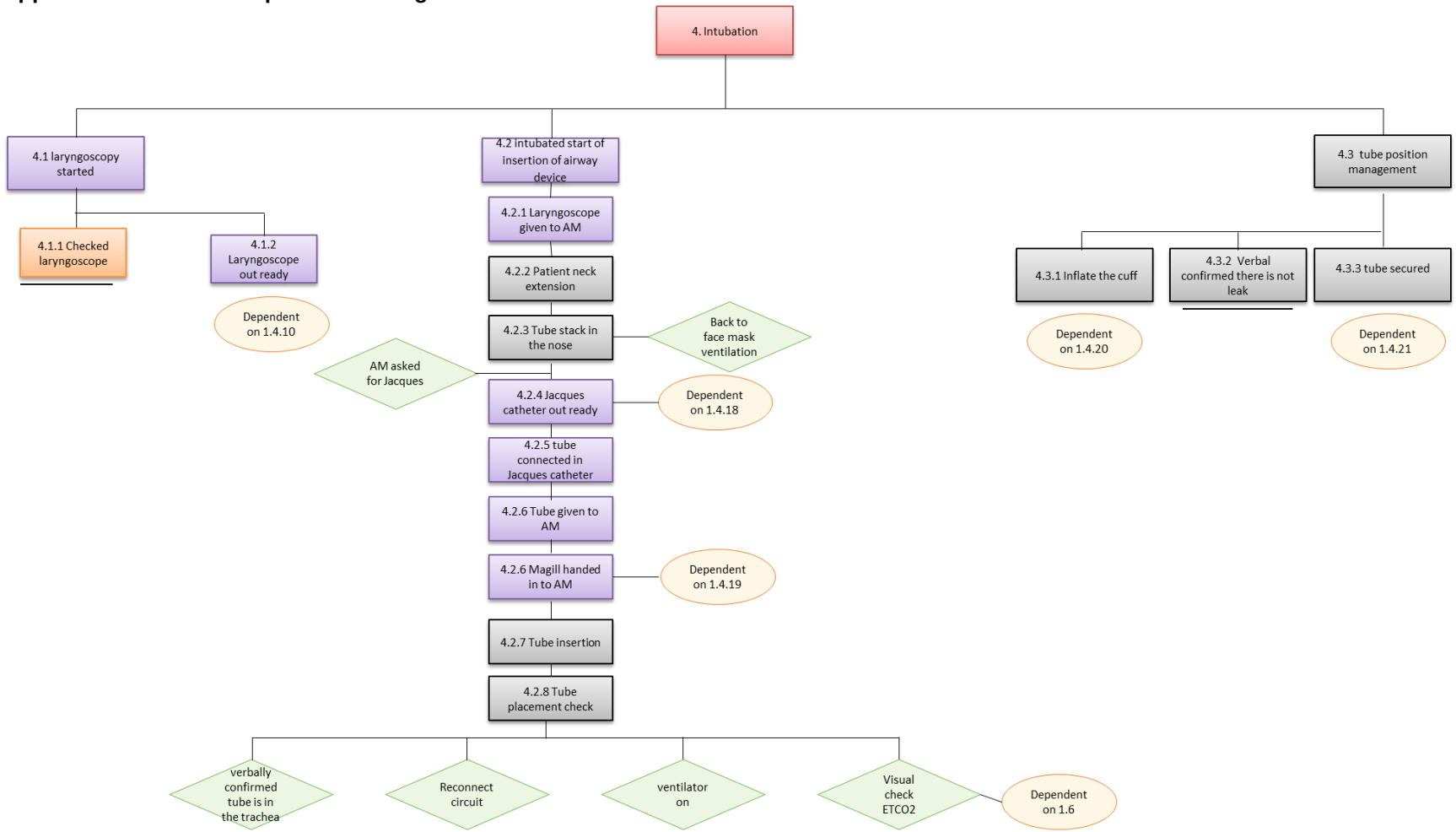
Appendix 13: Airtraq grade 3 view



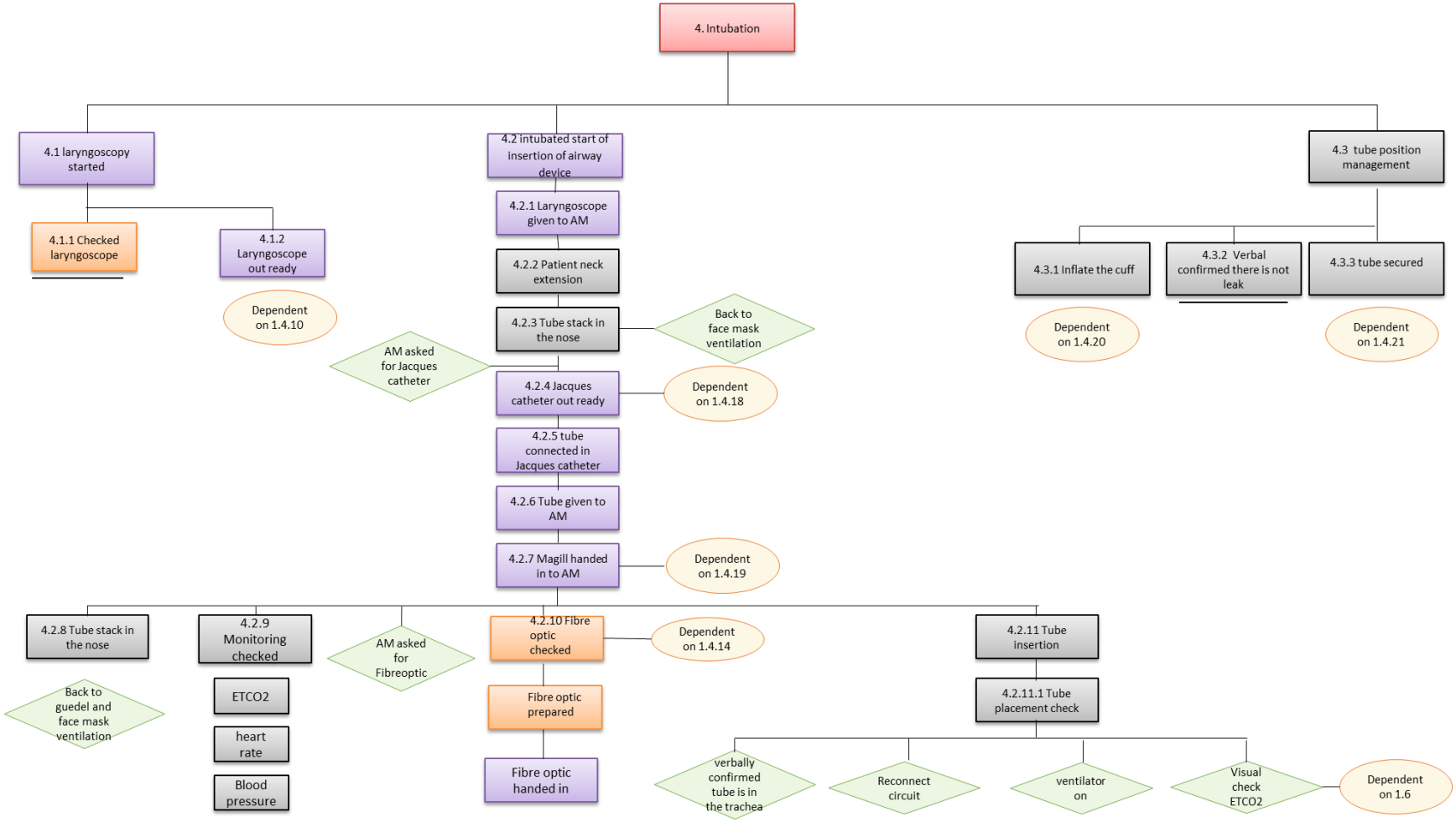
Appendix 14: Glideslope grade 3 view



Appendix 15: Intubation process through the nose



Appendix 16: Intubation process through the nose use Fibro-optic



Appendix 17: PRISMA - 2009-Checklista



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

PRISMA 2009 Checklist

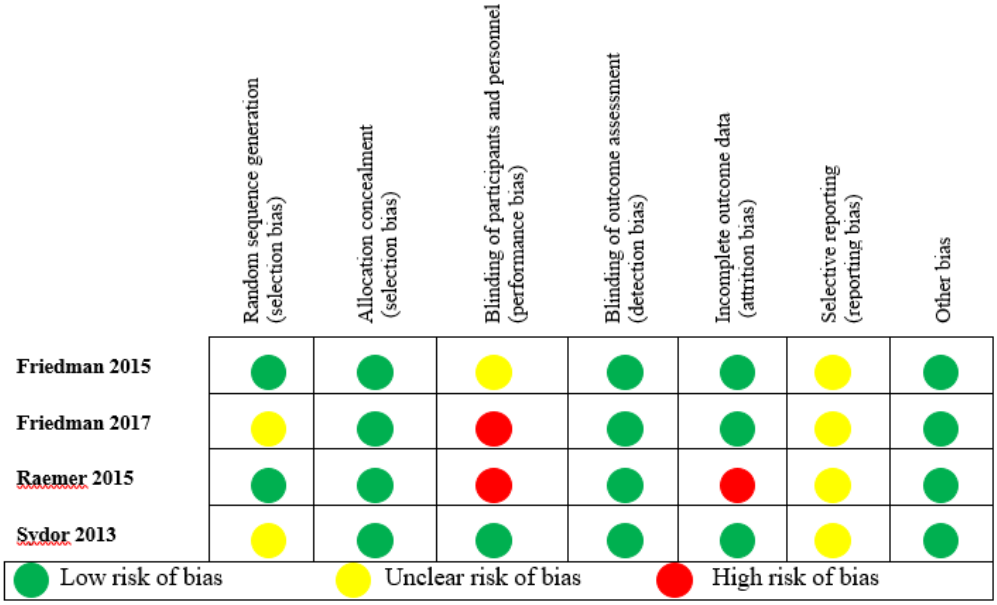
Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Appendix 4
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	7-11
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	11-15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15

Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	16

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**

Appendix 18: Summary of Risk of Bias



Teaching Residents the Two-Challenge Rule: A Simulation-Based Approach to Improve Education and Patient Safety
Pian-Smith et al 2009

Criteria	Yes	No	Other (CD, NR, NA)*
1. Was the study question or objective clearly stated?	✓		
2. Were eligibility/selection criteria for the study population prespecified and clearly described?	✓		
3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?	✓		
4. Were all eligible participants that met the prespecified entry criteria enrolled?			**CD**
5. Was the sample size sufficiently large to provide confidence in the findings?	✓		
6. Was the test/service/intervention clearly described and delivered consistently across the study population?	✓		
7. Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?			**CD**
8. Were the people assessing the outcomes blinded to the participants' exposures/interventions?	✓		
9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?	✓		
10. Did the statistical methods examine changes in outcome measures from before to after the	✓		

Criteria	Yes	No	Other (CD, NR, NA)*
intervention? Were statistical tests done that provided p values for the pre-to-post changes?			
11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?		✓	
12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?			**NA**

Quality Rating (**Good, Fair, or Poor)**

It is fair

Improvements in Teamwork During Neonatal Resuscitation After Interprofessional TeamSTEPPS Training

Sawyer et al 2013

Criteria	Yes	No	Other (CD, NR, NA)*
1. Was the study question or objective clearly stated?	✓		
2. Were eligibility/selection criteria for the study population prespecified and clearly described?		✓	
3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?	✓		
4. Were all eligible participants that met the prespecified entry criteria enrolled?		✓	
5. Was the sample size sufficiently large to provide confidence in the findings?		✓	
6. Was the test/service/intervention clearly described and delivered consistently across the study population?	✓		
7. Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?	✓		
8. Were the people assessing the outcomes blinded to the participants' exposures/interventions?	✓		
9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?	✓		
10. Did the statistical methods examine changes in outcome measures from before to after the	✓		

Criteria	Yes	No	Other (CD, NR, NA)*
intervention? Were statistical tests done that provided p values for the pre-to-post changes?			
11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?		✓	
12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?			NA

Quality Rating (**Good, Fair, or Poor)**

It is fair

Appendix 19: Characteristics of Excluded studies

Study ID	Country	Participants	Outcome	Reason for Exclusion	Publishing Journal
Bould, 2015 [314]	Canada	Anaesthesia residents	Clarify how hierarchy influences residents' reluctance to challenge authority with respect to clearly erroneous medical decision-making	No intervention related to speaking up training	Canadian Journal of Anaesthesia
Pattni, 2017 [315]	Canada	Respiratory therapists	Examine the effect of the physician's gender on respiratory therapists' ability to effectively challenge clearly incorrect clinical decisions during a life-threatening crisis.	Focused on conflict resolution and speaking up in general medical practice	British Journal of Anaesthesia
Lingard, 2005 [316]	Canada	Surgeons, nurses, and anaesthetists	Team communications training about tension patterns, disparity of professional perspectives, and implications for team function.	No intervention related to speaking up training	Academic Medicine
Beament, 2016 [305]	UK	Junior and trainees anaesthetists	Explores the concept of 'barriers to challenging	No intervention related to speaking up training	Anaesthesia

			seniors' for anaesthetic trainees, and proposes a conceptual framework		
Calhoun, 2013 [317]	USA	Different clinician groups,	Describe the case, present the outcomes of several representative enactments, and discuss the educational, ethical, and psychological issues inherent in such cases.	Focused on conflict resolution and speaking up in general medical practice	Simulation in Healthcare