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What airway and vascular access skills can be performed whilst wearing the NHS issued chemical, biological, radiation, and nuclear personal protective equipment?

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Submission for
Doctor of Philosophy in Health Service Research (via prior publication)

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**CITY UNIVERSITY
LONDON**

School of Health Sciences

Gas! Gas! Quick, boys! – An ecstasy of fumbling,
 Fitting the clumsy helmets just in time;
But someone still was yelling out and stumbling
 and flound'ring like a man in fire or lime...
Dim, through the misty panes and thick green light.
 As under a green sea, I saw him drowning
 In all my dreams, before my helpless sight.
He plunges at me, guttering, choking, drowning.

If in some smothering dream you too could pace
 Behind the wagon that we flung him in,
And watch the white eyes writhing in his face,
 His hanging face, like a devil's sick of sin;
 If you could hear, at every jolt, the blood
Come gargling from the froth-corrupted lungs,
 Obscene as cancer, bitter as the cud
Of vile, incurable sores on innocent tongues,

Wilfred Owen, *Dulce et Decorum Est*¹

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List of Abbreviations and specialist terms

Bougie	gum elastic bougie (tracheal introducer)
B.I.G.	bone injection gun
CASP	Critical Appraisal Skills Program tools
CBRN	chemical, biological, radiation and nuclear
CBRN-PPE	chemical, biological, radiation, nuclear – personal protective equipment
CI	confidence intervals (95% CI)
CPR	cardiopulmonary resuscitation
ED	Emergency Department
ERC	European Resuscitation Council
ETT	endotracheal tube
HPA	Health Protection Agency
ILMA	intubating laryngeal mask airway
LMA	laryngeal mask airway
LTA	laryngeal tube airway
NHS	National Health Service
PLMA	proseal laryngeal mask airway
PPE	personal protective equipment
RCT	randomised control trial
TOXALS™	Advanced Life Support for Toxic Injury
TTH	Thomas™ Tube Holder
UK	United Kingdom

Declaration

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Abstract

The introduction of chemical, biological, radiation and nuclear personal protective equipment (CBRN-PPE) across the National Health Service (NHS), in 2007, represented an increase in the capacity to treat patients following a CBRN incident. However, little was known on what impact the NHS CBRN-PPE would have on skill performance.

To date a number of studies have evaluated various skills performed whilst wearing a range of CBRN-PPE, none of which resembles the NHS CBRN-PPE. This gap in the evidence prompted a series of research studies addressing the following research question, *'What airway and vascular access skills can be performed whilst wearing the NHS issued chemical, biological, radiation, and nuclear personal protective equipment?'* The resulting nine published peer-reviewed papers are presented with a critical commentary in three chapters: Chapter 3 (Papers 1 to 4) assesses what clinical skills can be performed using the NHS CBRN-PPE; Chapter 4 (Papers 5 & 6) explores clinicians' views on the preferences and experiences of airway management whilst wearing CBRN-PPE; and Chapter 5 (Papers 7 to 9) evaluates the optimal strategies of airway management whilst wearing the NHS CBRN-PPE. Chapter 6 is a summary of the findings presented in this thesis and presents a number of new research questions to further expand our knowledge-base, regarding skill performance whilst wearing NHS CBRN-PPE, reflecting the developmental nature of this area of research.

The research contained in this thesis utilises a combination of randomised controlled trials, interviews and questionnaires, to ascertain the impact of the NHS CBRN-PPE on skill completion. Papers 1 to 4 recruited a group of mixed clinicians allowing subgroup analysis observing for inter-professional differences regarding skill performance. Whereas, Papers 7 to 9 recruited student paramedics ensuring similar levels of airway management skills, thereby isolating prior expertise as a variable.

The research presented in this thesis has been used during simulation training as part preparations for the 2012 Olympics, in the development of a CBRN training DVD and incorporated into a textbook. The results have also been shared with NHS England working party on CBRN-PPE and, are being incorporated into CBRN treatment protocols by an overseas ambulance service.

Preface

In 2007, Frimley Park Hospital, along with all United Kingdom (UK) ambulance services and Emergency Departments, received its supply of National Health Service (NHS) procured chemical, biological, radiation and nuclear personal protective equipment (CBRN-PPE). Emergency Departments also received inflatable decontamination shower units.²

Prior to 2007, the NHS was poorly equipped to deal with any size of CBRN incident³⁻⁷ and the issuing of CBRN-PPE, plus decontamination equipment across the NHS represented an attempt to improve capacity to respond to a chemical incident.^{2 8} At that time, there were increasing concerns regarding potential CBRN terrorism⁹, which was heightened further by the 2005 announcement that the 2012 Olympic Games would be held in London.¹⁰⁻¹⁴ At the present time, risk of a CBRN incident remains high as chemical weapons have recently been used in Syria¹⁵⁻¹⁷ and there is also ongoing risk from industrial related chemical accidents.¹⁸

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The unique requirements of NHS personnel precluded the wholesale introduction of military CBRN-PPE. More specifically military respirators are not suitable for people with respiratory conditions (e.g. asthma) as they increase the workload of breathing^{20 21}, require adaptation for individuals wearing glasses, have reduced effectiveness in the presences of facial hair, and require a minimum level of physical fitness to wear.²² Military respirators, improperly worn, also present a risk to the wearer.^{23 24} The resulting NHS CBRN-PPE is a fully encapsulating suit with integral butyl rubber gloves and chemical resistant boots. It incorporates a small motor that supplies filtered air making it suitable for staff with chronic respiratory conditions to wear (see Appendix 1). In addition the PPE has a wide panoramic visor allowing staff to wear their own glasses^{2 8 22} and provides a high level of protection to instil confidence in the wearer.^{2 22 25-27} Yet despite these adaptations the CBRN-PPE remained bulky, hot, claustrophobic and clumsy² to wear with the integral chemical gloves reducing sensation and dexterity.

Preface, continued

In 2007, the arrival of standardised NHS CBRN-PPE heralded my involvement in the issues surrounding CBRN-PPE as the hospital's Director of Nursing instructed me to instigate a hospital-wide CBRN-PPE training programme. I was selected to lead this project due to my day-to-day responsibilities of managing resuscitation training, ongoing involvement in major incident planning, and my close working relationship with the ambulance service and the Royal Army Medical Corp. It quickly became apparent that my experience of providing resuscitation training would equip me to deliver CBRN-based simulation training.

To prepare myself for this new role, I liaised with the local ambulance service, the Health Protection Agency (HPA), military experts and attended a workshop on CBRN-PPE. The workshop emphasised the importance of removing casualties from immediate danger and commencing decontamination, highlighting the importance of CBRN-PPE to prevent rescuer contamination^{2 28} but made no reference to patient treatment. Treatment guidelines from the Department of Health²⁹, the HPA²⁸ and consensus-based expert opinion^{30 31} recommended limiting interventions to basic life support until after decontamination. Complying with these recommendations would result in definitive care, such as intubation, being delayed for a minimum of 12 minutes per casualty representing the time required to complete decontamination.^{8 18} I felt that this represented an unacceptable delay in the treatment of critically injured casualties, a concern shared by Byers et al⁸ and Baker.³²

My concerns over delaying treatment were based on my observation of differing mortality rates following the release of sarin gas in Japan³³⁻³⁶ compared with the use of an incapacitating gas to end the Moscow theatre siege.³⁷⁻³⁹ Both of these incidents resulted in multiple casualties and yet the death rate was much higher in the latter incident.^{15 17 37} The use of an incapacitating gas by Russian special forces soldiers, in 2002, to end the Moscow siege resulted in 670 hostages requiring hospital admission with 127 dying.³⁷ Despite this being a planned rescue attempt casualty treatment was substandard with limited attempts at maintaining patent airways or instigating assisted ventilation resulting in potentially avoidable deaths.³⁷⁻⁴⁰ Conversely, despite over 5000 casualties attending various Tokyo hospitals only 12 patients died.³⁵ This is despite the fact that at least five patients were in respiratory and/or cardiac arrest on, or shortly after, arrival at hospital, with the instigation of basic (simple airway interventions) as well as advanced life support interventions (e.g. intubation) saving a number of patient's lives.^{34 35 41 42}

Despite these incidents, and the evidence from Tokyo that advanced life support intervention (on contaminated casualties) was life-saving, there was a lack of guidance regarding what skills could be performed whilst wearing the NHS CBRN-PPE, which resulted in the start of the research journey presented in this thesis. The resulting research was intended to address locally generated questions as to what clinical skills were feasible whilst wearing the NHS CBRN-PPE, to develop a simulation-based CBRN training programme, and inform a local major incident policy. The nine Papers presented within this thesis have concentrated on airway management and vascular access skills. The research underpinning Papers 1 to 3⁴³⁻⁴⁵ was undertaken in a UK hospital, recruiting clinicians who would be required to treat patients following a CBRN incident. These studies were subsequently used by the HPA as part of preparations for the 2012 Olympics⁴⁶, in development of a CBRN training DVD⁴⁷ and were incorporated in a textbook.⁴⁸

Papers 5 and 6 were designed to further develop the research question, by identifying a range of different supraglottic airway devices and intubation aids for further evaluation. These papers also examined the issue of what the NHS CBRN-PPE felt like to wear. Papers 7 to 9 concentrate on airway management expanding on Papers 1 and 3 and utilise the findings of Papers 5 and 6 in their design. Data collection for Papers 7 to 9 was collected in South Africa, where the research was of interest to universities offering degree level course in paramedical care.^{49 50}

The resulting thesis thus follows a non-traditional PhD route, as the research was commenced in response to an urgent clinical need, with the resulting nine peer-reviewed Papers reflecting the growth of the research story. These results are of particular interest to UK emergency planners and clinicians as some of the identified problems are unique to the NHS PPE, whereas the generic findings are of interest to a wider audience.

Throughout this thesis the peer-reviewed studies are referred to as Papers 1 to 9^{43-45 51-56}, and as they are integral to the thesis they are not continuously cross-referenced to the reference list at the end of this thesis. In addition, the term CBRN is used as a cover-all term for accidental or intentional release of a chemical, biological, radiological or nuclear agent. The primary focus of this thesis is on a chemical incident because this represents the greatest immediate threat to life, requiring healthcare personnel to react immediately whilst wearing CBRN-PPE.^{18 28} The potential for a chemical incident to occur in the UK is an established risk¹⁸, primarily due to the UK's status as a mass producer of chemical agents for national and international use.^{18 58} Furthermore, even though biological, radiation and

Preface, continued

nuclear incidents equally present risk to life, chemical incidents occur with greater frequency.^{18 57}

Chapter 1:

Setting the scene

1.1 Introduction

The 2001 attack on the World Trade Centre focused the UK government's attention on the risk of mass casualties following the use of a CBRN agent, resulting in the UK wide provision of CBRN-PPE and decontamination equipment.^{2 30 31} This was in no way a new problem, as Clarke et al¹⁸ noted that in 2005 there were over 1,000 chemical incidents in England and Wales affecting upwards of 4 patients per incident. The correct number is likely to be higher due to under-reporting.⁵⁷ However, prior to 2007 the NHS lacked the capacity to deal with a chemical incident³⁻⁶, with casualty rescue⁷ and decontamination being regarded as the responsibilities of the fire service.^{7 30 59}

This lack of preparation for a CBRN incident was not solely limited to the UK, occurring also in America^{60 61}, Canada⁶², Australia^{63 64}, Belgium⁶⁵ and most of Europe.⁶⁶ However, France⁶⁷ and Israel⁶⁸ have both had longstanding CBRN response plans that facilitate early treatment of casualties by healthcare professionals wearing CBRN-PPE. Therefore the resulting provision of mass CBRN-PPE across the UK represented a step-wise change in patient management requiring clinicians to develop new approaches to early casualty treatment.

1.2 The need for CBRN-PPE and decontamination

Biological agents including anthrax, salmonella, ricin and botulinum toxin (Table 1) have all been used in recent history.⁶⁹⁻⁷¹ Biological agents represent a unique problem to healthcare providers as the symptoms will occur over days and are not as instantaneous as following exposure to a chemical agent, such as chlorine.⁷²⁻⁷⁴ Patients and clinicians are at risk of biological contamination via a number of routes; for example anthrax, ricin and botulinum toxin can be spread by aerosol^{71 73}, whereas, botulinum toxin and salmonella can be spread by ingestion.^{69 71 73} Biologically contaminated patients can be treated by clinicians wearing Level-D PPE (Appendix 1) supplemented by goggles and masks⁴⁸, reflecting the level of PPE worn when responding to pandemic influenza.^{75 76} Level-D PPE, supplemented with a dust-filtering mask⁷⁷, is also adequate for responding to most radiation incidents.

Table 1: Post World War II use of Chemical and Biological agents

Who	When	Agent used
Egyptian forces	1963-1967	Mustard gas and irritants used in Yemen.
America during Vietnam war	1961-1970	Various agents including tear gas and chemical defoliants.
Bulgarian assassination	1978	Ricin used to assassinate exile in the UK.
Peoples Temple 'Jamestown massacre'	1978	Mass suicide and assassination of an American Congressman with cyanide.
Russia during Afghanistan war	1979-89	Various agents reportedly used but limited published proof with in peer-reviewed publications.
Iran-Iraq war	1980-1988	Mustard, lewisite, tabun & sarin gas used by both Iraq and Iranian forces.
Rajneeshee sect	1984	Salmonella used on indiscriminate civilian targets. 751 contaminated patients with no deaths reported.
Iraq	1987-88	Mustard and sarin gas used against Kurdish villages.
Aum Shinrikyo (Tokyo)	1990-1995	Numerous attempts to disseminate botulinum toxin, anthrax spores, and cyanide. In addition use of sarin gas in Matsumoto & Tokyo and isolated attempts to use VX nerve agent.
Postal anthrax attack	2001	Targeted anthrax letters at media/political leaders 5 deaths and 17 contaminated casualties requiring treatment. Significant infrastructure damage as a number of buildings could never be properly cleaned.
Insurgents in Iraq	2002	Chlorine tanker 'gas bombs' used by insurgents as part of improvised lorry bombs.
Russian defence forces	Oct 2002	Use of an incapacitating gas by Russian special forces to end the Moscow theatre siege.
Ricin contaminated letters	Oct 2003	Package containing ricin and a note threatening to poison water supplies discovered in an American postal facility.
Syria	2013-ongoing	Sarin, chlorine and military grade tear gas used.
Adapted from Loyd ¹⁵ , Baker ¹⁷ , Clarke ¹⁸ , Wax ³⁷ , Szinicz ⁶⁹ , Schier ⁷¹ , Coleman ⁷⁸ , Lee ⁷⁹ , Nozaki ⁸⁰ , Kaplan ⁸¹ , Kadivar and Adams ⁸² – Table presents selected examples and is not inclusive of all incidents		

Decontamination procedures are not routinely required for biological contamination although following exposure to anthrax washing with soap and water is recommended.^{71 73} Whereas exposure to radiation will only require decontamination if actual contamination occurs, however, the clinical priority remains the immediate treatment of critical injuries.^{8 74 83}

An industrial accident¹⁸ represents the greatest risk of a chemical incident potentially resulting in many thousands of patients¹⁹, although in the UK chemical incidents tend to involve only small numbers of patients.¹⁸ However, the use of CBRN agents as weapons of warfare remains a part of humankind's immediate and distant history.^{17 69} Chlorine gas was the first modern day mass chemical weapon^{69 78} and continues to be used as a chemical weapon¹⁸ in the modern era (Table 1). Chlorine also represents a common cause of industrial related chemical incidents.^{18 84 85} However, the impact of chlorine and other gases (e.g. phosgene), during World War 1, was rapidly blunted by the introduction of chemical warfare training and respirators.^{17 69 78 86 87}

The introduction of mustard gas in 1917 represented a significant escalation in gas warfare, as prior to the use of mustard gas soldiers received an acceptable level of protection from respirators, with gas casualties only requiring supportive medical treatment.^{69 78 87 88} Not only does mustard gas cause significant lung injury it also attacks skin and eyes, which are not protected by respirators. Normal uniform provides no protection from skin contamination.^{17 69 87-89}

Mustard gas is also highly persistent, with a prolonged latency period introducing the need for decontamination.^{17 69 87-89} Decontamination is required both as a treatment to protect patients from further injury⁸² and as a means of protecting uncontaminated personnel from cross-contamination.^{69 87-89} Cross-contamination is a particular risk for medical personnel, as documented by Cook⁸⁹ who described how World War 1 surgeons had to wear respirators and leather gloves when performing surgery on mustard gas casualties, which complicated surgical procedures.

The need to further refine CBRN-PPE and decontamination procedures continued with the development of nerve gases by Germany in 1938.^{69 86} Since their development nerve gases have been extensively used (Table 1). This has included the use of sarin gas by a Japanese religious cult, in 1994 and again 1995³³⁻³⁶, with the 1995 release of sarin gas on the Tokyo underground resulting in thousands of casualties.³⁴⁻³⁶ The development of increasingly potent nerve agents throughout the Cold War set the tone for modern-day CBRN response.^{8 74 90} Therefore clinicians may be faced with the need to balance immediate treatment of

casualties with the associated need to perform decontamination even though the treatment of airway, breathing and circulation emergencies remains time-critical.^{8 32}

1.3 The United Kingdom's response to a CBRN incident

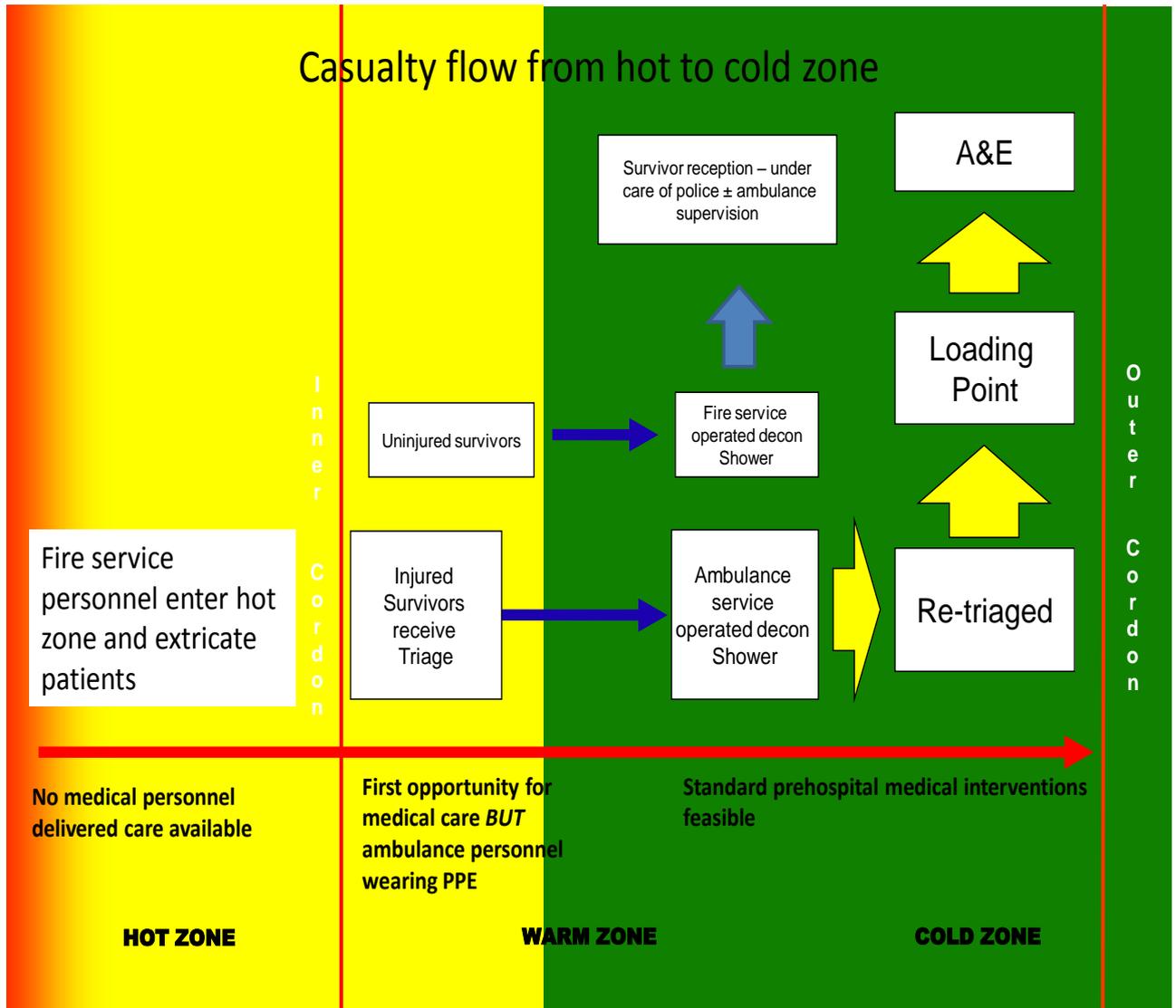
The UK response to a CBRN incident is based on an 'all hazard response'^{58 59 67} with the incident divided into hot, warm and cold zones (Illustration 1). This response is further supported by centrally held mobile treatment pods (Appendix 1) and emergency equipment vehicles containing additional equipment for use at the incident site or emergency department.⁹¹⁻⁹³

The main role of the hot, warm and cold zones is to control entry into the incident, with each zone identifying a particular degree of risk to unprotected personnel and indicating the level of CBRN-PPE required (Appendix 1).^{7 8} Entry into the hot zone is traditionally restricted to the fire service^{7 8 17 67}, but recently UK ambulance personnel have undergone training to operate in heavily contaminated areas.^{7 92 94 95} These specialist teams are limited in number and are spread across the UK making it unlikely that they will arrive during the initial phase of an incident.⁹² The same procedure is followed regardless of the number of casualties involved.^{8 18 96}

The UK's approach to a CBRN incident is consequently based around delaying treatment until after extrication from the **hot zone**, with **limited treatment**³⁰ occurring during the decontamination phase. The time needed to set-up decontamination equipment has been estimated as requiring a minimum of 1 hour⁹⁷ with decontamination requiring 12 minutes per casualty.⁸ The resulting treatment delays^{8 98 99} will potentially result in avoidable deaths.^{8 32}

The UK approach significantly differs from the practices adopted by other countries such as France⁶⁷, Israel⁶⁸ and Taiwan.¹⁰⁰ These countries operate systems which enable rapid on-site treatment in the hot zone by clinicians wearing CBRN-PPE, which is then supported by prompt evacuation. The slowness of the UK response has been criticised^{8 32} and has resulted in recommendations for the introduction of rapid on-site treatment.^{8 29 32} The introduction of CBRN-PPE across the NHS will facilitate earlier treatment of contaminated casualties; however, the impact that the NHS CBRN-PPE has on skill performance is as yet unknown. The intended purpose of this thesis is to ascertain what skills can be instigated whilst wearing the NHS issued CBRN-PPE.

Illustration 1: Traditional casualty patient flow from hot to cold zone



Adapted from Baker⁹⁴

1.4 The use of a chemical, biological, radiation and nuclear agents on civilians

As illustrated by Table 1, CBRN agents have been widely used since the end of World War 2. However, the use of sarin gas in Japan (1994 and 1995) and the use of an incapacitating gas to end the 2002 Moscow theatre siege, provide useful insight into civilian mass casualty CBRN incidents.

1.4.1 The Tokyo sarin gas and Moscow theatre siege incidents

The release of the nerve agent sarin by a Japanese religious group in Matsumoto⁴² and Tokyo³⁴⁻³⁶ is particularly pertinent to this thesis as it demonstrates the impact of CBRN agents when used against unprotected civilians. The casualty numbers in the two Japanese sarin incidents differ, and despite the use of less sarin^{18 101 102} (1.8kg versus 30kg) with a lower purity^{18 101 102} (35% versus 70%) the Tokyo incident resulted in significantly more casualties than the Matsumoto incident.³⁴⁻³⁶ This was due to the sarin being released in the enclosed confines of an underground train, demonstrating the impact of chemical agents in confined spaces. From a UK perspective, the act of releasing chlorine gas, or any similar chemical agent, into the London underground could result in many thousands of deaths.⁹⁸

Following the Tokyo sarin incident, the majority of the 5000 casualties had only minor symptoms of either sarin exposure or symptoms of mass hysteria.³⁵ However, Okumura et al³⁴ described the treatment of 640 patients who attended a single emergency department in the first hours after the release of the sarin gas. Out of a total of 640 patients, 111 patients had signs of severe to moderate poisoning.³⁴ One hundred and seven patients required atropine to treat symptoms of sarin exposure, with a further eight patients requiring diazepam to control nerve agent induced seizures. Four severely poisoned patients required intubation, with two of these patients also requiring cardiopulmonary resuscitation (CPR). One of the patients, who developed cardiac arrest, was contaminated after performing mouth-to-mouth resuscitation on a fellow casualty, thereby highlighting the risk to the unprotected rescuer.

The Tokyo sarin incident¹⁰¹ resulted in a total of 12 deaths out of over 5000 casualties compared to the 127 deaths³⁷⁻⁴⁰ (minimum) reported in the Moscow theatre siege. Information surrounding the Moscow incident is limited, but it has been postulated that earlier basic airway management and assisted ventilation would have prevented many of the deaths.^{39 40 74 103} This can be determined by viewing media photographs that show unconscious patients being transported to hospital with obstructed airways and without

medical escorts.¹⁰⁴ The lack of published, peer-reviewed accounts of the treatment received by the casualties of the Moscow incident impedes our ability to compare these two incidents. Despite this, the benefit of prompt treatment, following exposure to a CBRN agent is clear.

Notably during both incidents rescue personnel were affected by the chemical agents used. Whereas the incidences of rescuers being affected following the Moscow theatre siege are unvalidated^{17 38}, clear documentation exists for the incidences of rescuer contamination following the Tokyo sarin attack.^{17 34 105} The two main avenues for cross-contamination, during the Tokyo incident, were contaminated clothing and expired breath from the patients, a process termed 'off gassing'.¹⁰⁵ Staff contamination was further facilitated by poor ventilation in the ambulances¹⁰¹ and emergency departments.³⁴ Furthermore, doctors performing endotracheal intubation were noted to be at particular risk of developing symptoms of sarin poisoning due to exposure from the expired air of their patients.¹⁰⁵ This is an important observation, as external decontamination procedures will not remove the risk from off gassing¹⁷, thus highlighting that even after decontamination an ongoing risk exists.

The main symptoms affecting healthcare professionals were dimming of vision due to miosis, blurred vision and eye pain, as well as headaches, coughing and shortness of breath.^{41 101} It is noteworthy that although these effects were mild they impacted on the clinician's vision, which in turn affects clinical skills such as intubation, drug administration or gaining intravenous access. The use of CBRN-PPE is therefore important for staff protection and for ensuring effective patient treatment.

Similar incidents of medical personnel contamination have also recently been reported in Syria following the reported use of sarin.¹⁷ Whilst the use of chemical weapons in Syria remains under investigation, these additional reports of cross-contamination further support the incidents described above.

1.5 The impact of mass self-evacuation following a chemical incident

The purpose of CBRN weapons is to create confusion and panic.^{69 86} The mere mention of a CBRN incident evokes images of the mass gas casualties of World War One⁷⁸, the Tokyo sarin attack^{35 36} or the modern day Syrian conflict.¹⁵⁻¹⁷ As is well known, a CBRN incident has the potential to generate large numbers of casualties with physical and psychological injuries that can overwhelm medical facilities.^{17 78 86 88 106} One characteristic feature of a CBRN incident is the potential for patients to leave the incident and make their own way to hospital,

a process referred to as self-evacuation.⁹⁷ Self-evacuation, from incident site to the closest hospital, is a commonly occurring feature of any mass casualty incident.^{99 107-110}

It is this potential for high casualty numbers and associated panic that makes chemical weapons so attractive to terrorists but challenging for emergency services.¹⁰⁶ Panic following a CBRN incident can generate more casualties than the actual CBRN agent used.^{23 24 111} This panic is further fuelled by a lack of public awareness⁹⁷ about what to do during a CBRN incident. The combination of fear of the unknown, coupled with knowledge of historical precedent can result in mass casualties arriving at an unprepared hospital with a majority of these casualties presenting with symptoms of hysteria.^{23 112} Anxiety and fear of CBRN agents equally affects healthcare professionals, who highlight risk of contamination as a reason for not responding to a CBRN incident.^{27 113} Staff anxiety can be mitigated by providing clinicians with CBRN-PPE^{27 113-116} supported by education¹¹⁷, thus counteracting fear of the unknown with reality.

The Tokyo incident clearly demonstrates the sort of mass panic situations described in the preceding paragraph as only 7%¹⁰¹ of the 5000 patients who sought medical assistance^{35 36} arrived at hospital by ambulance.^{35 36} This unannounced and uncontrolled arrival of large numbers of patients resulted in the Tokyo hospitals becoming overwhelmed, with no patients undergoing any on-site decontamination.³⁴⁻³⁶ The lack of on-site decontamination was due to multiple factors including; initially confusing reports that the incident was due to an explosion and subsequent carbon monoxide exposure (which does not require decontamination), large numbers of patients self-evacuating to hospital, and the lack of a chemical incident plan.^{35 36}

So what does this mean for UK preparations for a CBRN incident, which is currently based on the premise that members of the public will wait at the incident site for decontamination, treatment and triage before being transported to hospital (Illustration 1)?^{8 118} Hildebrand and Bleetman⁹⁷ challenge this orderly scenario stating that a high percentage of potentially contaminated casualties will self-evacuate to hospital. This hypothesis was confirmed by Higginson⁹⁹ who describes how 23 patients affected by a chemical spill in a UK nightclub self-presented to the nearest emergency department. Higginson⁹⁹ emphasises that it took two hours to decontaminate the casualties using the NHS issued decontamination equipment; thus reaffirming my concerns about delaying treatment until after decontamination has been completed.

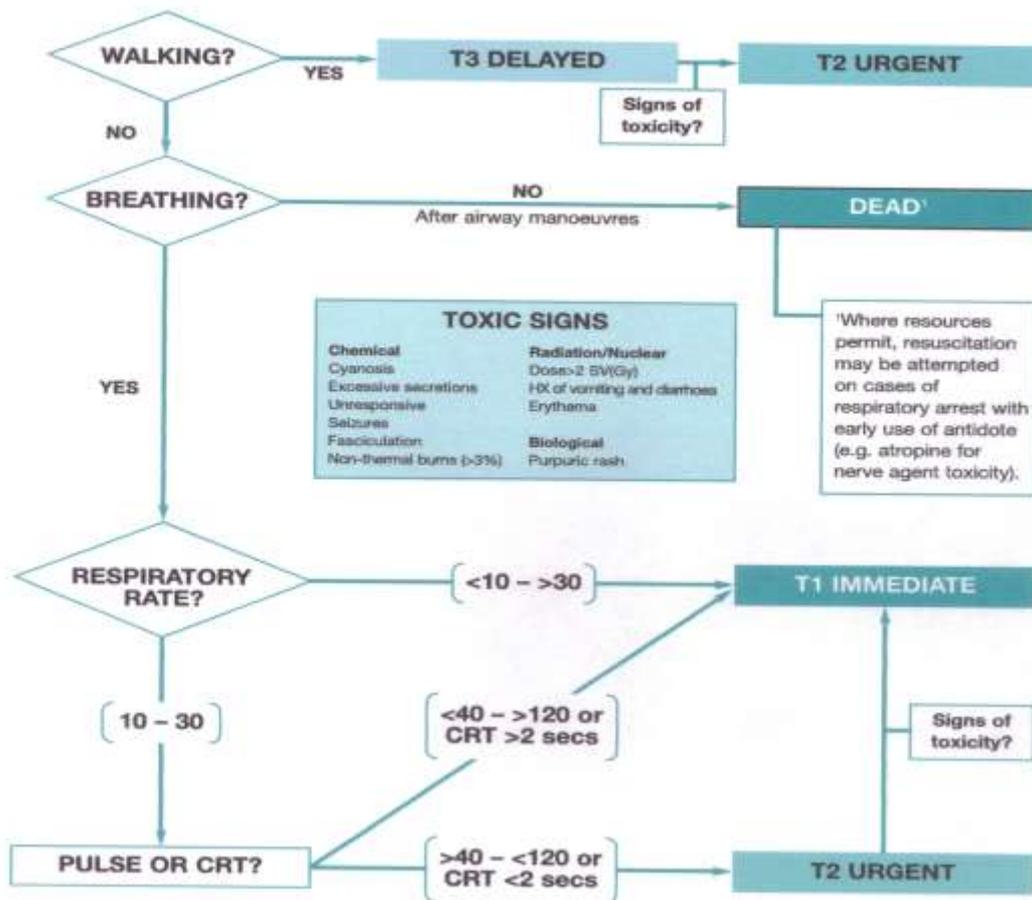
Although the incident described by Higginson⁹⁹ placed only a limited burden on the receiving hospital, the same is not true of the Tokyo sarin incident, where in the same two hour period a single hospital received over 500 casualties including 3 patients in cardiac arrest.³⁴ This process of self-evacuation makes a fallacy of the concept of on-scene triage, decontamination and orderly patient transfer to hospital, and thereby highlights the need for emergency departments to be able to respond to either a single or multiple contaminated patient with minimal warning.^{2 99}

1.6 Triage and withholding resuscitation following a mass casualty CBRN incident

Triage is a key element of mass casualty management; as it directs treatment resources according to treatment priorities.^{72 83 119 120} Traditionally, triage is done prior to undertaking any treatment¹²¹ and yet this practice was criticised by the public following the 2005 London bombing, resulting in changes to ambulance service triage protocols.^{92 122} The inclusion of treatment has recently been included in British military version of triage sieve, which now incorporates control of major haemorrhage, positioning of patients to optimise airway management and the instigation of CPR.¹²³ The changes to the military version of triage sieve represents a significant change in military doctrine¹²⁴ and was based on advancements in military medicine.¹²³

The recommended UK CBRN triage tool is the CBRN triage sieve⁸³ (Illustration 2), a consensus-based adaption of triage sieve.^{72 121} CBRN triage sieve places patients into four categories T1, T2, T3 and the dead. The allocated triage category is based on an assessment of the patient's ability to walk, his/her respiratory and heart rate, and is further supported by the presences of toxic signs and symptoms.^{72 74 83} If the patient is not breathing, they are triaged as dead. However, the accuracy of assessing for signs of breathing is hampered by the wearing of CBRN-PPE, making this aspect of CBRN triage sieve difficult to perform.¹²⁵⁻¹²⁷ This is particularly true of the NHS CBRN-PPE, as the fully encapsulating design of the hood/visor (Appendix 1) significantly impairs the wearer's ability to assess for signs of shallow breathing.¹²⁸

Illustration 2: Chemical, biological, radiation and nuclear triage sieve



Four triage categories

- T1 (immediate treatment)
- T2 (urgent treatment in 2 hours)
- T3 (delayed treatment)
- Dead
- Expectant/T4 is a T1 casualty who has a high probability of dying and therefore treatment is delayed until all other T1 are treated, **BUT** T4 casualties receive treatment before T2 casualties.

Adapted from Nutbeam and Boylan⁸³

The CBRN triage sieve algorithm allows for resuscitation of lifeless casualties ‘... *where resources permit [sic]*’ thus acknowledging the potential reversibility of respiratory arrest following exposure to a CBRN agent³⁴, but simultaneously identifies a lack of resources as a reason for withholding resuscitation. Resuscitation measures are also recommended following other mass casualty incidents, such as incidents following a lightning strike where patients in cardiac arrest are triaged as T1 and not as dead.¹²⁹⁻¹³¹

During an over-whelming mass casualty incident, where the number of casualties outstrips medical resources, a fifth triage category, ‘expectant’, can be instigated.^{74 121} The expectant category is applied to a T1 casualty who has a high probability of dying or who will require significant time and resources to treat.^{17 101 121 132 133} Patients placed in the expectant category may still survive their injuries, and therefore these patients are treated **after** all the T1 casualties have been tended too but **before** T2 casualties. The importance of repeat triage can be demonstrated by Lieutenant Lawrence MC, a Falklands conflict casualty, who was triaged into the expectant category and who survives to this day.¹³⁴

Non-CBRN triage sieve has been validated for use following traumatic injuries¹³⁵⁻¹³⁷, with a sensitivity of 46% and a specificity of 88% for detecting major trauma. Although following the 2005 London bombing Challen and Walter¹³⁶ noted that triage sieve actually identified 75% of T1 casualties and all of the T3 patients treated at a single hospital. The risk of over- and under-triage is an accepted aspect of major incident triage, and therefore triage is continually reviewed and represents a dynamic process.^{121 130 138} The effectiveness of CBRN triage sieve, however, remains unvalidated.^{132 139} Despite its limitations triage sieve, and by extrapolation CBRN triage sieve, offers a reproducible system that can be used by healthcare professionals^{119 136 140} and non-medical emergency personnel¹⁴¹ when faced with large numbers of patients.

The decision to withhold CPR following a major incident is based on the principle of offering the ‘most for the most’^{121 132 135}, this principle encapsulates the established maxim that it is futile to provide CPR to patients suffering cardiac arrest following a major traumatic injury.¹⁴²⁻¹⁴⁴ This maxim has recently been challenged^{123 145 146} due to the successful resuscitation of a number of patients following the London bombing in 2005¹⁴⁶ and advances in military medicine.^{123 135} Nevertheless, the use of apnoea as a criterion to indicate the presence of unsurvivable trauma is well established^{72 83 119}, and was defended by the coroner following the 2005 London bombing.¹²² Notably, though, had CBRN triage sieve been used following the Tokyo incident, the death toll would have been higher^{34 41} as at least 5 patients were

apnoeic on arrival at hospital, with 3 of these patients being successfully resuscitated. Underpinning these observations is the generally held assumption that respiratory and/or cardiac arrest following exposure to a CBRN incident is directly or the indirectly due to the effects of the chemical involved^{147 148}, although combined traumatic and chemical injuries remain a possibility.^{74 149}

The issuing of CBRN-PPE across the NHS was aimed at improving the care of mass casualties following a CBRN incident, and yet the typical UK chemical incident involves fewer than four patients.¹⁸ Whereas the size of a chemical incident does not eliminate the need to consider decontamination, or the wearing of CBRN-PPE, it does negate the need to perform triage. Consequently, there are numerous case reports¹⁵⁰⁻¹⁶⁰ which have highlighted the importance of prompt treatment of critically ill patients following exposure to various chemical agents (Table 2). A particularly interesting group of patients are those who have survived near-fatal organophosphate toxicity.^{150 152 154-156 159} Since organophosphate-poisoning produces similar symptoms as nerve gas exposure¹⁵⁹ and the survival amongst these near-fatal episodes of organophosphate-poisoning provides an insight into the benefits of early treatment.

Organophosphate-poisoning is a common mode of suicide in the developing world^{154 161}, but prompt treatment of airway, breathing, and circulation, as well as the administration of atropine, can be life-saving.^{150 152-156 159} In contrast delayed treatment can result in mortality rates as high as 25% in patients initially found with signs of life on first medical contact.¹⁵⁵ For example, in a case series by Sungur and Güven¹⁵⁴, three patients were deemed to have died directly due to delays in intubation. Although atropine is integral to the effective treatment of organophosphate and/or nerve gas poisoning it remains secondary to ensuring a patent airway, effective ventilation and the treatment of associated hypoxia.

Case reports by Geller et al¹⁵⁰ and Stacey et al¹⁵⁶ further demonstrate the importance of early treatment by describing how their patients survived cardiac arrests following organophosphate-poisoning. However, in both cases it occurred at the expense of attending medical personnel developing symptoms of organophosphate exposure.^{150 156} Geller et al¹⁵⁰ reported that all attending clinical staff required atropine to treat the symptoms of organophosphate-poisoning with one member of staff requiring ventilation for respiratory failure. Rescuer contamination has equally occurred following the treatment of casualties exposed to cyanide¹⁵¹ and hydrogen sulfide^{162 163} poisoning (Table 2).

Table 2: Patient and rescuer mortality and morbidity following chemical incident

Agent	Country	Total staff contaminated	Staff symptoms	Patient outcome	Comments
Organophosphate pesticide. ¹⁵⁶	UK	7	Minor: respiratory, hyper-salivation and chest tightness.	Patient was successfully resuscitated from cardiac arrest after attempted suicide.	Attempted to use NHS issued CBRN-PPE to treat patient but had difficulty with skill performance.
Cyanide ¹⁵¹	Hong Kong	5	Mild symptoms of dizziness, headaches, irritation of eyes/throat and chest pain. One fireman required hospital admission.	Two patients. Patient1 critically ill, unconscious admitted to intensive care, but discharged home. Patient 2 symptomatic of cyanide poisoning recovering fully with medical management.	Four of the firemen were wearing standard fire fighting PPE that included breathing apparatus. Authors highlighted the need to wear chemical specific gloves as absorption occurred via skin contact. The fifth fireman inhaled fumes whilst standing in a corridor and did not enter the contaminated building.
Organophosphate pesticide ¹⁵⁰	America	4	Major symptoms. All three staff members required atropine and one patient required over-night ventilation.	Patient was successfully resuscitated from cardiac arrest after attempted suicide.	No PPE worn by attending emergency department personnel. All staff members and patient recovered.
Incapacitating gas ³⁷	Russia	2	military personnel affected by gas. ^{17 38}	150-200 deaths (lack of reliable validated sources).	Only limited co-ordinated medical care prior to arrival at hospital.
Sarin gas ⁴²	Japan	Eight rescue personnel developed mild symptoms and an unknown number of hospital staff.	Mainly minor symptoms. One rescuer required hospital admission.	Two hundred and fifty three patients treated, 53 patients admitted over-night to hospital including a number of critically ill patients. Seven deaths.	No PPE worn by attending ambulance staff who initially thought the incident was due to mass food poisoning. The last death occurred in 2008 in a patient who had been in a coma since suffering a cardiac arrest.
Sarin gas ³⁴	Japan	1 (good)	Cardiac arrest.	Successfully resuscitated.	Bystander who performed mouth-to-mouth on

		Samaritan)			another victim of the Tokyo subway sarin gas attack.
Sarin gas ³⁶	Japan	One hundred and thirty-five ambulance crews.	Minor symptoms requiring treatment at hospital.	Ambulance crews transported 688 patients to hospital only 12% of patients required overnight admission.	No PPE worn and majority of ambulance personnel become symptomatic during drive to hospital due to off gassing in enclosed space. The number of ambulance service casualties equated to 10% of responding personnel.
Sarin gas ^{35 41}	Japan	110 staff at St Luke's hospital (23%).	Minor symptoms although one nurse was admitted.	Five Hundred and twenty-eight mild, 107 moderate and 5 severe casualties including 3 patients in cardiac arrest and 2 patients fitting with respiratory arrest. Two patients died.	Surgical gloves and theatre masks worn. Off-gassing from patients' clothes was the main source of staff contamination, equating to nearly 1 in 4 of those involved in patient care being affected. Data based on a post-incident staff questionnaire (return rate = 44%).
Sarin gas ¹⁰⁵	Japan	11 out of 15 doctors.	Dimming of vision, chest pain, hypersalivation, difficulty in breathing and chest pain.	Two cardiac arrests and 83 mild exposure walking casualties.	Five doctors required atropine and 1 received atropine and Pralidoxime. Paper did not report contamination of non-doctors. Worst affected were doctors performing CPR and handling clothes. No further symptoms occurred once windows were opened and contaminated clothing removed.
Hydrogen sulfide ¹⁶²	Japan	Suicide of a 14 year old girl with child's mother requiring hospital admission due to secondary contamination. Ninety local residents had to be evacuated due to the risk of secondary exposure.			
Hydrogen sulfide ¹⁶³	America	Between 2008-2010 thirty episodes of suicide with the use of hydrogen sulfide with six episodes of emergency service personnel becoming contaminated. Three required assessment in hospital.			
Accidental release ¹⁶⁴	America	Between 1993-2000 a total of 43,133 incidents of accidental hazardous material release were reported causing 16,594 casualties, including 730 rescue personnel. Firemen were the main casualties.			
Accidental release ¹⁶⁵	America	Between 1995-2001, across 13 health districts, a total of 44,045 incidents of accidental hazardous material release occurred resulting in 13,173 casualties including 1298 rescue personnel. Thirty two of the rescue personnel were hospital staff.			

The Tokyo sarin incident³⁴ and numerous case reports¹⁵⁰⁻¹⁶⁰ highlight that survival from poisoning appears to be strongly dependent on prompt treatment¹²⁹, including CPR^{34 150 156}, intubation and the early administration of selected antidotes. This does not mean that all apnoeic patients following a CBRN incident should be resuscitated, although, it does highlight that patients in respiratory arrest, and in certain circumstances cardiac arrest, can survive with prompt treatment. Considering the complexities of triage following a CBRN incident especially, as accurately assessing for signs of breathing is hampered by the wearing CBRN-PPE¹²⁵⁻¹²⁷, the role of prompt treatment appears valid.

1.7 Summary

The Tokyo sarin incident^{35 36} and the incident described by Higginson⁹⁹ highlight that emergency department personnel need to be able to care for patients following a chemical incident, even when these patients present without prior warning. Part of this response may involve the instigation decontamination. However, overemphasis on decontamination can distract from the need to provide prompt treatment^{8 99}, thereby jeopardising early opportunities to save life.^{8 32 98} It remains important to remember that decontamination is implemented to prevent ongoing harm to the patient whilst minimising the risk of cross-contamination to responding medical personnel.

As detailed in the previous section, much of the emphasis surrounding a CBRN incident is targeted on mass casualties, and yet the incident may involve numerous casualties with minor symptoms of poisoning and a small number of critically ill patients. This was clearly demonstrated following the release of sarin gas in Tokyo where the majority of patients had minor symptoms of nerve gas toxicity and only a small number of patients were critically ill. However, the identification and treatment of these critically ill patients saved many patients that CBRN triage sieve would have triaged as dead? Thankfully, mass chemical incidents are rare but as highlighted in this chapter the risk to staff from a single contaminated casualty exists, and yet these patients can even survive cardiac arrest with prompt treatment.

In consideration of the issues raised above the key elements for responding to a CBRN incident are, therefore, training^{69 78 86}, the provision of appropriate CBRN-PPE^{27 113-116} and prompt medical treatment.^{8 32} However, while prompt treatment of the chemically contaminated patient is potentially life-saving, it would require UK clinicians to perform clinical skills whilst wearing NHS CBRN-PPE. Therefore ascertaining what skills can feasibly

be performed whilst wearing the NHS CBRN-PPE is an important area of research enquiry. The research presented in this thesis, was designed to address this issue and represents the most detailed body of work to date that examines skill performance whilst wearing the NHS CBRN-PPE.

Chapter 2:

Literature review

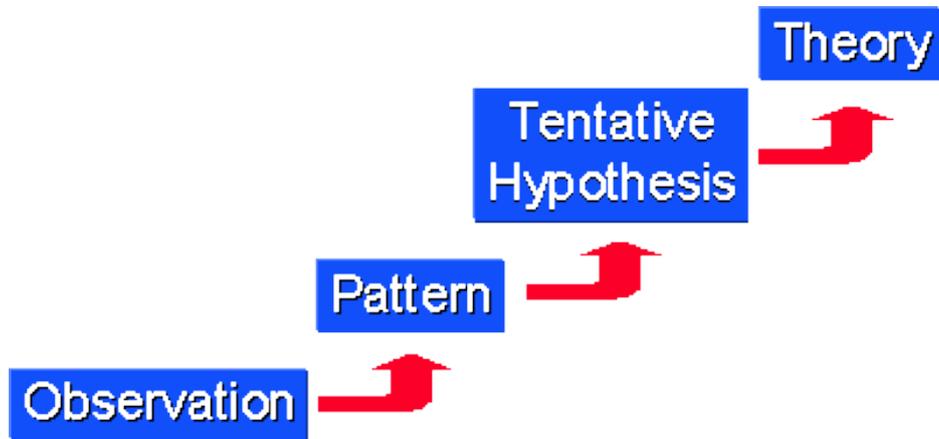
2.1 Introduction

Following the arrival of standardised NHS CBRN equipment² at my employing hospital, I was directed to instigate CBRN training. My immediate impression was that the delays in patient treatment, secondary to decontamination, were unacceptable and that the centrally held mobile mass casualty equipment pods (Appendix 1) were inappropriately stocked. More specifically, the pods retained equipment for intravenous cannulation and intubation skills that require the retention of fine motor skills and unimpaired vision to successfully complete, whilst also lacking any equipment for difficult intubation or devices for confirming correct endotracheal tube (ETT) placement.⁹¹ This situation existed despite published evidence indicating that CBRN-PPE impedes both vision^{166 167} and dexterity¹⁶⁸⁻¹⁷⁰, making skill performance more difficult. My concerns were further compounded by a lack of available guidance on how to treat casualties whilst wearing CBRN-PPE. These observations resulted in the research presented in this thesis, which is largely based on a series of prior publications.

2.2 Generating the research question

The initial approach chosen to identify a solution to this clinical dilemma was inductive logic (Illustration 3), where the data drives the hypothesis, reflecting a 'bottom up approach' to clinical problem solving.^{171 172} Hypothesis generation was further based on my reflective practice^{173 174}, as during each decontamination training session I would observe and discuss with colleagues the potential impact of CBRN-PPE on skill performance. These discussions were subsequently followed by me personally donning NHS CBRN-PPE and attempting to perform a range of clinical and non-clinical skills. Schön¹⁷⁵ describes this process as 'improvisation, inventing and testing' and by using Rolfe's reflective model¹⁷⁴ (Illustration 4), a formal research question was thereby generated: *'What airway and vascular access skills can be performed whilst wearing the NHS issued chemical, biological, radiation, and nuclear personal protective equipment?'*

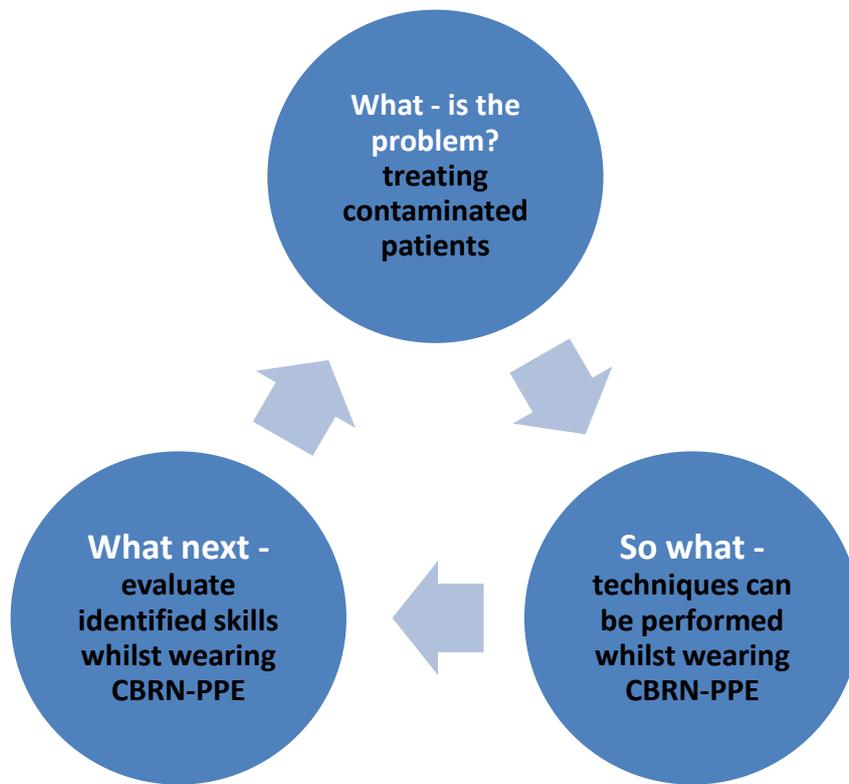
Illustration 3: Inductive logic a 'bottom up approach'



Adapted from Trochim and Donnelly¹⁰⁶

Rolfe's reflective model was chosen as it allowed the clinical problem to be deconstructed into three distinct questions^{173 174}, an approach ideally suited to problem-solving. The generation of a research hypothesis utilising reflective practice and inductive logic is an example of action research¹⁷⁶, which is about solving an immediate problem and is ideally suited for guiding clinicians attempting to improve clinical practice. The utilisation of action research and reflective practice is at the heart of the initial four Papers^{43-45 51} contained in this thesis.

Illustration 4: Applying Rolfe Reflective Model to the research question



Adapted from Rolfe¹⁷⁴

2.3 Literature review

As this thesis is being submitted for consideration of the award of a PhD via Prior Publication a summary of the literature is presented in Chapter 2. Whereas the methods employed to undertake the literature search, the critical appraisal along with excluded studies is presented in Appendix 2.

2.3.1 Search strategy, identified papers, inclusion and exclusion criteria

The purpose of the literature review was to systematically identify gaps in our knowledge regarding skill performance whilst wearing CBRN-PPE, thus placing this thesis into a wider context. Following the application of an inclusion criteria and a critical appraisal tool¹⁷⁷ appropriate to the study design, a total of 35 papers were selected for review.

Eight of these studies were excluded as participants did not wear a complete set of CBRN-PPE^{90 178-184}, and a further six studies were excluded through critical appraisal. Attempts to limit the literature search solely to skills performed whilst either wearing NHS CBRN-PPE or gloves with the same gauge as the NHS CBRN-PPE were abandoned as it would have excluded all identified studies. This was because only a single case study¹⁵⁶ was identified that used the NHS CBRN-PPE, whereas, the majority of remaining studies failed to indicate the gauge of the gloves used.

A total of 14 Papers were included in the final literature review with an overview of these papers presented in Appendix 2. With the exception of the cuffed oropharyngeal airway (COPA)¹⁸⁵, all the identified clinical interventions (or variations of devices) are used in the NHS.

2.4 What is the impact of CBRN-PPE on skill performance?

A range of medical interventions were identified, all of which require various levels of dexterity and the retention of unobscured vision to perform. All authors, with the exception of Suyama et al¹⁸⁶, commented on the negative impact that CBRN gloves had on dexterity and sensation. For example, King and Frelin¹⁷⁰ recruited nine medically trained soldiers demonstrating the gauge of the gloves worn significantly impaired skill performance. More specifically, they reported that butyl rubber gloves prolonged the time to complete medical skills by 53% as compared to wearing lower-gauge tactile preserving gloves, which maintained fine motor skills and sensation. Unfortunately, the tactile preserving gloves were easily damaged, which caused soldiers to lose confidence in the protective properties of the lower-gauge gloves. Similarly, Ben-Abraham et al¹⁶⁷ also noted that butyl rubber gloves impeded finger-thumb dexterity.

Further confirmation of these findings comes from both Krueger²¹ and Bensel.¹⁸⁷ Krueger²¹ reported that butyl rubber gloves reduced two-handed dexterity by between 35 to 40%, and single-handed dexterity by 30% resulting in a significant reduction in the performance of a range of non-medical military skills. Similarly, Bensel¹⁸⁷, reported the negative impact of high-gauge gloves on dexterity and sensation in comparison to lower-gauge gloves. As a consequence of these studies butyl rubber gloves have been replaced by narrower gauge tactile preserving gloves in a number of subsequent CBRN-PPE based research studies.⁹⁰

178 179

The impact of loss of dexterity associated with a higher-gauge of glove is an important factor when wearing NHS CBRN-PPE. The NHS CBRN-PPE incorporates gloves with a 0.9mm gauge at the fingertips that are integral to the PPE (Appendix 1), thus preventing clinicians from electing to wear narrower gauge gloves.^{2,22} Furthermore, as the gloves are integral to the PPE, a 'one size fits all' policy had to be adopted which means gloves are quite often poorly fitting further reducing finger-thumb dexterity and sensation.¹⁸⁸

The impact of respirators on skill performance is multi-factorial, with studies demonstrating that respirator visors can mist-up¹⁶⁶, affect hand-eye co-ordination¹⁶⁷, and impair the ability to communicate.¹⁸⁹ These issues are well known to the military^{20 82 190} and are further supported by a number of studies that did not meet the criteria for the literature review.^{179 191-193}

Although two studies identified during this literature review used the NHS CBRN-PPE none of the studies looked at clinical skill performance whilst wearing the NHS CBRN-PPE. For example, while Al-Damouk and Bleetman² observed NHS clinicians performing decontamination procedures noting similar issues with poor communication, restricted movement and visual difficulties they did not observe the performance of any clinical skills. Therefore this study was excluded from the literature review. A second example where NHS CBRN-PPE has been reported in the literature occurred in a case report by Stacey et al¹⁵⁶ which demonstrated that resuscitation-based skills were complicated by wearing CBRN-PPE. This case study fails to identify what skills were attempted with the patient having been intubated, prior to arrival in hospital, by paramedics wearing standard ambulance uniform. Although Stacey et al¹⁵⁶, failed to state the make and type of CBRN-PPE used during the treatment of their patient, the description they give appears to resemble the NHS CBRN-PPE and for this reason this case study was incorporated into the literature review. Attempts to contact the lead author for this study were unsuccessful. Overall, the absence of data regarding the impact of NHS CBRN-PPE on the performance of a range of clinical skills demonstrates that this remains an important unanswered area of research.

2.5 Can clinicians learn to adapt skills whilst wearing CBRN-PPE?

King and Frelin¹⁷⁰ demonstrated a generic learning effect occurring across a range of basic medical skills, when these skills were performed over a six day period by medically trained soldiers wearing CBRN-PPE butyl rubber gloves, low-gauge gloves that preserve fine motor skills or no gloves. Improvement occurred independent of the gauge of gloves worn, although CBRN-PPE gloves continued to have a negative impact on skill performance.

Flaishon et al¹⁶⁹ similarly noted a learning effect, reporting that novices became faster at laryngeal mask airway (LMA) insertion and faster at securing the LMA in situ with repetition. However, the noted learning effect was specific to the individual, occurring between the third and seventh repetition with no obvious plateau in learning detected.

Although the performance of novice clinicians improved with practice, Flaishon et al^{168 169} noted that experienced clinicians were still able to complete all skills more rapidly, thus demonstrating that prior experience of performing a skill is also an important factor when determining the effect of wearing CBRN-PPE. In non-CBRN studies the rate at which clinicians learn to perform different skills (i.e. the learning effect) varies¹⁹⁴⁻¹⁹⁸, with different professional groups appearing to require different levels of exposure to achieve competence in performing interventions such as intubation.¹⁹⁹⁻²⁰³ These findings raise a number of questions such as *'is there a point at which no further improvement is made?'* and *'is there an inter-professional difference when performing similar skills whilst wearing CBRN-PPE?'*

2.6 Vascular access and drug administration

The treatment of CBRN casualties may include the administration of a limited number of antidotes.^{48 74} To date seven studies^{167 186 189 204-206} have evaluated the impact of CBRN-PPE on obtaining intravascular access or techniques for drug administration.

2.6.1 Drug administration via the intramuscular, intravenous or intraosseous route whilst wearing CBRN-PPE

MacDonald et al²⁰⁴ compared subcutaneous injection with intravenous cannulation (Table 3) and reported that subcutaneous drug administration was on average 133 seconds faster to complete than intravenous cannulation. More specifically, MacDonald et al²⁰⁴ estimated that CBRN-PPE slowed skill performance by 30%. These findings differed from those reported by King and Frelin¹⁷⁰ who estimated it took 53% longer to complete a skill whilst wearing CBRN-PPE. However, this is reflective of varying levels of proficiency between the clinicians recruited into the different studies as well as the different studies assessing different skills.

Accepting that subcutaneous drugs are absorbed slower than intramuscular drugs, the process of administering drugs via either route is the same. Therefore for the purpose of this thesis the timings reported by MacDonald et al²⁰⁴, for subcutaneous drug administration, have been used as a surrogate for intramuscular injection.

Rebmann et al²⁰⁵ evaluated three different techniques for administering intramuscular drugs (Table 3), noting that a dual drug CBRN auto-injector was the fastest device. The CBRN auto-injector is a spring-loaded syringe that delivers a fixed dose of antidote (typically for nerve gas exposure).⁷⁴ The authors postulated that the dual drug auto-injector would allow the treatment of four times more casualties per hour compared with the needle and syringe technique. This prediction is based on simply doubling the time required to administer a single drug via a needle/syringe, and is both simplistic and unrealistic as it fails to consider numerous confounding variables such as fatigue or the development of a learning effect.

Participants in the study by Rebmann et al²⁰⁵ all had varying levels of experience using the auto-injectors but were all experienced at using the needle/syringe technique, thus introducing a bias in favour of the needle/syringe group. Despite recruiting 56 participants a maximum of 10 participants were allocated to each arm of the study with participants only performing a skill once while either wearing a normal uniform or CBRN-PPE. The use of a RCT crossover design would have improved this study by increasing the number of participants per study arm (with 56 participants per arm instead of 9-10) and would have controlled for the varying experiences of the participants by allowing each participant to act as his/her own control. Despite a number of design flaws, the Rebmann et al²⁰⁵ study reaffirms that CBRN auto-injectors are easy to use and appears to offer clear benefits over the needle/syringe technique.

Direct comparison between the studies undertaken by MacDonald et al²⁰⁴, referenced at the beginning of this section, and Rebmann et al²⁰⁵ is not meaningful because of variation in the research design, a commonly encountered problem when reviewing CBRN-PPE research. These differences can be highlighted by examining the needle and syringe data. McDonald et al²⁰⁴ reported skill completion took 87 seconds (95% CI 78-96 seconds) compared to Rebmann et al²⁰⁵ who reported a shorter completion time of 31.2 seconds (SD 7.6 seconds). The difference is due to MacDonald et al²⁰⁴ incorporating time to clean the skin prior to drug administration. The times reported by Rebmann et al²⁰⁵ are therefore more reflective of a clinical response to an emergency, but the difference in skill completion times due to performing an ancillary skill (skin cleaning) demonstrates the impact that varying research designs can have on results.

Table 3: Intramuscular administered drug whilst wearing CBRN-PPE

Author	Mean time (seconds)	95% confidence interval (seconds)	Comments
MacDonald et al ²⁰⁴	No PPE IV access 158 PPE IV access 220	140-176 193-247	Skin preparation time included in the drug administration technique.
	No PPE SQ 60 PPE SQ 87 p-value <0.01	54-66 78-96 p-value <0.01	SQ drug administration was 2.5 times faster than IV access. For the purpose of this thesis the times reported for completion (subcutaneous drug administration) have been used as a surrogate for intramuscular drug administration.
Author	Mean time (seconds)	Standard deviation	Comments
Rebmann et al ²⁰⁵	Single injector 16.9 (two drugs in 1)	8.7 (range 5-41)	No skin preparation time included in the drug administration technique.
	Dual-injector 27.1 (two separate cartridges for drug administration)	6.9 (range 13-43)	Only times whilst wearing CBRN-PPE were reported.
	Needle/syringe 31.2 All <i>p-values</i> <0.05	7.6 (range 18-51)	Only a single drug administered in the needle & syringe arm of the study.
All skill performed with participants wearing American Military CBRN-PPE and in both studies respirator had a bi-focal visor. SQ = subcutaneous, IV = Intravenous, PPE = Personal Protective Equipment.			

Five studies (Table 4) have investigated the impact of CBRN-PPE on obtaining intraosseous or intravenous access. Completion times vary across these studies due to variations in study design, which includes the inclusion or exclusion of ancillary skills (e.g. skin cleaning). However, the different types of intraosseous device are also possible confounding variables.

Ben-Abraham et al¹⁶⁷ observed the impact of CBRN-PPE on intraosseous placement by recruiting twenty doctors into an RCT, and instructing them to gain intraosseous access, using the bone injection gun (BIG), whilst wearing CBRN-PPE or military uniform. The authors noted that CBRN-PPE slowed intraosseous insertion by 10 seconds (22 seconds vs. 32 seconds; *p-value* <0.05). Failure was defined as incorrect placement or the skill taking longer than 45-seconds to complete. Failure rate (on first attempt) occurred once in the non-CBRN-PPE group and twice in the CBRN-PPE group, however, the reason for skill failure was not stated in the results. All of the insertions were successful by the second attempt and ancillary skills were excluded.

Within this study, the CBRN-PPE was noted to affect skill completion due to the loss of dexterity associated with wearing butyl rubber gloves and loss of hand-eye coordination secondary to visual disturbances associated with the respirator's visor. Ben-Abraham et al¹⁶⁷ estimated that wearing CBRN-PPE increased the time to secure intraosseous by 50% despite this, the resulting 10 second difference is not clinically significant.

Utilising a convenience sample of participants¹⁷² attending CBRN training, Vardi et al²⁰⁶ calculated the effectiveness of drugs administered via the intraosseous route, using the BIG, compared with the intramuscular route during simulated CBRN emergencies (Table 4). All participants wore CBRN-PPE and there was no non-CBRN PPE control. The intended purpose of the study was to monitor time to complete either skill, and to compare the speed of predicted onset of therapeutic benefit of drugs administered via the two different routes.

Table 4: Intravascular access whilst wearing CBRN-PPE

Author	Intraosseous (mean presented in seconds unless stated otherwise)	IV (mean presented in seconds)	Ancillary skills	Comments
Ben-Abraham et al ¹⁶⁷	No PPE 22 +/- 2 (SD) PPE 32 +/- 3 (SD) <i>p-value</i> < 0.05 1 st time success = 80%	Not included	No	IO device = BIG. Twenty doctors who had NO previous experience of performing intraosseous access. The report of 20% 1 st time failure rate is higher than similar studies using the EZ-IO intraosseous device. The authors noted that loss of finger/thumb dexterity and impaired vision impacted on the use of the BIG.
Suyama et al ¹⁸⁶	Needle to skin time No PPE 12.8 (95% CI 11.3-13.13.3) Range 6.6-19.10 PPE 14.03 (95% CI 12.5-15.5) Range 9.2-22.8 Skill completion PPE 52.76	Needle to skin time No PPE 36.28 (95% CI 30.3-42.3) Range 24.3-88.1 PPE 45.65 (95% CI 40.1-52.5) Range 27.1-82.30 Skill completion PPE 104.64	Yes	IO device used = EZ-IO. Ancillary skill times were reported separately with their own associated 95% CI reported and was not included in the time required to complete vascular access. Needle to skin time equates to picking-up and preparing the device. Vascular access time equates to needle to skin time PLUS time to place the IO/IV device into the manikin.
MacDonald et al ²⁰⁴	Not included	No PPE 158 (95% CI 140-176)* PPE 220 (95% CI 193-247)* * <i>p</i> < 0.01	Yes	CBRN-PPE appears to add approximately 60 seconds to intravenous cannulation.
Lamhaut et al ²⁰⁷	No PPE 50 (SD +/- 9) 1 st success rate = 100% PPE 65 (SD +/- 17) 1 st success rate = 100%	No PPE 70 (SD +/- 30) PPE 104 (SD +/- 30)	Yes	IO device used = EZ-IO. Author states 'no complications were noted', implying no failed insertions. This finding was confirmed following an email from the lead author. The times reported by Lamhaut et al for skill completion (PPE 104 (SD +/- 30) times directly reflect the total skill completion times reported by Suyama et al (PPE 104.64).

				Time-saved by using IO instead of IV when wearing no CBRN-PPE 20 (+/-24 p <0.001). Time-saved by using IO instead of IV wearing CBRN-PPE 39 (+/-20 p <0.001).
Berkenstadt et al ¹⁸⁹	Times not reported	Not included	Yes	IO device used = BIG. No times reported – authors state gloves were the main limiting factor.
Vardi et al ²⁰⁶	Mean 207 (SD 106) seconds – range 1-9 minutes 1 st time success rate 89% <i>p-value</i> = <0.001 64 recruits – Unbalanced as quasi randomisation used based on days of week = 3 for IO group 2 days for IM group.	Mean 590 (SD 54) seconds. Range not stated but all but 1 simulation took longer than 10 minutes to complete. <i>p-value</i> = <0.001		IO device used = BIG. IO group had an estimated survival of 74% compared to 3.3% in the intramuscular group. Survival benefit was unaffected by age of simulated patient (<i>p-value</i> 0.74) or training/seniority of the treating doctor (<i>p-value</i> 0.64). Predicted survival is based on how long seizure activity is known to last following the administration of intravenous verses intramuscular drugs.
IO = intraosseous, IV = intravenous, PPE = Personal Protective Equipment, IQR = Interquartile range, SD = Standard Deviation.				

Based on published data regarding the response rates for controlling seizures with intravenous or intramuscular benzodiazepines^{208 209}, Vardi et al²⁰⁶ estimated a 74% survival rate for drugs administered via the intraosseous route compared to a 3.3% survival rate for the same drugs administered via the intramuscular route. It is notable that the onset of therapeutic benefit of drugs administered via the intraosseous route is equivalent to intravenous drug administration.^{210 211}

Whilst the timing for termination of seizures used by Vardi et al²⁰⁶ are based a non-CBRN population the results reflect the time to control seizures following exposure to CBRN agents in animal-based studies. Eisenkraft et al²¹² reported faster control of seizures in piglets poisoned by organophosphates when midazolam was administered via the intraosseous route compared with intramuscular midazolam. This was due to higher plasma levels of midazolam following intraosseous administration (peak plasma level of 717 ng/ml at **2 minutes**) compared to intramuscular midazolam (550 ng/ml at **10 minutes**). Similar clinical benefit has been reported following intraosseous administration of atropine, pralidoxime and hydroxocobalamin²¹³ during the treatment of acute poisoning.

An important limitation of animal studies is whether the results can be applied to human subjects. Use of animal models is inevitable, given the ethical objections of deliberately administering toxins to human volunteers. The results reported by Eisenkraft et al²¹² are representative of a literature review by Towne and DeLorenzo²¹⁴ who looked at the use of intramuscular midazolam to control seizures in human subjects. Furthermore, separate studies by Grob²¹⁵ and Ketchum et al²¹⁶ have confirmed, in human volunteers, that patients will respond more quickly to intravenous atropine than intramuscular atropine. Therefore whilst intramuscular drug administration is faster to complete²⁰⁴, it is slower at reversing the effects of poisoning since the speed of skill completion does not reflect the onset of therapeutic benefit, as outlined in Table 5.

Table 5: Predicted onset of therapeutic action of drugs administered via the intramuscular or intravenous route.

Time to intramuscular drug administered 78-96 seconds (95% CI) resulting in time to therapeutic levels of benzodiazepine = 600 seconds following intramuscular injection.
Therefore by combining 78 seconds with 600 seconds the minimum time to onset of therapeutic action following an intramuscular injection would <u>be 678 seconds (>11 minutes) from start of procedure (e.g. picking-up syringe).</u>
Time to intravenous access obtained 193-247 seconds (95% CI). Time to therapeutic levels of benzodiazepine 200 seconds following intravenous injection.
Therefore by combining 193 seconds to 100 seconds the minimum time to onset of therapeutic action following an intravenous injection would <u>be 293 seconds (<5 minutes) from start of procedure.</u>
Therefore intravenous, and therefore by extrapolation intraosseous, drugs would achieve therapeutic levels at least 6 minutes faster than the same drug administered intramuscularly.
Data based on timings presented by MacDonald et al ²⁰⁴ and Eisenkraft et al. ²¹²

However, as earlier stated drug administration is faster via a CBRN auto-injector when compared to the use of a needle and syringe technique. Furthermore, absorption of drugs administered via the CBRN auto-injector is also faster than when drugs are administration via a needle and syringe.²¹⁷⁻²¹⁹ Conversely, not all drugs used to treat poisoning are suitable for intramuscular injection^{102 220 221}, whereas, any drug administered via the intramuscular route is affected by tissue perfusion which is prolonged during shock.^{149 222 223}

Despite these issues the CBRN auto-injectors still have a role when responding to a mass CBRN casualty incident or for self-treatment following rescuer contamination.²²⁰ This is due to their ease of use^{68 102 190} and fixed dosing schedule contained within the auto-injector.^{68 74} Therefore if intramuscular drugs are to be used to deliver antidotes, a special designed auto-injector should be selected, especially, as these devices continue to be developed and refined.²²⁴

Suyama et al¹⁸⁶ and Lamhaut et al²⁰⁷ compared intraosseous access using the EZ-IO drill against intravenous cannulation. Any study comparing intravenous cannulation with intraosseous access will by default favour intravenous cannulation which is performed more frequently than intraosseous access.²²⁵ This is an impossible bias to avoid and should be considered when reviewing the results. Lamhaut et al utilised an RCT, whereas Suyama et

al¹⁸⁶ utilised a quasi-experimental design based on a case control study. Both studies incorporated a non-CBRN-PPE control arm but neither study presented a power calculation in the method section of their papers. Nevertheless but both papers appear adequately powered (Appendix 1).

Participants in the study by Suyama et al¹⁸⁶ initially performed intraosseous access or the placement of an intravenous cannula whilst wearing normal clothing, then whilst wearing CBRN-PPE and finally with both the participant and the manikin wearing CBRN-PPE. The study design did not control for the development of either a learning effect or fatigue. Moreover the recruitment of qualified and student paramedics introduces the risk of varying clinical expertise, which may account for the outliers in the intravenous group (minimum 24.30 vs. Maximum 88.10). However, by reporting times for skill completion at various stages of the intraosseous and intravenous process, this study allows the reader to monitor the impact of CBRN-PPE on different aspects of intravascular access.

Comparison of Suyama et al¹⁸⁶ with Lamhaut et al²⁰⁷ is complicated by the fact that different methodologies were used by the research teams, but by combining the reported mean times from Suyama et al¹⁸⁶ and comparing these to the completion times reported by Lamhaut et al²⁰⁷, we observe that intravenous cannulation time is similar in both studies (104 ± 30s vs. 104.6s) with a 13 seconds difference (52.76 vs. 65) in the intraosseous group. Lamhaut et al²⁰⁷ also estimated a timesaving of 20 ± 24 seconds when using the EZ-IO drill, and by calculating the differences between the intravenous and intraosseous arms reported by Suyama et al¹⁸⁶, a maximum timesaving of 50 seconds is noted, reflecting the upper limit of timesaving identified by Lamhaut et al.²⁰⁷

A factor not considered in the research of these two studies is the complexity of obtaining intravenous access when treating clinically shocked patient²²⁶, which can take between 2.5-13²¹⁰ minutes extending to upwards of 30 minutes in patients with difficult vascular access.²²⁷ Such failed and prolonged intravenous access attempts delay drug administration.^{210 228} Similar issues are not noted with the intraosseous route, as drugs are injected into the bone marrow cavity, which does not collapse during circulatory failure.^{229 230} Therefore the speed of intraosseous access coupled with the ease of obtaining vascular access, makes it the ideal route for the administration of drugs whilst wearing CBRN-PPE.

The optimal intraosseous device for use during a CBRN incident remains unknown. To date, only the BIG^{167 206} and the EZ-IO^{174 195} have been evaluated for use in the context of a CBRN incident. One consideration favouring the use of the EZ-IO drill is that the reported technical^{167 189} and safety issues that occurred when using the BIG^{167 206} have not occurred

with the EZ-IO.^{186 207} Moreover, in non-CBRN studies the EZ-IO has proven to be the superior device.²³¹⁻²³⁵ The issue of whether any particular intraosseous device is superior to another following a CBRN incident remains unsettled given the lack of a data comparing the use of various makes of intraosseous device whilst wearing CBRN-PPE.

2.7 Airway management whilst wearing CBRN-PPE

Following exposure to a CBRN agent, a common mode of death is airway obstruction, with respiratory failure leading to hypoxia and ultimately cardiopulmonary arrest^{112 149}, therefore early airway management is a clinical priority.^{8 32 236} Five studies (Table 6) have assessed the impact of CBRN-PPE on different airway techniques. Direct comparison between these studies is hampered, however, by the mixture of human, animal and manikin-based simulations that have been used in the different studies.

MacDonald et al²⁰⁴ observed the impact of CBRN-PPE on intubation in a manikin-based RCT, incorporating all aspects of the intubation process, including preparation of intubation equipment and confirmation of correct endotracheal tube (ETT) placement. The authors reported that CBRN-PPE had no effect on intubation. However, the CBRN-PPE intubation times exceeded 60 seconds (95% CI 65-93 seconds), which in the case of a hypoxic patient represents a clinically significant extended period of apnoea that will result in worsening hypoxemia.²³⁷⁻²³⁹

The intubation times reported by MacDonald et al²⁰⁴ are the slowest of the intubation-based studies (Table 6). This is probably due to their study design as, unlike other CBRN intubation studies^{166 168}, MacDonald et al²⁰⁴ incorporated the time required to prepare intubation equipment and the time required to confirm ETT placement in their overall intubation performance parameters. These aspects of the intubation process were excluded by other studies.^{166 168} As a consequence, the MacDonald et al²⁰⁴ study is likely to be more representative of the time required to perform intubation whilst wearing CBRN-PPE than other studies. The findings reported by MacDonald et al²⁰⁴ are not directly applicable to UK CBRN intubation practice as ETT placement was confirmed using a stethoscope, which is not feasible whilst wearing NHS CBRN-PPE due to its fully encapsulating design (Appendix 1). Furthermore, all participants used an intubating stylet^{240 241} which is infrequently used in the UK as UK intubation guidelines²⁴⁰⁻²⁴³ favour the gum elastic bougie (bougie).

Table 6: Airway interventions whilst wearing CBRN-PPE: Laryngeal mask airway and intubation

Author	Laryngeal mask airway – Time in seconds	Intubation – Time in seconds	Comments
Goldik et al ¹⁶⁶	Anaesthetists (CBRN-PPE) Mean 3.6 (SD+/- 1.2) Median 3 Failure 0%	Anaesthetists (CBRN-PPE) Mean 25.3 (SD+/- 10.1) <i>p</i> <0.0001 Median 26 Failure 35%	No control group. Skills only performed whilst wearing CBRN-PPE. <i>P-values</i> reported for the differences between intubation and LMA insertion.
	Non-anaesthetists (CBRN-PPE) Mean 3.7 (SD+/- 0.8) Median 3 Failure 0%	Non-anaesthetists (CBRN-PPE) Mean 32 (SD+/- 10.3) <i>p</i> <0.0001 Median 32 Failure 55%	
Flaishon et al ¹⁶⁸	Anaesthetists CBRN-PPE mean 44 (SD +/- 20) No PPE mean 39 (SD +/- 11)	Anaesthetists CBRN-PPE mean 54 (SD +/- 24) No PPE mean 31 (SD +/- 7)	Time difference between LMA insertions in/out of CBRN-PPE not significant.
Flaishon et al ¹⁶⁹	Anaesthetists CBRN-PPE mean 40 (SD +/- 12) Failed attempts 0 No PPE mean 39 (SD +/- 14) Failed attempts 0	Not included	Anaesthetist 100% first attempt success compared to 55% first attempt success by non-anaesthetists. Novice group demonstrated rapid improvement, achieving the same performance as anaesthetists with between 4 and 7 attempts.
	Non-anaesthetists CBRN-PPE mean 102 (SD +/- 40) <i>p</i> -0.0001 Failed attempts 17 No PPE mean 64 (SD +/- 40) Failed attempts 6		
MacDonald et al ²⁰⁴	Not included	No PPE 69 (95% CI 55-83) CBRN PPE 79 (95% CI 65-93)	Confirmation of ET-tube placement by stethoscope not transferable to NHS CBRN-PPE.
Cuffed Oropharyngeal airway (COPA)			
Ben-Abraham ¹⁸⁵	No PPE	Mean 28 (+/- 10) 100% 1 st time insertion success	Twice as slow to insert whilst wearing CBRN-PPE.
	CBRN-PPE	56 (+/- 34) 84% 1 st time insertion success	This airway device is not widely used in the UK.

The use of an intubating aid (stylet) to support intubation in the MacDonald et al²⁰⁴ study is also a key difference in research design as compared to other CBRN-PPE intubation studies.^{166 168} The only other CBRN-PPE based intubation study to incorporate an intubating aid was Garner et al¹⁹² who allowed the use of either a stylet or a bougie. Neither study elected to evaluate the benefit of using an intubation aid whilst wearing CBRN-PPE. Despite this oversight the use of intubating aids is an interesting aspect of the intubation process that to date has not been fully evaluated in CBRN-PPE research.

The stylet and the bougie are both established intubation aids (Illustration 5)^{240 242 244} but the two devices differ in design and how they are used. The stylet resembles a pipe cleaner that is inserted into the ETT to shape it into the ideal intubating shape, similar to a hockey stick, thereby improving intubation success.²⁴⁰ The bougie, in contrast, is a long flexible tube that is placed into the trachea and the ETT is then inserted along its length into the trachea.^{240 242}²⁴⁵ The bougie can also be inserted into the ETT with the tip protruding through the end to guide the ETT into the trachea.²⁴⁰ The use of intubation aids to improve intubation success during a difficult intubation reflects national²⁴² and international guidelines.^{244 246} Currently there are no guidelines informing clinicians how best to attempt intubation whilst wearing CBRN-PPE.

Goldik et al¹⁶⁶ and Flaishon et al¹⁶⁸ compared intubation against LMA insertion in a crossover RCT. Goldik et al¹⁶⁶ recruited anaesthetic trainees and airway novices, whereas Flaishon et al¹⁶⁸ only recruited anaesthetic trainees. Anaesthetists in both studies had between two-to-five years' experience, thus ensuring a good level of intubation skill. Neither study employed a power calculation but both studies were adequately powered (Appendix 2).

The absence of a non-CBRN-PPE control arm in Goldik et al¹⁶⁶ weakens their results by preventing a comparison of the impact of CBRN-PPE on skill performance. This is an unfortunate oversight as LMA insertion is already known to be faster than intubation and has a higher success rate.^{226 247} However, their methodology did facilitate an assessment of the impact of experience on skill performance as anaesthetists were faster than the non-anaesthetists.

Illustration 5: Stylet and bougie

Stylet placed into an endotracheal tube to facilitate shaping the tube to facilitate intubation.



Bougie is either placed into the trachea or placed into the endotracheal tube with the tip protruding to allow manipulation into the trachea



Direct comparison of the two studies is difficult as Flaishon et al¹⁶⁸ recruited human volunteers, whereas Goldik et al¹⁶⁶ used *Maccacca Fascicularis*, arguing that the airways of simians and human are similar. Goldik et al¹⁶⁶ reported the highest intubation failure rate, affecting both anaesthetists and novices, of any CBRN intubation-based study.^{168 192 204 248} The selection of simians is potentially the cause of this disparity as, in an attempt to prevent individual animal variability a weight range of 3.5 to 4kg was set; this resulted in an intubation technique more reflective of paediatric intubation than adult intubation and thus introduced a variation in skill difficulty between the different studies.

Flaishon et al¹⁶⁹ also undertook an LMA-only study using human volunteers. This study compared anaesthetists (two-to-five year's anaesthetics experience) with trainee surgeons (manikin-based training) and novices (limited training) in a crossover RCT. This study was designed to observe the impact of CBRN-PPE on LMA placement and determine whether experience influenced the rate of skill completion. The anaesthetists were the fastest at LMA insertion, recording a 100% first-time success rate. The surgical trainees demonstrated a mean LMA insertion time which was slower than endotracheal intubation performed by anaesthetists wearing CBRN-PPE, as previously observed by Flaishon et al.¹⁶⁸

The slow insertion speed of the LMA by non-anaesthetists resulted in a statistically significant (*p-value* 0.005) reduction in measured oxygen levels in comparison to when the LMA was inserted by anaesthetists. The drop in measured oxygen levels was most noticeable in the novice group, resulting in a single episode where the measured oxygen levels dropped below the safety point of 92%. This is an important observation, as despite all patients undergoing pre-oxygenation²³⁸, a process that would be suboptimal following exposure to a chemical agent^{148 249}, transient drops in measured oxygen-levels were still detected. Considering that LMA insertion, or other supraglottic airways, are increasingly recommended for use during airway emergencies by non-anaesthetists²²⁶ the impact of CBRN-PPE on LMA insertion by non-anaesthetists is an interesting observation. Especially, when, considering, as noted above, that Flaishon et al¹⁶⁸ had previously demonstrated that anaesthetists could insert an ETT faster than non-anaesthetist can insert a LMA when both groups were wearing CBRN-PPE.

As well as intubation and LMA insertion the cuffed oropharyngeal airway (COPA), has been evaluated in a crossover RCT that recruited human volunteers (Table 6).¹⁸⁵ Noting that the COPA was slower to insert than they had previously noted with the LMA.^{168 169} The results of this study have limited applicability to the UK as the COPA is not widely used in UK.

2.7.1 Securing the endotracheal tube in situ post-intubation

The final aspect of airway management is to secure the LMA or ETT in situ, thus minimising the risk of ETT accidental extubation or migration of the ETT into the right bronchus.²²⁶ Four studies^{168 169 185 250} have monitored the impact of CBRN-PPE on 'tying-in' either an ETT or LMA in their findings (Table 7). Berkenstadt et al¹⁸⁹ observed, during simulation-training, that securing the ETT in situ prolonged overall skill completion, with all studies^{250 168 169 185 189} concluding that securing an ETT/LMA in situ was time-consuming and identified the loss of dexterity due to wearing butyl gloves as the main reason. Flaishon et al¹⁶⁹, did, however, noted that pre-enrolment experience improved the time to secure an ETT in situ, and that novices improved with skill repetition. However, with the exception of Luria et al²⁵⁰, none of these studies describe the tying-in technique used, thus preventing inter-study comparisons.

Luria et al²⁵⁰ evaluated four different techniques for securing an ETT in situ using a crossover RCT supported by qualitative data. Three of the techniques evaluated involved commercially available securing devices, whereas the 'Israeli technique' was an elaborate technique for tying in an ETT using a cotton tie. Each participant completed each of the securing techniques five times, but only the final time for each participant was reported. This study demonstrated that the Thomas™ Tube Holder was the superior device with regards to speed of application and the degree of security of holding the ETT in situ. The lead author was contacted (via email) to see if the original datum was still available or if the authors had considered monitoring for a learning effect. Regrettably, the data were no longer available and so it is not possible to compare the authors findings with Flaishon et al¹⁶⁹ to confirm or refute the presence of the learning effect.

Table 7: Securing airway devices in situ whilst wearing CBRN-PPE

Author	Results	Comments
Flaishon et al ¹⁶⁸	Anaesthetic trainees No PPE 0.9 minutes (SD +/- 0.1 minute) CBRN-PPE 2.3 minutes (SD +/- 0.6 minutes) <i>p-value <0.001</i>	Technique not described.
Flaishon et al ¹⁶⁹	Anaesthetic trainees No PPE 23 seconds (SD +/- 7) CBRN-PPE 39 seconds (SD +/- 9) <i>p-value <0.01</i> Surgical trainees No PPE 37 seconds (SD +/- 13) CBRN-PPE 57 seconds (SD +/- 13) <i>p-value <0.01</i> Airway novices No PPE 55 seconds (SD +/- 28) CBRN-PPE 82 seconds (SD +/- 27) <i>p-value <0.01</i>	Technique not described. Novices improved with practice reaching similar performance as surgical trainees between the 4 th and 6 th attempt.
Luria et al ²⁵⁰	NO PPE Bite block (VBM) 27.1 sec (SD +/- 6.0) quality of securing 3.2* (SD +/- 0.4) Elastic band 30.0 sec (SD +/- 11.5) quality of securing 2.9* (SD +/- 0.6) Thomas™ Tube Holder 21.9 sec (SD +/- 4.0) quality of securing 4.9* (SD +/- 0.1) Israeli (technique) 81.0 sec (SD +/- 17.5) quality of securing 4.6* (SD +/- 0.7) PPE Bite block (VBM) 39.9 sec (SD +/- 12.4), quality of securing 3.3* (SD +/- 0.7) and ease of learning to use 3.1 Elastic band 36.6 sec (SD +/- 14.4), quality of securing 2.9* (SD +/- 0.5) and ease of learning to use 2.4 Thomas™ Tube Holder 26.6 sec (SD +/- 6.5), quality of securing 4.9* (SD +/- 0.1) and ease of learning to use 5 Israeli (technique) 97.7 sec (SD +/- 21.8), quality of securing 4.6* (SD +/- 0.3) ease of learning to use 1.7	This is the only study that compared quality of securing an ETT in situ obtained with evaluated techniques as part of its results. *Securing quality and ease of learning to use is based on a score of 1 (poor) to 5 (best).
Ben-Abraham et al ¹⁸⁵	Anaesthetic trainees No PPE 19 (SD 14) seconds <i>p-value <0.05</i> CBRN-PPE 34 (SD 16) seconds <i>p-value <0.05</i>	Technique not described.

2.8 Patient simulators and environmental factors

The studies in this literature review have used various simulators as surrogates for CBRN casualties, including human volunteers undergoing anaesthesia during routine surgery, simians, intraosseous training bones, turkey legs (for intraosseous use), intravenous cannulation pads, and different models of manikins. This wide variation of simulated casualties impairs our ability to make comparisons between the different studies, as the variation in simulated casualties introduces an independent variable that could potentially change the outcome of the studies.

2.8.1 The potential impact of patient simulators

Human studies are considered the gold standard when evaluating clinical skills as they confer a high degree of external validity and the findings can be extended to the general population. Three studies have recruited human volunteers^{168 169 185}, allowing for the monitoring of patient-specific variables such as the development of hypoxia¹⁶⁹, and thus strengthening the validity of the data. Due to safety constraints, these human-based studies lack consistency as each skill has to be performed on a different volunteer. The variation of volunteers prevents the performance of each skill, such as intubation, from being truly identical as each volunteer will be different. Furthermore, none of these human-based studies controlled for volunteer height, body mass index or gender, resulting in participants being exposed to a wide range of patients types (Table 8).

This variation in human volunteers and the potential impact it can have on data validity can be demonstrated by looking at the recruitment protocol used by Flaishon et al.¹⁶⁸ For safety reasons, Flaishon et al¹⁶⁸ excluded any patient who was deemed as being difficult to intubate. This assessment was based on the modified Mallampati score²⁵¹, which assesses potential intubation difficulty based on a number of patient physical characteristics and allocates a score between zero (very easy) to four (difficult). Flaishon et al¹⁶⁸ excluded all patients with modified a Mallampati score of four. Whilst this approach ensured the safety of the volunteers, it added a volunteer-specific variable as it was not possible to ensure that each participant intubated a patient with the same Mallampati score. Therefore the resulting study design allowed that a participant could be expected to intubate a 42kg female with a Mallampati score of 0, whilst wearing standard theatre clothing, before repeating the same skill on a 105kg male with a Mallampati score of three whilst wearing CBRN-PPE (Table 8).

Goldik et al ¹⁶⁶ minimised the impact of their surrogate patients by selecting *Maccacca Fascicularis*, stating that simians have similar airway anatomy to humans. They reported the highest failed intubation rate of any CBRN-PPE intubation study and as discussed in section 2.7 this is potentially due to the size of the simians, which ranged only from 3.5 to 4.5 kg, resulting in an intubation attempt more representative of paediatric intubation.

Table 8: Total number of volunteers per study

Author	Participants	Number of volunteers
Flaishon et al ¹⁶⁸	Anaesthetic trainees n = 15 34 male and 26 females. Average weight 74kg (range 42-105kg)	n = 60. There are 4 arms to the study: intubation in/out of CBRN-PPE and LMA in/out of CBRN-PPE.
Flaishon et al ¹⁶⁹	Anaesthetic trainees n = 20 Surgical trainees n = 22 Novices n = 6 60 male and 81 female. Average weight 72kg (range 48-98)	n = 40 n = 44 n = 57 (assessment of learning effect)
Ben-Abraham et al ¹⁸⁵	Anaesthetic trainees n = 12	n = 24

In contrast to Goldik et al ¹⁶⁶ and Flaishon et al ^{168 169}, MacDonald et al²⁰⁴ and Berkenstadt et al ¹⁸⁹ used intubation manikins. Berkenstadt et al ¹⁸⁹ also used questionnaires to demonstrate the effectiveness of manikins for CBRN training. Whilst human-based studies provide optimal external validity and allow for the measurement of patient-specific data, the need to ensure patient safety simultaneously introduces patient-to-patient variability, thus reducing internal validity. These issues do not occur with manikin-based research as each participant is presented with the same manikin, which successfully isolates the simulated patient as a variable and thereby increases internal validity.¹⁷²

2.8.2 The role of verisimilitude during data collection and training

Taylor and Orlansky ²⁰, in their literature review of military CBRN training, highlight the importance of realism during CBRN simulation. However, to date only studies by Vardi et al ²⁰⁶, Berkenstadt et al ¹⁸⁹ and Rissanen et al ²⁵² have performed data collection outside of a controlled environment. Vardi et al ²⁰⁶ and Berkenstadt et al ¹⁸⁹ research involved simulation-training and did not include any randomisation with all participants being exposed to the

same environment. Whereas, Rissanen et al ²⁵² randomised their participants to different environments, based on ambient temperature, noting that cold further impacted skill performance whilst wearing CBRN-PPE. Despite the study by Rissanen et al ²⁵² being excluded from this literature review, due to methodological flaws (Appendix 2), it serves to highlight the potential impact of environmental factors on skill completion.

Therefore, with the notable exception of Rissanen et al ²⁵², none of the CBRN-PPE studies identified in this literature review have considered the impact of realism on their data collection. Realism is potentially a key factor in skill performance, particularly when considering environmental factors such as patient position or ambient light. This lack of realism could affect the validity of results, as emergencies do not occur under control conditions and skills that are successfully performed in optimal conditions typically have higher failure rates when performed in the real world.²⁵³⁻²⁵⁶

Medical education based simulation, has drawn heavily on the development of simulation in the aviation industry, where pilots are expected to demonstrate key responses to a host of emergencies, typically performed in complex flight simulators.²⁵⁷ As a consequence, the key aim of simulation-training is to recreate, as realistically as possible, the situations in which clinicians are expected to provide care.²⁵⁸ However, there will always be limitations to the degree of realism that can be generated during a simulation, as the need to ensure student safety is paramount. Nevertheless as highlighted by Taylor and Orlansky²⁰, the provision of realistic training is the cornerstone of ensuring an effective CBRN response.

2.9 Addressing the gap in our knowledge regarding skill performance whilst wearing the NHS CBRN-PPE?

Only two papers were identified that incorporated NHS CBRN-PPE in their methodology ^{2 156}, however, despite the lack of studies looking at the NHS CBRN-PPE, a number of issues were identified from the literature search that is pertinent to skill performance whilst wearing the NHS CBRN-PPE. The nine Papers presented in this thesis attempt to address these issues as well as identifying future avenues of research enquiry.

Paper 1 addresses the impact of the NHS CBRN-PPE on the ability to perform low-dexterity and high-dexterity skills. Additionally the paper investigates whether there is any benefit from having previously worn NHS CBRN-PPE during familiarisation training, the influence of professional background, and the impact of skill repetition. Similarly, Papers 3 and 4 also address the impact of the different skill levels of different professional groups and the impact

of skill repetition. Participants' perceptions of the importance of training and skill repetition were highlighted during face-to-face interviews reported in Paper 5 and 6.

Paper 2 evaluates the impact of CBRN-PPE on securing an ETT in situ by comparing the hospitals established approach of tying-in an ETT with the Thomas™ Tube Holder. Paper 2 also utilises face-to-face interviews to gain a better understanding of the difficulties that participants experience whilst attempting to use either device.

Paper 3 addresses the impact of patient position on airway management, with Paper 7 expanding on Paper 3 findings by attempting to identify the optimal 'on floor' intubating position. Paper 4 is designed to monitor the impact of CBRN-PPE on aspirating drugs from a range of drug presentations. To date, the impact of CBRN-PPE on this phase of drug administration has been poorly evaluated.^{178 204 248}

Papers 5 and 6 were designed to develop the research methods later employed in Papers 7 to 9 by gauging the opinions and experiences of the participants who had been recruited into the studies reported in Papers 1 to 3. Papers 5 and 6 are the only studies to date employing face-to-face interviews to ascertain what skills clinicians believe to be feasible whilst wearing NHS CBRN-PPE. This is an area of research ideally suited to qualitative research techniques, such as face-to-face interviews.²⁵⁹ The completion of Papers 5 and 6 also required an examination of the published literature regarding a range of supraglottic airways devices and intubating aids that had been identified for further evaluation. This exercise was essential preparation to undertake the research reported in Papers 8 and 9.

Paper 8 evaluates six different supraglottic airway devices in an attempt to ascertain which device was the fastest and easiest to insert whilst wearing CBRN-PPE. The importance of overall speed of supraglottic airway insertion was demonstrated by Flaishon et al¹⁶⁹, who noted that the time taken to complete LMA insertion whilst wearing CBRN-PPE resulted in a drop in measured oxygen levels in number of healthy patients who had been pre-oxygenated. This finding is particularly pertinent to those who become critically ill following exposure to a CBRN agent, such as the use of sarin in Tokyo³⁴ or exposed to the incapacitating gas used to end the Moscow siege.³⁷ As in these situations any attempts at pre-oxygenation, before performing airway interventions, will be sub-optimal.^{148 249} The impact of established hypoxia, prior to performing emergency airway management, has been confirmed by Davies et al²³⁹ highlighting the importance of speed in the performance of airway management skills.

Paper 9 is the only RCT to investigate the potential benefit of using intubation aids whilst wearing NHS CBRN-PPE, which is a clinically relevance question when we consider the adverse impact that wearing CBRN-PPE, has on intubation. This is particularly noteworthy when considering the increased mortality and morbidity in critical ill patients following multiple intubation attempts.²⁶⁰⁻²⁶²

Papers 1, 3 and 9 retain intubation as a clinical skill as intubation remains an important treatment option for patients who require airway support and ventilation after exposure to a CBRN agent.^{74 148 220} However, ETT incorrectly placed in the oesophagus is rapidly fatal²⁶² and correct confirmation of ETT placement in the trachea is a vital aspect of patient safety.^{226 243 264} Therefore, Papers 1, 3 and 9 adopted the 2005 European Resuscitation Council Guidelines (ERC)²⁶⁴ for confirming correct ETT placement.

Neither the 2005²⁶⁴ nor the 2010 ERC guidelines²²⁶ are able to recommend a single ETT placement technique that provides 100% assurance of correct ETT placement. As a consequence the current recommendation is that two independent evaluation techniques should be used. This recommendation is further supported by pre-hospital intubation guidelines.^{243 265} The use of two different techniques for confirming ETT placement is a key methodological difference between the intubation-based studies presented in this thesis and other intubation-based studies.^{166 168 191 192 204 248} Although MacDonald et al²⁰⁴ confirm ETT placement by using lung auscultation, the reliance on a single confirmation technique does not comply with best practise guidelines.^{226 264 265} Furthermore, Baker²⁶⁶ highlights that CBRN-PPE may prevent the use of a stethoscope due to the design of respirators. This is particularly pertinent to the NHS CBRN-PPE as its fully encapsulating design (Appendix 1) precludes the use of a stethoscope to confirm ETT positioning.

Following the ERC guidelines²⁶⁴, the Positube™ and a colorimetric end-tidal CO₂ detector were used to simulate the process of confirming ETT placement throughout this thesis. Both devices were in clinical use at the UK and South African research sites. The Positube™ resembles a 50 ml syringe which is attached to the ETT; the syringe's plunger is rapidly pulled, aspirating air from in the patient's lungs. If the ETT is correctly placed in the trachea, 50 ml of air is easily withdrawn, whereas if the ETT is placed in the oesophagus, the increased pressure caused by rapidly withdrawing air causes the oesophagus to collapse.²²⁶ The colorimetric end-tidal CO₂ detector sits between the ETT and the bag-valve-mask or ventilator and changes colour in the presence of expired CO₂.²²⁶

2.10 Conclusion

The foregoing literature review supports the premise that LMA insertion is faster than intubation but indicates that only three supraglottic airways have been evaluated for use in a CBRN incident. This is despite the availability of a wide range of supraglottic airway devices.²⁶⁷ The literature also supports the role of intramuscular drugs, when delivered via a CBRN auto-injector, in the management of patients exposed to a CBRN agent but highlights that the onset of therapeutic benefit will be delayed compared with either intravenous or intraosseous drug administration. And whilst intraosseous access appears superior to intravenous cannulation, the optimal intraosseous device is as yet unknown.

Although this literature review identified two studies that reported on wearing the NHS CBRN-PPE, neither study evaluated clinical skill performance whilst wearing PPE.^{2 156} Whereas a number of identified studies indicate that CBRN-PPE interferes with skill performance, the lack of any study directly examining the NHS CBRN-PPE means that it is only possible to infer, but not confirm difficulties with skill performance associated with the NHS CBRN-PPE. This is a serious omission, and therefore the identification of what skills can be successfully performed whilst wearing the NHS CBRN-PPE, as well as the confirmation of the presence of a learning effect associated with repeating skills whilst wearing PPE, remains an important research question.

Chapter 3

What airway and vascular access skills can be performed whilst wearing the NHS CBRN-PPE?

3.1 Introduction

The first four Papers reported in this thesis represent my initial attempts to ascertain what skills could be performed whilst wearing the NHS CBRN-PPE. The selected clinical interventions represent those skills commonly performed at the research site, and all the recruited clinicians had proven competencies in using the selected techniques.

Data for the first three Papers discussed in this chapter, were obtained during CBRN-PPE skills training, with Papers 2 and 3 presenting additional data drawn from face-to-face interviews, which were conducted to more fully interpret the impact of the NHS CBRN-PPE on performing specific clinical skills. The research presented in Paper 4 was conducted in collaboration with a UK based university that has experience of training emergency nurses and paramedics, which provided access to a large pool of potential participants.

Furthermore, the universities allowed access to a large skills laboratory to enable data collection, provided assistance with data collection and also provided the support of a statistician.

3.2 It's all about dexterity and experience

Paper 1: Castle N, Owen R, Hann M, Clarke S, Reeves D and Gurney I. Impact of Chemical, Biological, Radiation, and Nuclear Personal Protective Equipment on the performance of low- and high-dexterity airway and vascular skills. *Resuscitation* 2009; 80: 1290-1295.

Paper 1 was designed to assess the impact of low-dexterity (LMA and intraosseous access) and high-dexterity (intubation and intravenous cannulation) skills performed whilst wearing NHS CBRN-PPE. This study was also designed to detect the presence of a learning effect gained from repeating the skills and/or from having previously worn NHS CBRN-PPE. The chosen interventions were commonly performed emergency skills²²⁶, and one of the main reasons for undertaking the study was to facilitate the development of a local CBRN training programme.

3.3 Method

A crossover RCT design ensured that each participant acted as their own control and facilitated comparison between professional subgroups. Randomisation was based on a Latin square, which ensured that a low-dexterity or high-dexterity skill was always followed by an opposite dexterity skill, thus minimising any crossover learning effect. This particular study was manikin-based, with all airway interventions being performed on a Laerdal® Advanced Airway Trainer, with intravenous cannulation or intraosseous placement occurring on cannulation pads or simulated bone. No intubation aids²⁴² were provided in order to accurately reflect the contents of the mass casualty treatment pod contents⁹¹, even though a number of candidates requested either a bougie or a stylet.^{240 242}

A power calculation indicated 64 candidates were required and participants attending CBRN training were recruited using a convenience sampling method.¹⁷² Participants were from varying clinical backgrounds but all were expected to provide clinical skills during resuscitation attempts, and their roles indicated that they could be called upon to treat patients following a CBRN incident. All participants were competent in intubation, LMA insertion, placement of an intraosseous needle and intravenous cannulation.

3.4 Data analysis - airway skills

The time to complete intubation reported in Paper 1 is consistent with intubation times reported in other CBRN studies (Table 9), although as previously noted, the variation in intubation times was affected by numerous factors; such as including the time required to confirm correct ETT placement. Paper 1 identified an 11% first-time intubation failure rate whilst wearing CBRN-PPE, which is in keeping with non-CBRN-PPE data^{268 269} but is lower than the intubation failure rate reported by Goldik et al¹⁶⁶ (non-anaesthetists 55% vs. anaesthetists 35%) whilst wearing CBRN-PPE. It is, however, higher than the 0% reported by Flaishon et al¹⁶⁸ and MacDonald et al.²⁰⁴ Sub-group analysis of Paper 1 demonstrates that intubation failure was associated with the participant's clinical background, with trainee emergency department (ED) physicians having the highest intubation failure rate (17.6%) and the slowest intubation times (median 82.4 seconds), as compared to consultant anaesthetists, who had a 100% intubation success rate and were the fastest intubators (median 48.6 seconds).

The intubation failure rate of the trainee ED physicians coupled with the associated prolonged intubation times would represent a clinical risk to a patient exposed to a CBRN agent who is likely to be hypoxic prior to any intubation attempt.²⁴⁹ Whilst Paper 1 was not powered to measure differences between professional groups the results are, however, intuitive indicating the importance of intubation experience when attempting advanced airway management whilst wearing CBRN-PPE. The failure rate noted in Paper 1 reinforces the importance of adhering to guidelines for confirming correct ETT placement.²²⁶

Eleven intubation attempts, undertaken whilst wearing CBRN-PPE, resulted in a right bronchus intubation with none occurring whilst wearing normal clothes. This represents 7% of all the intubation attempts whilst wearing CBRN-PPE and is significantly higher than the 1.5% (6 out of 381) incidence of right bronchus intubation recently reported for emergency department intubations.²⁷⁰ This increased risk of right bronchus intubation, associated with wearing CBRN-PPE, has not previously been reported and occurred with all participants except the consultant anaesthetists and consultant emergency physicians.

For the purposes of Paper 1, right bronchus intubation was regarded as a successful intubation attempt. However, right bronchus intubation is less than ideal as it is associated with an increased risk of barotrauma leading to a higher risk of pneumothorax, as well as causing hypoventilation leading to worsening hypoxia and increased mortality.^{271 272} The risk of barotrauma is particularly pertinent to the treatment of casualties following a CBRN incident, as numerous chemical agents cause pulmonary oedema, bronchospasm and

increased airway secretion, requiring high-ventilation pressures to ensure effective ventilation.^{82 112 147 148 220} Diagnosing right bronchus intubation, whilst wearing CBRN-PPE, will be challenging as neither the Positube™ nor the colorimetric end-tidal CO₂ devices are designed to detect right bronchus intubation. Typically, confirmation that an ETT has not be inserted into the right bronchus involves chest auscultation and observing how the patient chest rises.²²⁶ However, the design of the NHS CBRN-PPE prevents chest auscultation and observational techniques are subjective and prone to misdiagnosing misplaced ETT.^{226 265} Nonetheless it would appear, that increasing clinicians awareness through training, can reduce the incidence of right bronchus intubation²⁷¹ and therefore the risk of misplaced ETT should be incorporated into CBRN simulation-training.

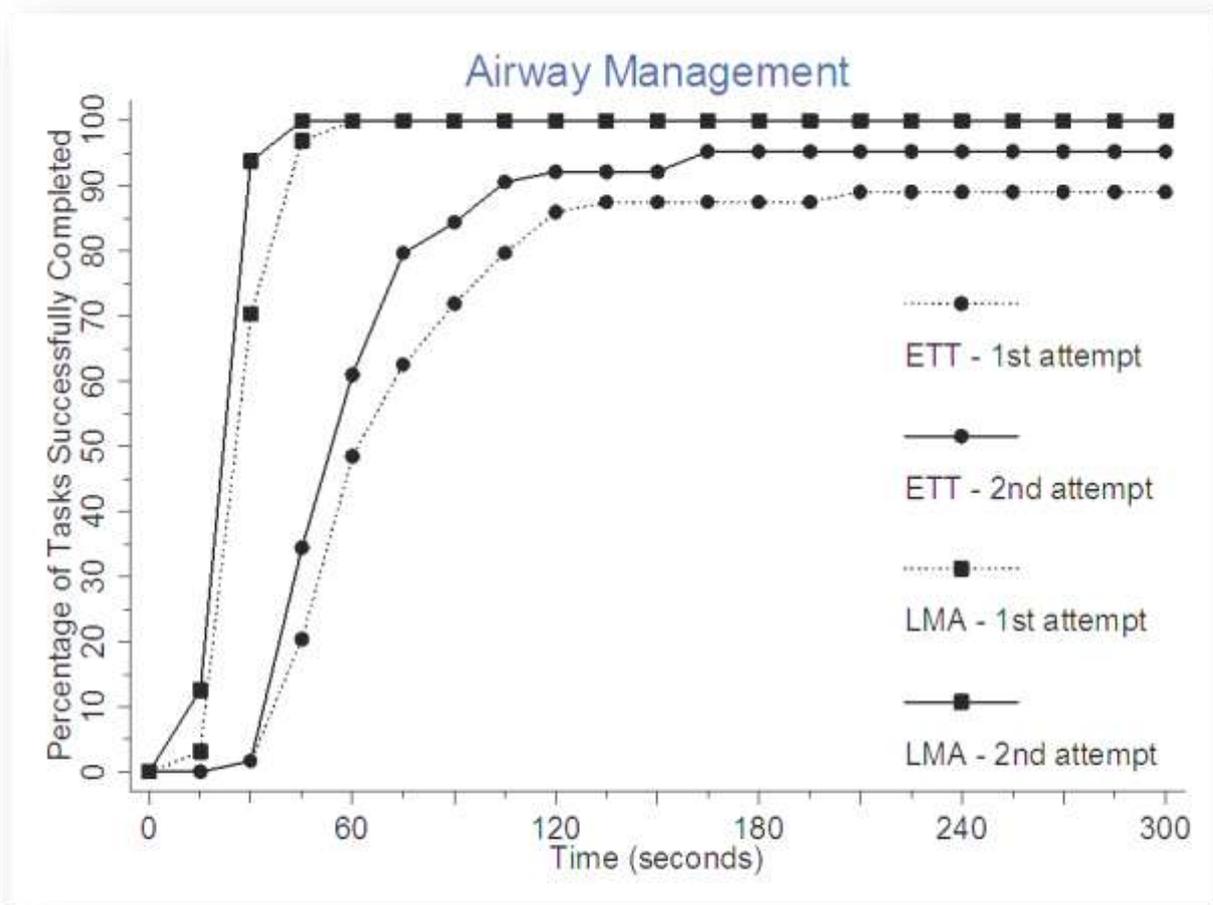
Another findings reported in Paper 1 was that the LMA insertion was consistently faster and easier to perform in comparison with intubation, with 100% of LMA's inserted in 60 seconds (Figure 1). Whilst LMA insertion differed across professional groups even the slowest reported mean of 31.6 seconds is clinically acceptable in comparison to the fastest mean intubation time of 54.3 seconds.⁴³

Table 9: Comparison of time to complete intubation as reported in Paper 1 compared with previously published studies

Study	Time (mean) to complete intubation; no CBRN-PPE (in seconds)	Time (mean) to complete intubation wearing CBRN-PPE (in seconds)	Comments
Paper 1 ⁴³	36.1 (95% CI 34.2-38)	67.5 (95% CI 63.3-71.7)	Includes time to confirm ETT position but not time to prepare equipment
Flaishon et al ¹⁶⁸	31 (± 7)	54 (± 24)	Excludes time required to confirm ETT position or to prepare equipment
MacDonald et al ²⁰⁴	69 (95% CI 55-83)	79 (95% CI 65-93)	Includes time to confirm ETT position and time to prepare equipment
Times reported in Paper 1 are for the first attempt whilst wearing CBRN-PPE as neither Flaishon et al ¹⁶⁸ nor MacDonald et al ²⁰⁴ recorded times for skills being repeated.			

The data presented in Table 10 is of particular interest, as by comparing LMA insertion times in Paper 1 and Flaishon et al¹⁶⁹ we can demonstrate that the non-anaesthetists in Paper 1 were at least three times faster at LMA insertion than the non-anaesthetists recruited by Flaishon et al. ¹⁶⁹ More specifically, even the fastest non-anaesthetists recruited by Flaishon et al ¹⁶⁹ took, on average, over 100 seconds to complete LMA insertion, which resulted in a prolonged period of apnoea and a statistically significant reduction in oxygen saturation. While it is possible these differences could be attributed to the use of human subjects versus manikins they are just as likely due to varying clinical skills, as all of the participants in Paper 1 were experienced at LMA insertion.

Figure 1: The percentage of successfully completed airway management skills in a given time.



Castle et al⁴³

Table 10: Time difference for LMA insertion between professional groups

Author	1 st Attempt CBRN PPE (Mean seconds)	2 nd Attempt CBRN PPE (Mean seconds)
Castle et al data ⁴³		
Anaesthetists [a]	16.1	20.7
Emergency physicians & Prehospital doctors [a]	28.6	20.6
Paramedics and Resuscitation Officers [a]	31.6	24.5
Flaishon et al data ¹⁶⁹		
Anaesthetists [b]	40	N/A
Surgeons [b]	102	N/A
Novices [b]	120	Times improved with practise
A) In Paper 1 all participants had received anaesthetic room LMA insertion training and frequently responded to cardiac arrests and other airway-related emergencies.		
B) In Flaishon et al ¹⁶⁹ only the anaesthetist had any documented anaesthetic room experience.		

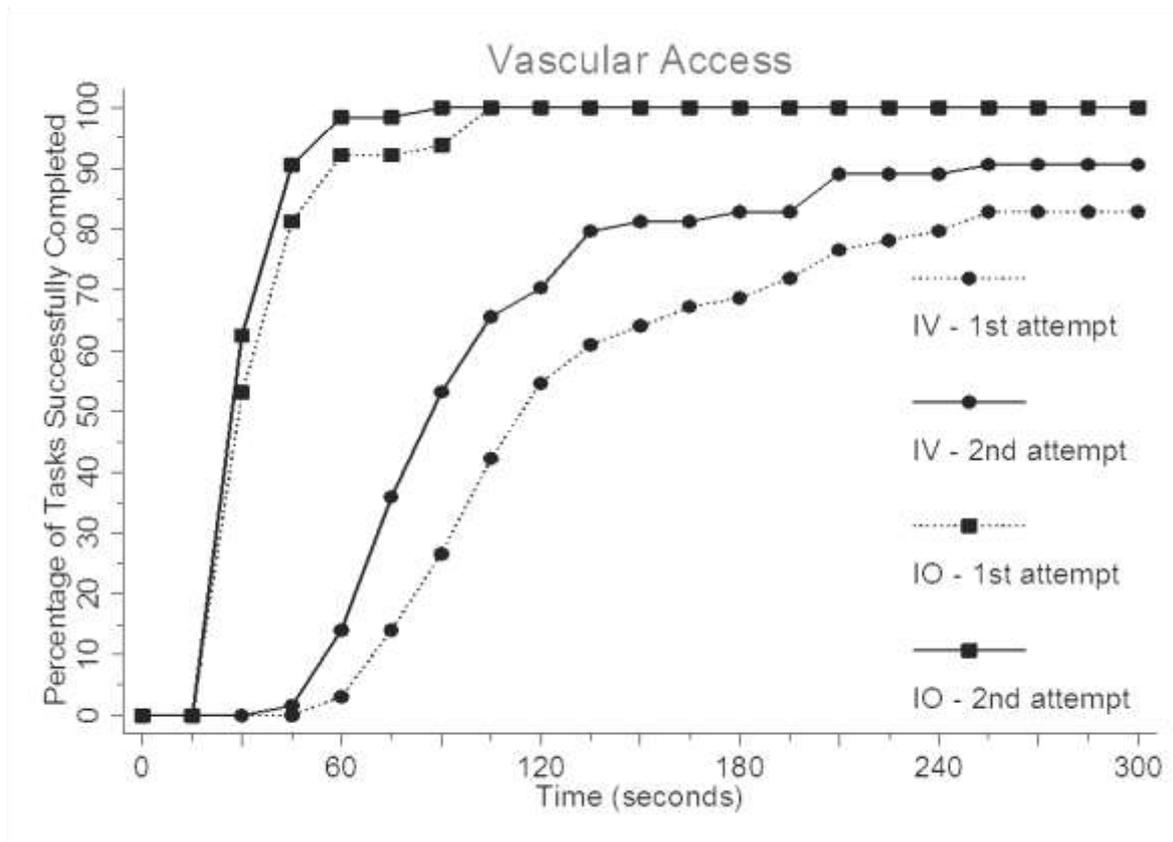
3.5 Data analysis - Vascular access skills

Paper 1 was designed to compare the impact of the NHS CBRN-PPE on the placement of an intravenous cannula (high-dexterity skill) with intraosseous access (low-dexterity skill). The EZ-IO drill was selected as it was the standard intraosseous device used at the participating research site, and all participants received training in its use during annual resuscitation training.

As previously discussed, comparison between intravenous cannulation and intraosseous placement theoretically favours the intravenous cannula as intravenous cannulation is a more frequently performed skill.^{225 226 264} To minimise this bias, all participants acted as their own control and were familiar with using the EZ-IO drill. Furthermore, a Latin square randomisation schedule was used that minimised any crossover learning effect between devices.

Paper 1 confirms the superiority of intraosseous access (Figure 1) reporting a 90 second timesaving for intraosseous insertion, with a 100% first attempt success rate compared to an intravenous cannulation success rate of 90% by the second attempt. Comparison between Paper 1 and previous studies is complicated by varying study designs, but Suyama et al¹⁸⁶ reported the same 100% first-time insertion rate when using the EZ-IO as reported in Paper 1.

Figure 2: The percentage of successfully completed vascular access skills in a given time.



Castle et al.⁴³

3.6 What is the impact of prior exposure of wearing CBRN-PPE?

In an attempt to detect whether prior exposure to wearing CBRN-PPE improved skill performance, half of the recruited participants in Paper 1 had previously worn NHS CBRN-PPE during familiarisation training but not skill-based training. No benefit was detected from having previously worn the NHS CBRN-PPE (*p-value* 0.28). The wide 95% CI indicated that this aspect of the study was underpowered (-18.6-4.5) but regression analysis using the application of 10,000 bootstrap samples confirmed that there was no correlation between prior wearing of CBRN-PPE and skill performance.

This arm of the study was not matched to professional background, with only one of the consultant anaesthetists having previously worn NHS CBRN-PPE; this situation thus presented a potential confounding variable. The failure to balance the recruitment of

clinicians with or without experience of wearing NHS CBRN-PPE into groups from similar clinical backgrounds is an oversight, but to have done so would have required a more complex recruitment strategy and a larger study. However, as previous experience of having worn NHS CBRN-PPE was restricted to familiarisation and not skill-based training it is unlikely that this level of exposure would have resulted in skill improvement. This criterion, however, did result in a self-selecting group, as those clinicians who had previously worn NHS CBRN-PPE and had disliked the experience would have been unlikely to volunteer as study participants.

3.7 Is there a learning effect?

Paper 1 confirms that skill repetition results in the development of a learning effect (Figures 1, 2 and Table 11), thus confirming the results reported in previous studies.^{169 170} This is an important element of Paper 1, as it will assist with future CBRN simulation-training programmes. The greatest improvement was noted for the high-dexterity skills of intubation and intravenous access, but was less marked for low-dexterity skills (Figures 1, 2 and Table 11).

From a clinical stand-point, LMA and intraosseous insertion were completed faster and with a higher success rate than either intubation or intravenous access across all attempts. Intraosseous access attempts were typically completed in less than 60 seconds, with a 100% success rate (Table 11) and were approaching three times faster than intravenous access at the upper end of the maximum range of skill completion (89 v. 251 seconds). Laryngeal mask airway insertion, by comparison, was completed (Table 11) on average 45s faster than intubation, which means an overall shorter apnoea²³⁸ compared with intubation. It is also noteworthy that even on the second intubation attempt oesophageal intubation occurred on 4.5% of occasions and the time to complete the second intubation attempt was slower than the first attempt at inserting the LMA whilst wearing CBRN-PPE.

Paper 1 reports a wide range of skill completion times between the different professional groups (Table 12). Anaesthetists performed all the skills more quickly and demonstrated the least amount of improvement between the first and second attempts whilst wearing CBRN-PPE. However, all clinicians achieved similar times for their second attempt when performing the low-dexterity skills (Table 12), regardless of their professional background. This narrowing of skill completion times was not noted for higher-dexterity skills.

Table 11: Performance of low- and high-dexterity skills whilst wearing CBRN-PPE

Skill		Number of successful completions	Mean successful completion time	95% CI	Range (Min – Max)	Failures to successfully complete
LMA placement (low dexterity)	Unsuited	64 (100%)	17.7	(17.0; 18.4)	10–33	
	Suited attempt 1	64 (100%)	26.6	(25.6; 27.6)	13–51	
	Suited attempt 2	64 (100%)	21.8	(21.1; 22.6)	6–35	
Endotracheal intubation (high dexterity)	Unsuited	64 (100%)	36.1	(34.2; 38.0)	18–99	
	Suited attempt 1	57 (89%)	67.5	(63.3; 71.7)	28–210	2 abandoned (3%) 5 oesophageal (7%)
	Suited attempt 2	61 (95%)	59.4	(56.0; 62.7)	26–161	3 oesophageal (4.5%)
Intra-osseous cannulation (low dexterity)	Unsuited	64 (100%)	19.4	(18.8; 20.1)	11–37	
	Suited attempt 1	64 (100%)	36.0	(33.5; 38.4)	18–100	
	Suited attempt 2	64 (100%)	29.8	(28.4; 31.2)	18–89	
Intra-venous cannulation (high dexterity)	Unsuited	64 (100%)	40.8	(38.9; 42.7)	19–110	
	Suited attempt 1	55 (85%)	129.6	(119.7; 139.6)	48–488	9 abandoned
	Suited attempt 2	58 (90%)	95.8	(90.0; 101.7)	42–251	6 abandoned
Data is based on the combined means of the results from ALL participants to include failed as well as abandoned attempts.						
Adapted from Castle e t al. ⁴³						

A possible explanation for both the higher skill performance and limited learning effect noted by the anaesthetists is their greater experience at performing the selected skills in routine clinical practise. This hypothesis is supported by two different studies by Flaishon et al^{168 169} who noted that anaesthetists demonstrated consistent LMA insertion times (40 ± 12 vs. 39 ± 11 seconds) despite the data being obtained from different groups of anaesthetists. Similarly, during a non-CBRN study by Wahlen et al¹⁹⁸, anaesthetists inserted a range of supraglottic airway devices more quickly than other professional groups, with improvements peaking between the first and second insertion, as compared with non-anaesthetists who demonstrated ongoing learning.

Not all CBRN studies have identified the presence of a learning effect. Hendler et al⁹⁰, for example, demonstrated no learning effect amongst anaesthetists performing intubation but did note that the experience level of the anaesthetists improved performance (*p-value* <0.01). Similarly, Berkenstadt et al¹⁷⁹ demonstrated no learning effect amongst medically trained soldiers performing intravenous cannulation. There are key differences between Paper 1, Hendler et al⁹⁰ and Berkenstadt et al¹⁷⁹, as the two latter studies used tactile preserving gloves rather than butyl rubber gloves. This is an important variable as the gauge of the glove adversely affects skill performance.^{170 187} Hendler et al⁹⁰ also provided each anaesthetist with an assistant.

A possible reason for no improvement occurring in Berkenstadt et al¹⁷⁹ study is that their participants were inexperienced at performing intravenous cannulation. This can be demonstrated by the high failure rate, which occurred in both arms of their study (65% vs. 56%) as well as similar completion times (303 ± 115 and 351 ± 113 seconds). However, all the participants in Paper 1 were skilled at all the evaluated skills. The poor performance of the medically trained soldiers resulted in Berkenstadt et al¹⁷⁹ recommending that intramuscular drugs, administered via a CBRN auto-injectors, should replace attempts at gaining intravenous access.

In Paper 1, the speed and ease of LMA insertion noted whilst wearing CBRN-PPE^{43 166 168 169} in comparison with intubation may have occurred because the LMA is viewed as being an easier skill to complete, consistent with the recommendations for its use during CPR in the 2005²⁶⁴ and the 2010 ERC resuscitation guidelines.²²⁶ The easier insertion of the LMA is highlighted in Table 11, where the insertion times for the LMA second attempt compares favourably with the control group, thus demonstrating a rapid learning effect. By comparison, although the second attempt at intubation shows improvement over the first attempt, the time need to complete intubation is still nearly three times slower than the control group.

Table 12: Mean times to complete skills by professional grouping whilst wearing CBRN-PPE

Professional grouping	Low-dexterity		High-dexterity		Low-dexterity		High-dexterity	
	LMA Placement		Intubation		Intra-osseous cannulation		Intra-venous cannulation	
	Suited attempt 1	Suited attempt 2	Suited attempt 1	Suited attempt 2	Suited attempt 1	Suited attempt 2	Suited attempt 1	Suited attempt 2
Anaesthetist (n=15)	16.1	20.7	58.8	53.9 (0)	28.0	31.2	110.6	85.6
Emergency Physicians (n=25)	28.6	20.6	88.0	70.5 [3]	38.1	28.7	133.7	96.1
Paramedic/Resus Officer/prehosp doctor (n=24)	31.6	24.5	76.1	59.6 (0)	38.9	30.4	161.2	124.6

Adapted from Castle et al.⁴³

The degree of difficulty required to complete a skill is an important factor in its performance, but it would be overly simplistic to believe this is the only factor affecting time needed to perform a skill whilst wearing CBRN-PPE. Especially as all the participants, in Paper 1, were deemed competent in completing all the evaluated skills. It is noteworthy that all participants were observed to adapt the manner in which they subsequently performed skills between the first and the second attempt. This process of learning to adapt an established skill in a different environment highlights that skill improvement is multifactorial and goes beyond one technique being easier to perform than another.

3.8 Participants' perceptions of ease of skill performance whilst wearing CBRN-PPE

A questionnaire was used to measure participants' perceptions of the difficulties of performing intravenous cannulation, intraosseous access, LMA insertion and intubation (Table 13). The questionnaire was based on a five-point Likert scale which allowed participants to award a neutral score²⁷³, and was adapted from a questionnaire previously used to assess student paramedics' preferences regarding airway devices in a non-CBRN-PPE based study.²⁷⁴ Participants' graded the high-dexterity skills as being more difficult to complete than the low-dexterity skills. This finding reflects the prolonged completion times and minimal learning effect noted for high-dexterity skills. Intravenous cannulation, the most frequently undertaken skill by all of the participants in daily clinical practise, was regarded as being the most difficult to achieve whilst wearing CBRN-PPE due to the loss of finger-thumb dexterity and loss of sensation due to wearing CBRN gloves.^{167 170 187}

Table 13: Clinicians' assessment of the difficulty to complete skills whilst wearing CBRN-PPE

Clinician Assessment	LMA Placement		Intubation		Intra-osseous cannulation		Intra-venous cannulation	
	Rep.1	Rep.2	Rep.1	Rep.2	Rep.1	Rep.2	Rep.1	Rep.2
1 (very easy)	17	25	0	1	14	34	0	0
2	26	34	7	9	39	26	2	5
3 (neither easy nor hard)	20	5	13	24	7	3	12	22
4	1	0	26	26	4	1	17	20
5 (very difficult)	0	0	18	4	0	0	33	17
median (IQR)	2 (1, 3)	2 (1, 2)	4 (3, 5)	3 (3, 4)	2 (2, 2)	1 (1, 2)	5 (4, 5)	4 (3, 5)
Castle et al.⁴³								

3.9 Study limitations

The differing professional background of the participants in Paper 1 and their varying personal experiences introduces the potential for variation in skill completion due to varying professional competencies. However, as a key outcome of Paper 1 was to inform the design of a local CBRN-PPE skill-based simulation course, an understanding of the training needs across a range of clinicians, whose professional role involves responding to emergencies, was desired. Nevertheless, the impact of different professional groups and their abilities to perform clinical skills is an important consideration in future research design. For example, the selected skills in Paper 1 favoured the anaesthetists, whereas had different skills been selected a different professional group might have outperformed the anaesthetists. Whilst the variation in experience of skill performance, and its subsequent effect on skill completion times, may have affected the internal validity¹⁷² of Paper 1, it simultaneously helped to improve the external validity¹⁷² of the data we collected as, following a genuine CBRN incident, the 'ideal' clinician might not be immediately available.

Paper 1 was also designed to identify whether low-dexterity skills were easier to complete than high-dexterity skills whilst monitoring for any impact associated with skill repetition. The wide range of clinicians recruited into the research reported in Paper 1 facilitated subgroup analysis and allowed meaningful comparison between professional groups, which increased the generalisation of the results presented in Paper 1. Subgroup analysis indicated that daily

experience of performing a particular skill resulted in improved performance when performing the same skills whilst wearing CBRN-PPE.

For ethical, as well as practical reasons Paper 1 was a manikin-based simulation study using the Laerdal® Advanced Airway Trainer which has been identified as providing realistic airway simulation.^{275 276} However, study participants had varying experience of performing skills on manikins. Three of the consultant anaesthetists, for example, had never intubated a manikin, whereas the resuscitation officers were frequent manikin intubators, thus introducing a possible source of bias. Yet, despite the fact that the consultant anaesthetists had the least amount of experience in performing skills on manikins they were nevertheless consistently found to be faster at performing all skills on manikins.

One missed opportunity in Paper 1 was the lack of a pre-recruitment questionnaire that could have been used to evaluate perception of individual skill level and how difficult skills might be to perform whilst wearing CBRN-PPE. The results of such a questionnaire would have provided useful comparison data between pre-recruitment and post-recruitment perceptions of skill difficulties associated with wearing CBRN-PPE.

3.10 Clinical implications of results

Paper 1 confirms the negative impact of the NHS-CBRN-PPE on skill performance and demonstrates the presence of a learning effect, which is independent of any benefit to be gained from having previously worn CBRN-PPE during familiarisation training. Although anaesthetists performed all skills faster than non-anaesthetists, the fact that repetition improved skill performance for all participants indicates that clinicians can learn to perform skills whilst wearing CBRN-PPE. This is a reassuring finding as the availability of specialist clinicians may be limited during a mass casualty event.²⁷⁷ However, the lack of benefit to be gained from just wearing CBRN-PPE as part of familiarisation training, without actually practicing skill performance highlights the importance of including skills performance in CBRN simulation-training.

Considering that all study participants were deemed as competent at performing intubation, the high failure rate, whilst wearing CBRN-PPE, is of clinical concern. However, Paper 1 does indicate that both the Positube™ and a colorimetric end-tidal CO₂ detector can be used whilst wearing CBRN-PPE to detect an oesophageal intubation. However, no device for confirming correct ETT placement is 100% accurate²⁷⁸ and neither the Positube™ nor a colorimetric end-tidal CO₂ detector will detect a right bronchus intubation.^{226 279} Whereas the

potentially high airway pressures, following exposure to a chemical agent, may result in the Positube™ indicating an oesophagus intubation has occurred when the ETT is actually placed in the trachea.²⁷⁸ Therefore, the intubating clinician needs to be aware that wearing CBRN-PPE increases the risk of either a right bronchus or oesophageal intubation.

The overall incidence of right bronchus intubation was too small to analyse through subgroup analysis; however, it only occurred during intubation attempts made by non-consultants. McCoy et al²⁷¹ noted that haste in completing a skill and the inexperience of the intubator were common factors resulting in right bronchus intubation. Coupled with the results reported in Paper 1, this is clear indication that, wherever possible, intubation should be performed by the most experienced clinician and that this clinician should have had prior experience of performing intubation whilst wearing the NHS issued CBRN-PPE.

The EZ-IO was more effective at achieving vascular access than intravenous cannulation, but it was still affected by wearing CBRN-PPE. On observing participants using the EZ-IO this was primarily due to loss of dexterity associated with wearing butyl rubber gloves and not due to reduced vision secondary to the visor. This differs from the findings of Ben-Abraham et al¹⁶⁷ who reported that the gloves and the visor were both independent contributing factors when utilising the bone injection gun (BIG). The difference is likely to be due to the panoramic visor contained in NHS CBRN-PPE, which optimises vision¹⁸⁰, compared to the binocular design evaluated by Ben-Abraham et al.¹⁶⁷ Although the techniques to operate the BIG and the EZ-IO differ^{231 232}, and so this may have also had an impact on skill completion.

The evidence regarding vascular access confirms my belief that if emergency intravascular access is required during a CBRN incident, intraosseous access is the preferred route. On a practical basis an intraosseous device also provides more secure access to the intravascular circulation as accidental removal occurs less frequently than with intravenous cannulation²⁸⁰, as the intraosseous device 'self-secures' by going through the periosteum and into the cortex of the bone. Whereas an intravenous cannula has to be secured in place with tape, resulting in possible cannula removal during wet decontamination, as tape poorly adheres to wet, clammy skin²⁸¹ and is not very effective at preventing accidental dislodgement during patient movement.^{282 283} Furthermore 'peeling' adhesive tape from a roll requires finger-thumb dexterity^{189 252} which, as confirmed by Paper 1, is impaired by wearing NHS CBRN-PPE.

Whilst the benefits of using intraosseous access are clear the issue surrounding airway management is more complex as CBRN agents can cause pulmonary oedema, bronchospasm and increase upper airway secretions.^{82 147 148 249} Thus there are additional advantages to be gained from intubation^{74 222} especially as LMA insertion, when performed by inexperienced clinicians¹⁶⁹, was found to be slower than intubation performed by more skilled clinicians in Paper 1. Since the publication of Paper 1, the mass treatment pods and emergency equipment vehicles have been re-equipped and now contain supraglottic airways, intubation aids and end tidal CO₂ monitors for confirming correct ETT placement.⁹² These changes were based on consensus opinion.^{92 93}

3.11 The negative impact of loss of dexterity

Paper 2: Castle N, Owen R, Clark S, Hann M, Reeves D, Gurney I. Comparison of technique for securing the endotracheal tube while wearing chemical, biological, radiological, or nuclear protection: A manikin study. *Prehospital Disaster Medicine* 2010; 25 (6): 589–594.

Paper 2 investigates the impact of NHS CBRN-PPE on securing the ETT in situ following successful intubation, which is the final phase of airway management and represents an essential aspect of patient safety.²²⁶ Currently there are no standardised securing techniques and practice varies between clinicians.^{226 284} Paper 2 evaluates two different techniques that may be used to secure an ETT; the Thomas™ Tube Holder (TTH) and a cotton tie.

Although both techniques are used at the research site, the cotton tie is the preferred technique as it is the one used most commonly during elective anaesthesia. However, the technique for tying-in an ETT with a cotton tie differs between clinicians. The most common tying-in technique involves using a knot which is more secure than using a bow.²⁸⁵ The type of knot used appears to make little difference²⁸⁶, but any knot-tying technique will require the retention of finger-thumb dexterity and fingertip sensation.

3.12 Method

A crossover RCT design supported by semi-structured focused face-to-face interviews was adopted. The order in which the ETT was tied-in place and by what device was randomised, with a total of 75 participants being recruited using a convenience sample²⁸⁷ of clinicians undergoing CBRN training. Participants were instructed to secure an ETT in situ using either the TTH or a cotton tie. No instruction in how to use the cotton tie was given reflecting the lack of a standardised technique. The frequency in which the cotton tie is used at the research site, in preference to the TTH, created a bias in favour of the cotton tie. However, all clinicians had experience of using the TTH. No non-CBRN-PPE control arm was utilised.

Following data collection participants were invited, via email, to attend interviews to discuss their experiences of wearing NHS CBRN-PPE and attempting to secure an ETT in situ whilst wearing PPE. All interviews were completed within three months of initial recruitment into the study. These interviews formed part of an additional study intended to facilitate future

research design.^{52 53} A reflective purposive sampling technique was used^{91 172}, with a minimum of two anaesthetists, emergency physicians, paramedics, resuscitation officers, and prehospital care doctors being interviewed. The qualitative data was analysed by content.^{172 288-290} The maximum number of interviewees was flexible with data collection continuing until no new themes were identified.

3.13 Data analysis

To date, only Paper 2 and Luria et al²⁵⁰ have used an RCT to evaluate ETT securing techniques whilst wearing CBRN-PPE. Both studies demonstrated the superiority of the TTH and reported similar times for skill completion (Luria et al²⁵⁰ 26.64 vs. Paper 2 29.0 seconds). The time reported by Luria et al²⁵⁰ for using a cotton tie were slower (97.78 ± 21.85 seconds) than those reported in Paper 2 (58 seconds 95% CI 52.0-148.2), but this is likely to be due to the elaborate prescribed tying-in method used by Luria et al.²⁵⁰

Paper 2 did not consider whether clinicians from different professional groups differed in how fast they secured ETT in situ, as all the clinicians were deemed competent at securing an ETT in situ with either device. The reported times in Paper 2 for securing an ETT in situ with a cotton tie (58s 95% CI 52.0-148.2 seconds) are reflective of the data presented by Flaishon et al¹⁶⁹ for their surgical trainees (57 seconds ± 13), who were faster than the novice group (82 seconds ± 27) but slower than the anaesthetists (39 seconds ± 9). This indicates that having prior experience of securing an ETT in situ may improve performance. Regardless of this observation, the time reported in Paper 2 to secure an ETT in situ with the TTH, was still 10 seconds faster to complete than Flaishon et al¹⁶⁹ reported for anaesthetists when using a cotton tie (29.0 vs. 39 seconds). Furthermore, Flaishon et al¹⁶⁹ did not comment on the degree of security obtained with their tying-in method which is the primary function of tying-in an ETT.

Whilst the quantitative data supports the use of the TTH with regards to speed of skill completion and degree of security obtained, it cannot reveal why a particular technique is more effective. This is best achieved by recording the experiences and opinions of the clinician, which is best achieved through participant interviews.^{172 259 291}

A total of 25 participants were interviewed to determine their experiences of wearing the NHS CBRN-PPE and attempting to secure an ETT in situ with both devices. Interviewees consistently identified that the loss of sensation and finger-thumb dexterity, due to the gauge of the gloves, impaired their ability to use the cotton tie (Table 14). A similar loss of dexterity

and sensation did not affect use of the TTH. A number of participants stated that the design of the TTH appeared to reduce their reliance on dexterity for skill completion, allowing them to more effectively secure the ETT in situ.

Table 14: The impact of CBRN-PPE on securing an endotracheal tube in situ

Question	Reply
What did the suit feel like to wear?	Clumsy. Warm... a little bit claustrophobic. Big gloves. No finesse in the suit... it's all big movements.
How did you find securing the ETT with a cotton tie?	Impossible. Tying knots was absolutely impossible. Things got easier the second time... but not tying-in the tube with the cotton tie that was just impossible.
How did you find securing the ETT with the Thomas™ Tube Holder?	It was much easier. On the whole I found the mechanical device [TTH] very easy. It has a big screw you can grab hold off and turn... It's much easier to use than a cotton tie.
Adapted from Castle et al. ⁴⁴	

Although the quantitative data did not take into account whether different professional groups were better able to secure the ETT in situ, the qualitative data revealed that all professional groups found securing the ETT in situ using the cotton tie as being difficult. For example, an experienced anaesthetic trainee (over 5 years anaesthetic experience) stated that he found it difficult to secure the ETT with the cotton tie and much easier with the TTH, while, an ED consultant, with over 2 years anaesthetic experience, stated '*...That's the best I can do [when applying a cotton tie]... but I wouldn't accept it in my resuscitation room*'⁴⁴ demonstrating that the cotton tie inadequately secured the ETT. The inclusion of face-to-face interviews enabled the researcher behind Paper 2 to gain valuable insight into the complexities of skill performance whilst wearing NHS CBRN-PPE.

3.14 Limitation

The lack of a non-CBRN-PPE arm within Paper 2 prevents any comparison between wearing and not wearing NHS CBRN-PPE. Whilst it could be argued that such a comparison

may have been potentially useful, a recently published non-CBRN-PPE based RCT²⁹² by two of the researchers from Paper 2 demonstrated a clinically non-significant difference in the time to apply a cotton tie (mean 33.1 seconds standard deviation 8.6) over the TTH (mean 28.1 seconds standard deviation 8.2). Therefore, it is reasonable to conclude that the absence of a control arm did not affect the relevance of Paper 2.

The presence of a learning effect was not investigated in Paper 2, which represents a missed opportunity. However, considering that the times reported by Luria et al²⁵⁰ (25.6 seconds \pm 6.5) and by the authors of Paper 2⁴⁴ (29 seconds \pm 6.5) for securing an ETT with the TTH are similar to the times reported by Owen et al²⁹², in which no CBRN-PPE was worn (mean 28.1 seconds standard deviation 8.2), a study containing at least 442 participants would be required to detect a 10 second improvement gained via skill repetition. While the demonstration of a 10 second improvement in skill performance would no doubt be statistically significant the clinical significance of this finding would be debatable.

Paper 2 did not consider varying skill performance by the different professional subgroups recruited into the study. It is possible that some participants may have been more skilled at securing an ETT in situ than others, but considering all participants in Paper 2 were experienced at tying-in an ETT, any inter-professional difference is likely to have been minimal and of questionable clinical significance.

3.15 Clinical Implications of the results

By combining both qualitative and quantitative data, Paper 2 demonstrates that the TTH successfully achieves two fundamental elements of securing an ETT in situ, namely speed of skill completion and degree of security obtained. In contrast, the use of cotton ties was time-consuming and provided poor security from accidental ETT migration, thus proving to be a suboptimal securing technique. Nevertheless, the use of a cotton tie is a frequently taught technique²⁴⁰, reflecting the absence of any international guidance on how to secure an ETT once intubation is completed.²⁹² Thus while Paper 2 supports the use of TTH, the established 'custom and practise' of using a cotton tie²⁴⁰ is likely to be difficult to change. Consequently, any CBRN-PPE training programme, that incorporates intubation as a skill will need to highlight the difficulties associated with trying to secure an ETT in situ if clinical practice is to change.

3.16 What is the impact of patient position on intubation performance?

Paper 3: Castle N, Owen R, Clarke S, Hann M, Reeves D, Gurney I. Does position of the patient adversely affect successful intubation whilst wearing CBRN-PPE? *Resuscitation* 81 (2010) 1166–1171.

All the published studies to date, that have looked at airway management have ensured that the manikin, human volunteer or simian was positioned at the optimal height for performing intubation, thereby failing to consider the impact of the patient's position on airway management whilst the clinician is wearing CBRN-PPE. This omission is despite a number of non-CBRN studies highlighting the negative impact of patient position on intubation performance.²⁹³⁻²⁹⁷ This situation therefore reflects a gap in the literature as following a CBRN incident the most critically ill patients will be unconscious, in need of airway management and positioned on the floor.

3.17 Method

This was a manikin-based simulation study using a convenience¹⁷² sample of 75 clinicians attending CBRN training. Paper 3 utilised a crossover RCT supported by semi-structured, focused face-to-face interviews designed to investigate any adverse effect of manikin position on skill performance. Paper 3 was also designed to monitor for any benefit from having previously worn NHS CBRN-PPE, as well as to identify any continuation of learning from having performed intubation or LMA insertion twice whilst standing-up before transferring skill performance onto the floor. The requirement to monitor for the continuation of a learning effect between the two attempts performed whilst standing-up and the attempt performed on the floor, meant that the last skill performed (intubation or LMA insertion) always occurred at floor level.

To minimise the risk of introducing a bias, and in consideration of the fact that there is no approved technique for 'on-floor intubation', the participants received no direction in how to intubate on the floor. The recruitment of a mixed group of professionals facilitated sub-group analysis. Within three months of data collection participants were interviewed to explore their experiences of wearing CBRN-PPE and attempting airway skills whilst at the floor level.

3.18 Data analysis

Tables 15 and 16 demonstrate the adverse impact of attempting intubation with the manikin positioned on the floor whilst simultaneously demonstrating no impact on LMA insertion. A key finding of Paper 3 is that the learning effect achieved between the first and second intubation attempt (both standing-up) was reversed when intubation was performed at floor level (Table 15). This reversal of a learning effect did not occur with LMA insertion, which continued to improve between the first, second and third insertions.

The greater than four-fold time difference between LMA insertions on the floor compared to intubation on the floor (mean 20.9 vs.100.7 seconds), coupled with a 26% intubation failure rate, is clinically unacceptable. This finding is clinically significant as critically ill or injured patients requiring emergency airway management are usually hypoxic before intubation is attempted.²³⁷ Hypoxia will worsen during prolonged intubation attempts^{238 239}, and the need for more than one intubation attempt is associated with increased mortality and morbidity^{260 261}, whereas an oesophageal intubation will be rapidly fatal if not detected.^{263 298-301} Paper 3 challenges the appropriateness of attempting to intubate on the floor in the context of a CBRN incident and argues in favour of using the LMA as a viable alternative.

Table 15: The impact of patient position on intubation whilst wearing CBRN-PPE

Skill	Position	Successful (%)	Mean time (sec)	95% CI	Range (sec)	Failures (%)
Intubation	Standing 1st	68 (90.6)	70.3	62.5, 78.0	28.1-209.7	7 (9.4)
	Standing 2nd	72 (96)	59.1	53.2, 64.9	25.6-160.7	3 (4)
	Floor	55 (73.3)	100.7	88.4, 113.0	38.8-209.7	20 (26.6)
LMA	Standing 1st	75 (100)	25.7	23.8, 27.6	12.3-51	0
	Standing 2nd	75 (100)	21.5	20.1, 22.9	6.1-38.1	0
	Floor	75 (100)	20.9	19.5, 22.4	10.3-38.1	0
Standing equated to 'standing with manikin positioned at waist height' deemed to be the optimal intubation position, floor equated to 'manikin positioned on the floor' with intubator adopting an intubation position of their choice.						
Adapted from Castle et al. ⁴⁵						

The quantitative data demonstrates that the position of the manikin adversely affects intubation and the interview data demonstrates why skill reversal occurred (Table 16). During the interviews, the participants revealed that vision was unimpaired when standing-up and looking forward, thereby allowing intubation to be performed. However, when attempting intubation on the floor, the visor and the hood of the CBRN-PPE moved as the clinician leant forward, obscuring the intubator’s vision (Illustration 6 and Table 16). This was noted to occur amongst all intubators regardless of their intubating experience. It is further noteworthy, that experienced ‘on floor’ intubators indicated that the movement of the hood and visor interfered with intubation, even when adopting their preferred intubating position. However, despite the movement of the visor and hood also occurring during LMA insertion, this movement had no impact on skill completion. This was due to the LMA insertion technique, which is not dependent on being able to visualise the patient’s larynx.³⁰² Subsequently 92% (23 out of 25 interviewees) of the participants, who were interviewed, stated that during a mass casualty CBRN incident they would elect to use the LMA as their initial airway of choice, citing ease and speed of insertion.

Table 16: What are the opinions of clinicians’ attempting airway management on the floor whilst wearing the NHS CBRN-PPE?

Question	Reply
How was intubating on the floor?	<p>... Impossible.</p> <p>Difficult to get a good view [of the airway].</p> <p>Your vision is obstructed by the hood of the suit.</p> <p>It was difficult to know whether you should squat, kneel, lie down or sit and lean back.</p> <p>I tried lying down but it didn’t work so I tried kneeling up. I normally lie down to intubate on the floor .</p> <p>By the time I got the tube down the patient would have been in the morgue.</p>
What about LMA insertion on the floor?	<p>[LMA] It wasn’t any different; I just got quicker.</p> <p>It’s a gross motor skill [LMA], it’s easy to get in.</p> <p>The LMA does not require as much vision... it was the vision on the floor [with intubation] that was the main problem.</p> <p>After this study... I would go straight to an LMA if the patient was on the floor.</p>
Adapted from Castle et al. ⁴⁵	

Illustration 6: Intubation on the floor whilst wearing NHS CBRN-PPE

Note how the visor is tilted downwards with the non transparent hood moving forward to occlude the intubator's vision when attempting to intubate on the floor. This was universally commented on by all interviewees as the reason for failed on floor intubation.



The main theme to emerge from the interviews in Paper 3 was the impact of the NHS CBRN-PPE on vision, with none of the participants commenting on loss of dexterity associated with wearing gloves. Al-Damouk and Bleetman² similarly noted the movement of the visor but did not state what impact this had on the vision of the clinicians. Furthermore, interventions in this study were solely limited to decontamination procedures.

The degree to which the movement of the visor affected intubation at floor level was an unexpected finding in Paper 3, only becoming apparent during data collection. Movement of the hood and the visor is directly attributed to the design of the NHS CBRN-PPE and so is not something that a clinician is likely to learn to overcome during simulation-training. It does, however, further highlight the importance of practicing skills whilst wearing CBRN-PPE to enable clinicians to experience potential difficulties so they can adapt clinical practise. This is a key benefit of simulation-training.^{303 304}

3.19 Impact of prior experience

Paper 3 was also designed to explore any benefit from having previously worn the NHS CBRN-PPE. The results show a non-statistically significant improvement of 15 seconds in clinicians who had previously worn NHS CBRN-PPE with regard to intubation (*p-value* = 0.188 95% CI -37.9-7.8) but not with regards to LMA insertion (*p-value* = 0.903 95% CI -3.3-2.9). Considering that the prior experience of wearing NHS CBRN-PPE was solely limited to familiarisation training, and not skill-based training, any benefit identified in Paper 3 is likely to be due to chance. Particularly, as Paper 1 failed to identify any positive impact gained via familiarisation training across a range of clinical interventions.

The recruitment of a mixed group of clinicians facilitated inter-professional subgroup analysis, with Paper 3 reaffirming the importance of prior exposure on skill completion. Anaesthetists continued to perform all skills faster than non-anaesthetists regardless of manikin position, whereas prehospital clinicians were upwards of 30 seconds faster at performing intubation on the floor (128.6 vs. 101 seconds) with a higher success rate when compared to hospital-based clinicians.³⁰⁵ Whilst the difference between prehospital and hospital-based clinicians lacked statistical significance (*p-value* >0.1) the combination of lower failed intubation rate and faster intubation times would be clinically significant and warrants further investigation.

3.20 Was the study appropriately powered?

Although a power calculation was undertaken for Paper 3, the available data could only be used to estimate sample size for intubation or LMA insertion whilst standing-up. This is because Paper 3 is the first CBRN-PPE study to evaluate intubation performed on the floor. The application of regression analysis using 10,000 bootstrap samples confirmed that there was no correlation between prior wearing of CBRN-PPE and intubation performed on the floor. Therefore, whilst a larger sample size might result in a narrowing of the 95% CI for intubation performed on the floor, it would be unlikely to contradict the results reported in Paper 3.

From a clinical stand-point, the data in Table 15 shows a wide range of intubation performance times, with the most striking differences occurring between the first intubation attempt performed when standing-up and the third intubation attempt performed on the floor. It is noteworthy that if intubating position was not an independent factor then the third intubation attempt should theoretically have been faster, in accordance with the learning effect demonstrated in Paper 1. However, intubation attempts performed on the floor were not only slower than the first attempt whilst standing-up but also had a higher failure rate, demonstrating a reversal of any learning effect that had occurred between the first and second intubation attempt performed whilst standing-up.

3.21 Limitations

The data presented in Paper 3 and the subsequent subgroup analysis further emphasise the importance of taking into account the experience of individual clinicians when designing research. Nonetheless, as the main focus of Paper 3 was to observe any impact of manikin position on airway management by clinicians deemed clinically competent to perform intubation, no attempt was made to balance this study to reflect varying clinical backgrounds of the participants. However, as the majority of UK prehospital intubators are paramedics³⁰⁶³⁰⁷, the more pressing issue is identifying what is the optimal intubating position to adopt whilst wearing NHS CBRN-PPE.

It is feasible that a different design of CBRN-PPE could overcome the issue of the visor moving whilst attempting to intubate on the floor. Nevertheless, no other studies addressing this issue were identified during a literature search. Furthermore, any theoretical improvement that may be achievable in vision obtained, whilst attempting to intubate on the floor, with a different design of CBRN-PPE cannot detract from the fact that intubation on the floor is known to be more difficult^{237 293-295}, and that the concentration of numerous CBRN

agents will be higher at floor level. In addition the intended purpose of this thesis is to identify what airway and vascular skills can be performed while wearing the NHS issued design of CBRN-PPE.

An additional factor not considered during the recruitment of participants for Paper 3 and subsequent analysis of the data was the varying physical fitness of the participants. This is unlikely to have been an issue when performing skills whilst standing-up, but it may have had an impact on skill performance on the floor. However, any impact of physical fitness is likely to have been nullified by the fact that the commencement of intubation timing occurred at the time the clinician picked up the laryngoscope and not when they were settling into an intubating position. No participant reported issues with regards to mobility although a number of clinicians were unable to tolerate wearing the NHS CBRN-PPE due to claustrophobia and therefore could not complete CBRN training.

During the interviews, the participants expressed a high degree of frustration when attempting intubation on the floor, universally reporting difficulties with loss of vision, lack of manoeuvrability, and being uncomfortable whilst wearing the NHS CBRN-PPE. None of those interviewed identified loss of dexterity due to wearing the butyl gloves as an issue affecting skill completion. However, it is feasible that the high-level of frustration expressed due to the loss of vision and being uncomfortable may have obscured other recollections of the experience of intubating on the floor, which more focused questioning might have revealed.

3.22 Clinical implications of results

The reversal of the learning effect, the protracted intubation times and the high failure rate associated with intubating on the floor all challenge the effectiveness of this approach to airway management during a CBRN incident. The inappropriateness of intubating on the floor was further supported by the fact that 92% of interviewees stated that they would elect to use an LMA during a mass casualty CBRN incident. A further concern, associated with attempting intubation on the floor, is that it may represent a risk to the intubator due to high concentrations of CBRN agents at floor level and the possibility that the PPE could be damaged. Paper 3 does not attempt to ascertain whether there is an optimal on floor intubating position as currently each clinician develops his/her own technique for intubating on the floor. Paper 3 does, however, confirm that even experienced on floor intubators found that their preferred intubating positions were adversely affected by the NHS CBRN-PPE.

The key limiting factor with regards to intubation on the floor is the design of the NHS CBRN-PPE which impairs the intubator's vision. As intubation on the floor whilst wearing CBRN-PPE is at best a suboptimal technique, the immediate insertion of a LMA may represent a more appropriate emergency airway intervention during the response to a CBRN incident.

3.23 The role of dexterity in skill performance

Paper 4: Castle N, Bowen J, Spencer N. Does wearing CBRN-PPE adversely affect the ability for clinicians to accurately, safely, and speedily draw up drugs? *Clin Toxicol* 2010;48(6):522-27.

Paper 4 investigated the impact of the NHS-CBRN-PPE on aspirating drugs by comparing two prefilled syringes designed for use in emergencies (Aurum and Minijet) against plastic and glass ampoules. The aim of Paper 4 was to identify which technique was the fastest and most accurate, as well as to identify any potential safety issues (e.g. needle stick injuries) associated with using the selected drug presentations.

The techniques for aspirating drugs from the various drug presentations vary. The plastic and glass ampoules required the use of a needle and a syringe to aspirate the drug, while the Minijet prefilled syringe required assembly. The Aurum prefilled syringe comes already assembled but does contain a small air bubble which the clinician is required to dispel by engaging the syringe's plunger. Therefore, both prefilled syringes require some degree of preparation prior to drug administration. All four drug presentations are widely used throughout the NHS, and drug preparation represents a key aspect of drug administration which will need to be replicated during the treatment of contaminated casualties. However, during the literature review no studies looking at drug preparation whilst wearing the NHS CBRN-PPE were identified.

3.24 Methods

A crossover RCT design ensured that each participant acted as their own control, with the recruitment of a range of clinicians allowing subgroup analysis. Paper 4 was designed to monitor the interaction of CBRN-PPE on four different drug presentations, whilst monitoring for the presence of a learning effect. The wearing of CBRN-PPE or normal clothing, as well as the order in which drugs were aspirated from the different drug presentations, was randomised.

Performance was measured against time needed to complete the skill and, total volume of drug aspirated into the syringe (or remaining in the prefilled syringe post-assembly). The ease of use of each device and perceived risk of damaging the CBRN-PPE were assessed by questionnaire. The questionnaire data was collected on a 5-point Likert scale that allowed participant's to award a neutral score of 3.

The four drug presentations evaluated have not previously been investigated in the context of drug preparation whilst wearing the NHS CBRN-PPE. Therefore, data from Udayasiri et al²⁴⁸, who examined the impact of CBRN-PPE on preparing the Minijet prefilled syringes, and timings obtained from a pre-study pilot study involving five non-participating clinicians were used to inform the sample size. A power calculation indicated that a minimum number of 48 participants would be required.

The pilot study data identified that there was a risk of Type-1 error occurring during data analysis. This was due to the fact that the time required to prepare both types of prefilled syringes was very similar, but that the prefilled syringes appeared to be significantly faster to prepare than aspirating drugs from either the plastic or glass ampoules. Whereas despite, both the glass and plastic ampoules appearing to be slower to prepare than either of the prefilled syringes, the time required to aspirate drugs from either type of ampoule was in fact very similar to each other.

The differences in preparation time were due to the design of the prefilled syringes and the technique required to aspirate drugs from ampoules. For example, the Minijet prefilled syringe was presented in two halves which required assembly before a drug could be administered, whereas the Aurum prefilled syringe comes fully assembled but contains a bubble of air which the clinician needs to dispel before administering a drug. However, both the plastic and the glass ampoule required the clinician to break open an ampoule, attach a needle to a syringe before aspirating the contents into the syringe via the needle. All four drug presentations were presented in their sterile/protective wrapping requiring participants to remove all packaging as part of the drug preparation.

This marked difference in the time required to prepare drugs for administration between the prefilled syringes and the glass or plastic ampoules is further complicated by the similarities between the time required to prepare prefilled syringes and the time required to aspirate drugs from ampoules. In order to minimise this observed risk of a Type-1 error a *p-value* 0.01 was selected for the level of significance. The greatest risk that such an error could occur would be during the comparison of the two different prefilled syringes and comparison between the two presentations of ampoules.

An additional focus of the pilot study was to evaluate the effectiveness of a measuring beaker to record the amount of drug available from each drug presentation following aspiration. The pilot study demonstrated that some drugs effervesced when injected into a measuring beaker, making measurement unreliable. Subsequently, only prefilled syringes of adrenaline or ampoules of water were used during data collection, as neither preparation was noted to effervesce during the measuring process.

Although McDonald et al³⁰⁸ incorporated the aspiration 0.3 ml of adrenaline from a 1 ml ampoule (type of ampoule not indicated) in their CBRN-PPE study, they incorporated the time required to clean the skin of a manikin, as well as the time required to inject the drug in the overall time of skill completion. It is, therefore impossible to ascertain how long drug aspiration took in their study. Therefore the pilot study provided important insight into how best to design Paper 4.

Recruitment of participants for Paper 4 occurred over 5 days. An invitation to take part was extended to qualified emergency department nurses and paramedics undertaking post-graduate courses at a UK university, qualified nurse or paramedic lecturers and student paramedics. All student paramedics had documented competencies in drug administration. A total of 82 participants were recruited, further optimising the power of the study. Two nurses subsequently withdrew due to claustrophobia associated with wearing the NHS CBRN-PPE. The data from these two participants was incomplete and was excluded from analysis.

3.25 Data analysis

Preparation time needed to administer drugs from the four different drug presentations was found to widely differ between the four different drug preparations (Table 17). The results can be grouped into the prefilled syringes versus the ampoules, with the prefilled syringes always being the fastest to complete, regardless of wearing NHS CBRN-PPE. A generic learning effect was identified across all four drug presentations with the second attempt, whilst wearing CBRN-PPE, always being faster than the first attempt.

In addition to being fastest method, prefilled syringes were also regarded as being the easiest and safest drug presentations to use in comparison to the ampoules. With regards to the ampoules, plastic ampoules were deemed to be easier and safer to use than the glass ones.

3.26 Clinical background and speed of aspirating drugs

Subgroup analysis reaffirmed the importance of a clinician’s pre-enrolment experience. For example, emergency nurses were the fastest at aspirating drugs from glass ampoules, reflecting the frequency with which they perform this skill. The difference between clinicians using prefilled syringes was, however, negligible. The results of Paper 4 further support the hypothesis presented in Paper 1, as they indicated that a higher level of day-to-day skill exposure has a positive impact on skill performance whilst wearing CBRN-PPE.

One important finding of Paper 4 is that this positive impact of previous skill performance is not professionally based but appears to be directly related to the frequency a skill is performed during normal day-to-day clinical practice. The findings of Paper 4 reflect and reinforce the observations made Paper 1 where anaesthetists performed all skills faster, and with a higher success rate than non-anaesthetists. A similar benefit was also noted in Paper 3 where anaesthetists continued to perform intubation or LMA insertion faster regardless of manikin position. Furthermore, separate subgroup analysis of Paper 3, indicated that when all in-hospital clinicians were combined as a single group and compared with prehospital clinicians a statistically non-significant, but intuitive, trend for prehospital clinicians to intubate faster and with a higher success rate was observed.³⁰⁵ These are important observations as they indicate that expertise in a skill, obtained whilst not wearing CBRN-PPE, is transferable into the CBRN environment.

Table 17: Speed of aspirating drugs by device when wearing CBRN-PPE

Device	Time in seconds to draw-up drugs by device				
	Minimum	Lower quartile	Median	Upper quartile	Maximum
Aurum prefilled syringe	0.93	3.95	6.0	17.92	40.57
Minijet prefilled syringe	4.6	14.22	19.10	42.67	111.61
Plastic ampoule	13.91	33.05	51.02	138.62	235.88
Glass ampoule	17.03	49.13	71.10	171.1	255.1

Adapted from Castle et al.⁵¹

As Table 17 indicates prefilled syringes were faster to use than either of the ampoules, and that plastic ampoules were faster to use than glass ampoules. In addition, the Aurum prefilled syringe was faster to use than the Minijet as it required less assembling. The speed of use of the prefilled syringes is not unduly surprising as these devices are designed for use during emergencies, such as cardio-pulmonary resuscitation.

These results suggest that, from a clinical stand-point, it could be advantageous to combine drug administration using the fastest prefilled syringe (median 6 seconds) with delivery via the intraosseous route in order to improve patient survival rate in comparison to drugs being aspirated from glass ampoules (median 71.1 seconds). Notably, if we extrapolate the data presented by Vardi et al²⁰⁶ the additional 65 seconds saved by using the Aurum prefilled syringe would reduce the treatment time in the predicted survivor group from a mean of 180 seconds to 115 seconds. However, the impact this time-saving would have on survival is difficult to predict as Vardi et al²⁰⁶ do not outline the formula for estimating survival in their paper.

3.27 Accuracy of aspirating drugs

In a third of cases, a varying amount of drug volume (Table 18) was lost, but in two-thirds of attempts all 10 mls of drug was accurately aspirated. The loss of drug volume occurred most frequently with glass ampoules and least frequently with prefilled syringes (Table 18). The impact that this would have on patient management is debatable and would depend on the final amount of drug available for administration. However, on a number of occasions participants failed to aspirate any of the drug whilst wearing CBRN-PPE (Table 18) which would delay patient treatment as the clinician would be required to repeat the drug preparation process. The most reliable drug presentations were the prefilled syringes.

The performance of the two prefilled syringes differed slightly, with the Aurum prefilled syringe demonstrating the least amount of drug volume loss. This is due to the design of the Aurum syringe, which is presented fully assembled, whereas the Minijet system requires syringe assembly. During the assembly of the Minijet, a number of incidents occurred in which the operator over-screwed the ampoule into the body of the syringe, ejecting some of the drug volume. The amount of drug that was lost varied, but on one occasion nearly all the drug volume was lost. Excluding this incident from the data-set would have reduced the difference between the Minijet and Aurum syringe findings, but to have done so would have been inappropriate as this failure to assemble the equipment properly reflects what can happen during emergencies. The inclusion of this episode of volume loss, during drug aspiration, highlights the external validity and generalisability of the results presented in Paper 4.

Table 18: Aspirated drug volume by drug presentation

Device	Volume (mL) draw-up					
	Minimum	Fifth percentile	Lower quartile	Median	Upper quartile	Maximum
Aurum prefilled syringe	9.2	9.9	10	10	10	10
Minijet prefilled syringe	1.0	8.65	9.9	10	10	10
Plastic ampoule	0.0	8.5	9.5	9.9	10	10
Glass ampoule	0.0	7.65	9.45	9.9	10	10

Adapted from Castle et al.⁵¹

3.28 Ease of use and risk of CBRN-PPE damage

The questionnaire data for Paper 4 provides further confirmation that prefilled syringes were easier to use than either type of ampoule and that the plastic ampoules were easier to use than glass ampoules. The questionnaire data also indicates that glass ampoules, or the requirement to use needles to aspirate drugs were deemed the most likely factors to cause CBRN-PPE damage. This issue was emphasised during data collection as a number of participants cut their fingers when opening glass ampoules. Whereas puncturing of the protective gloves represents a varying, but generally low, risk of chemical contamination (depending on the agent and its concentration), it presents a greater risk of transmission of blood borne infection and localised trauma.

3.29 Limitations

To facilitate data collection, a 10 ml ampoule was selected for use, which is consistent with the volume contained in the commonly used prefilled syringe and some of the ampoules stored in the mass casualty treatment pods.⁹¹ Whilst this methodology is valid, it is possible that had we used a smaller-size ampoule (e.g. 1mg/ml atropine) the time to aspirate drugs might have been extended. This is based on the presumption that loss of finger-thumb dexterity and fingertip sensation while wearing NHS CBRN-PPE would cause even greater difficulty with manipulation of the smaller-sized 1 ml ampoule. Thus, Paper 4 may have under-estimated the 'real world' speed of aspirating drugs. Nevertheless, the benefit of using prefilled syringes is clearly demonstrated by this simulation study.

3.30 Clinical implications of results

It could be argued that the results presented in Paper 4 were predictable, but to date no previous study has attempted to evaluate the process of aspirating a range of commonly used drug preparations whilst wearing CBRN-PPE. This is despite the fact that the administration of some drugs, such as atropine, is integral to the management of patients following exposure to particular CBRN agents, such as sarin.^{17 74 220} Furthermore, the confirmation that day-to-day exposure of aspirating drugs from glass ampoules increases the speed of skill completion provides useful insight, as it was noted to occur in clinicians other than anaesthetists. These findings will help the development of CBRN simulation-training, as does the further confirmation that the learning effect is obtained through practice.

Prefilled syringes are clearly faster and more accurate to use than either glass or plastic ampoules, as reported within Paper 4. This finding may represent a clinical benefit with regard to the administration drugs used during the treatment of critically ill patients following a CBRN incident. A number of prefilled syringes are now stocked in the re-equipped mass casualty pods and emergency equipment vehicles.⁹³ However, the range of drugs available in a prefilled syringe is limited, resulting in a continuing need to aspirate drugs from ampoules for the foreseeable future.

Stockpiling of drugs for a major incident (regardless of the type) requires a fine balancing act between making drugs available in a timely manner and in adequate quantities^{222 309}, with due consideration to cost, particularly as the cost of stockpiling drugs may also be subject to scrutiny.³¹⁰ One very effective approach to minimising costs would be to change from the use of prefilled syringes to plastic ampoules.³¹¹

Safety of the attending clinician is also an important consideration. Paper 4 highlighted that clinicians felt that glass ampoules and the need to use a needle to aspirate drugs represented a risk of damaging the CBRN-PPE. The actual risk of injury when using glass ampoules can be demonstrated by the fact that 3 out of 80 participants cut their fingers when opening glass ampoules.

Chapter 4

Expanding the research question; ‘what airway and vascular access skills can be performed whilst wearing NHS chemical, biological, radiation and nuclear personal protective equipment’?

4.1 Introduction

The initial four Papers presented in this thesis confirmed that NHS CBRN-PPE impedes skill performance. However, these initial four studies evaluated a limited number of airway devices, based on those airway intervention used at the research site, this introduces a risk of selection bias.^{172 312 313} In addition to Papers 1 to 4 incorporating the potential risk of selection bias a number of confounding variables were also noted. Whilst at face value, this may appear to be a methodological flaw, in reality it reflects how the initial research hypothesis was generated using a combination of inductive logic, action research and reflective practice to answer a local clinical question. However, to further expand on the research question ‘*What airway and vascular access skills can be performed whilst wearing National Health Service chemical, biological, radiation and nuclear personal protective equipment?*’ additional airway management techniques need to be examined. Therefore, an approach to the selection of subsequent airway techniques for further evaluation that minimise the risk of selection bias^{172 312 313} was required. As well as amending the research design of subsequent studies to take into account of the confounding factors discussed within this chapter.

4.2 Optimising the selection of devices for further evaluation

The risk of selection bias affecting devices evaluated in subsequent research was mitigated by interviewing clinicians who had been recruited into the studies resulting in Papers 1 to 3. This allowed an expert panel of clinicians to identify the devices that were subsequently evaluated. Importantly, the recruitment of a range of clinicians from varying professional backgrounds ensured a breadth of opinions were captured, regarding which supraglottic airway devices and intubation aids clinicians felt would, or would not be suitable for use whilst wearing PPE. Furthermore, the interviews allowed the clinicians to verbalise their experiences of wearing the NHS CBRN-PPE. Qualitative techniques^{172 259}, such as interviews, are ideally suited for exploring clinicians experiences and opinions.²⁵⁹ In

addition qualitative techniques, can help to generate research hypotheses when there is limited data available.^{172 314}

Prior to the Papers presented in this thesis, there had been no interviews conducted with clinicians who had previously worn CBRN-PPE, in order to gauge their experiences and opinions. Consequently, the evaluation of airway techniques that have been conducted in other studies reflected the opinions of the research teams alone. And whilst expert opinion is valid, it is still not without risk of bias^{312 313 315} and may lack the insight of clinicians who have worn CBRN-PPE whilst attempting to perform clinical skills, and whom have had an opportunity to reflect on the experience.¹⁷⁴

4.3 Controlling for the impact of pre-enrolment skill

Although the recruitment of a non-homogenous group more accurately represents the range of clinicians who are likely to respond to a CBRN incident, the variation in clinical background introduces a confounding variable¹⁷², as a percentage of any variation in skill performance may be independent of the impact of the CBRN-PPE and simply reflect pre-enrolment expertise. Furthermore, higher levels of pre-enrolment expertise may improve a clinician's ability to adapt skill performance whilst wearing CBRN-PPE. As the purpose of this research was to concentrate on the impact of CBRN-PPE on skill completion, pre-enrolment skill was a factor that needed to be control for in subsequent research as it represents a confounding variable.

Control was achieved by recruiting participants from the same professional group into subsequent experiments. Therefore the experiments reported in Papers 7 to 9 recruited paramedic students, thereby ensuring similar levels of experience with regards to intubation, intubating on the floor and similar levels of experience of performing skills on manikins. Furthermore, these experiments were undertaken in South Africa where student paramedics are screened for claustrophobia as a prerequisite of rescue training.⁵⁰ This was an additional benefit of undertaking the research in conjunction with a South African university, as it was anticipated that this would help to minimise losing research participants as claustrophobia had previously been noted as an issue during data collection. Finally, moving data collection to South Africa ensured that the participants recruited into Papers 7 to 9 had not previously worn the NHS CBRN-PPE.

Furthermore, four Laerdal® Advanced Airway Trainers were purchased solely for the research project, thereby ensuring that all airway skills would be performed on the same make and type of manikin. The level of realism offered by various manikins can vary but the Laerdal® Advanced Airway Trainer has been proven to realistically replicate airway management.^{275 276} The purchase of new intubation manikins ensured that all the manikins were similar to intubate by eliminating any impact of manikin wear and tear on skill completion.

4.4 Challenges of participant recruitment and extended recruitment timelines

Data collection for Papers 1 to 3 utilised convenience sampling of participants attending CBRN training, whose clinical roles would include treating patients following a CBRN incident. A similar recruiting process was employed by Vardi et al.²⁰⁶

Convenience sampling offered both benefits and challenges. From a logistical stand-point, combining training with data collection provided a large pool of candidates, but as a number of candidates were simply attending out of interest, and were not in roles that would entail treating casualties following a CBRN incident, they were excluded from the study. The exclusion of these candidates protracted the data collection as these individuals still required varying degrees of CBRN-PPE training. At face value the exclusion of candidates infers that convenience sampling was not used, and whilst recruiting ‘all comers’ to the study would be reflective of true convenience sampling, as in Vardi et al²⁰⁶, the intended purpose was to selected clinicians who would be called upon to perform skills whilst wearing CBRN-PPE. Therefore by definition these clinicians had to have a minimal skill set in airway management and vascular access. However, as the sampling method did not target specific professional groups or clinical seniority (trainee vs. consultant) it is more representative of a convenience sampling technique than purposeful sampling techniques.¹⁷²

The main challenge, associated with the sampling technique used was that data collection for Papers 1 to 3 took over three months to complete, which introduced a potential risk of data contamination as there was no way of stopping candidates from sharing views of the research with future candidates for the study. This risk was further enhanced by the fact that the majority of the participants worked at the same hospital. This issue primarily affected the research reported in Paper 3, as protracted data collection provided candidates with an opportunity to discuss optimal intubating positions. The risk of data contamination, within Paper 3, was minimised by how the timing of intubation was measured. As all intubation timings commenced once the clinician had assumed his/her preferred position and had pick-

up the laryngoscope. The subsequent moving of data collection to South Africa enabled all data collection to be completed in one day. This facilitated the process of isolating participants who had completed the study from those about to take part. Thus, it was easier to prevent the possibility of past and future participants discussing the research process.

4.5 What supraglottic airway devices should be evaluated for use whilst wearing CBRN-PPE?

Paper 5: Castle N. Care after chemical, biological, radiation or nuclear events. *Emergency Nurse* 2010; 18 (7): 26-36.

Supraglottic airways are well-established devices for use in routine and emergency airway management, with a wide range of devices being commercially available.^{226 247 267}

Increasingly, supraglottic airways are used instead of intubation during emergency airway management as they are considered to be easier to insert than endotracheal intubation.²²⁶

^{247 267} And yet despite there being a wide range of supraglottic airways available only the LMA^{166 168 169}, the COPA¹⁸⁵ and the Intubating LMA³¹⁶ (ILMA) have been evaluated for use in a CBRN incident. Paper 5 was designed to ascertain what supraglottic airways should be further evaluated in a RCT, with the devices being identified through face-to-face interviews of an expert group of clinicians who had previously worn CBRN-PPE. Data was collected during the same interviews that informed Papers 2, 3 and 6 with data analysis and research methodology discussed in sections and 4.11.

4.6 Data analysis and results of Paper 5

The interviewees identified six supraglottic devices for further study, with all six devices having established roles in resuscitation.^{226 267} The LMA was the most popular device, having being recommended by 100% (25/25) of the interviewees; the Igel was the second most popular device, having been identified by 18 participants (72%) for inclusion or exclusion from any future RCT. The Laryngeal Tube Airway (LTA) and the Combitube were identified only twice, reflecting their limited use in the UK (Table 19).³¹⁷⁻³¹⁹ No interviewees identified the COPA and so it was excluded from subsequent studies.

Table 19: 'What supraglottic airways, intubation aids and devices for confirming endotracheal tube placement does your organisation provide for emergency out-of-theatre airway management?'

Service/hospital	Supraglottic airway device	Intubation aid	Confirmation of endotracheal tube placement	Comment
Ambulance (A)	Igel	Bougie	EtCO ₂ & Stethoscope	Newly qualified paramedics not allowed to intubate
Ambulance (B)	Igel	N/A	N/A	Intubation removed from paramedic practise 2012
Ambulance (C)	LMA	Bougie	EtCO ₂ & Stethoscope	LMA by paramedics only
Air ambulance (A)	Igel & ILMA	Bougie	EtCO ₂ & Stethoscope	All intubations done using a bougie regardless of predictive intubation difficulty
Air ambulance (B)	Igel	Bougie	EtCO ₂ & Stethoscope	All intubations done using a bougie regardless of predictive intubation difficulty
Hospital (A)	LMA	Bougie Styler	EtCO ₂ , posi-tube & Stethoscope	Reviewing the roles of the Igel
Hospital (B)	LMA	Bougie	EtCO ₂ & Stethoscope	Arrives in a specialist rucksack
Hospital (C)	Igel	Bougie	Stethoscope	EtCO ₂ under consideration
Hospital (D)	Igel	Bougie	Stethoscope	EtCO ₂ under consideration
Hospital (E)	Igel	Bougie	Stethoscope	EtCO ₂ under consideration
Hospital (F)	LMA	Bougie	Stethoscope	EtCO ₂ under consideration
Hospital (G)	LMA	Bougie	Stethoscope	EtCO ₂ under consideration
Hospital (H)	LMA	Bougie	Stethoscope	No data available
Hospital (I)	No reply	No reply	No reply	No reply
Hospital (J)	No reply	No reply	No reply	No reply
Ambulance service return rate was 100% and hospital return rate was 80%				
ILMA = Intubating laryngeal mask airways, EtCO ₂ = end tidal CO ₂				
Castle (2011). Unpublished email survey.				

Specific devices were identified for a number of reasons, with ease of use and familiarity being the most common reasons for recommendation. Personal preference also played a noticeable role, particularly with respect to the Igel, as number of interviewees expressed strong views for and against it (Table 20). The non-identification of the COPA, due to its limited use in the UK ³¹⁷⁻³¹⁹, is further confirmation of the importance that familiarity and experience have on recommending airway devices. Non-clinical factors, such as local policy, might also have affected which devices trainee clinicians chose to recommend. For example, if local policy did not favour use of a particular device then clinicians would lack exposure in its use, this can be highlighted by a comment from a trainee anaesthetists '*... I like it [Igel] but the bosses here don't so it's not used*'.

Despite the LMA being the most commonly recommended device for use during a CBRN incident, a number of interviewees challenged whether it would be able to effectively support ventilation in a patient with high airway pressures. This is a clinically relevant observation, as a number of CBRN agents cause increased airway pressures through various mechanisms, such as pulmonary oedema.^{74 82 147 148 236} Where interviewees identified this limitation, they recommend the LMA Proseal (PLMA) as an alternative, commenting on the design of the PLMA and indicating that it is more effective when ventilating patients with high airway pressures.²⁶⁷

The identification of specific benefits regarding airway devices, such as potentially improved ventilation with the PLMA, is one piece of valuable information drawn from interviewing clinicians, demonstrating how interviewees combined knowledge of different airway devices with knowledge of the clinical effects of a CBRN agent. A similar process was noted with regard to the ILMA, where clinicians identified its ability to facilitate endotracheal intubation^{198 226} as potentially useful when treating a contaminated patient.

Table 20: Qualitative data supporting intubation aids and supraglottic airways

Device	Supportive	Negative
Bougie	<p>'Essential equipment'</p> <p>'I don't intubate without a bougie'</p>	<p>'It's too fiddly'</p> <p>'You wouldn't feel the clicks as bougie the passes over the tracheal ridges'</p> <p>'It will be difficult to pick-up wearing thick gloves'</p>
Malleable intubating stylet	<p>'The stylet will give you a bit more rigidity'</p> <p>'Would make intubation a gross [motor] skill'</p>	<p>'They are traumatic'</p> <p>'They should never be used'</p> <p>'... horrible'</p>
Igel	<p>'You just push it in'</p> <p>'Easier to use than an LMA'</p>	<p>'I like it [Igel] but the bosses here don't so it's not used'</p> <p>'This [Igel] is terrible'</p>
LMA	<p>'I'm used to using them. We use them a lot [here]'</p> <p>'Quick and easy and many staff are trained to use them'</p>	<p>'... an LMA would not be able to deal with the high airway pressures'</p> <p>'I don't like the disposable ones'</p>
ILMA	<p>'You can put it [ILMA] in and then when things settle down intubate through it'</p>	<p>'I find it fiddly and it may be difficult wearing [CBRN] gloves'</p> <p>'Not as easy to use in real patients as it is on a manikin'</p> <p>'You have to use a syringe to inflate the cuff'</p>
LTA	<p>'I have used them a lot in Africa they are really easy'</p>	<p>No negative comments</p>
Combitube	<p>None</p>	<p>'This is like the unicorn of airway devices...'</p> <p>'it is obsolete'</p>

Adapted from Castle et al.^{52 53}

4.7 Limitations, clinical applications and discussion

The Limitations, clinical applications and discussion relating to Papers 5 and 6 are presented in section 4.16.

4.8 What intubation aids should be evaluated for use whilst wearing CBRN-PPE?

Paper 6: Castle N. A qualitative interview based study of clinician's opinions of what intubation aids should be used following a CBRN incident? *Journal of Paramedic Practice* 2012; 4 (4): 226-234

As demonstrated in Paper 1 and 3, wearing CBRN-PPE complicates intubation and yet the mass casualty pods initially excluded intubating aids.⁹¹ This situation was despite national²⁴²²⁴³ and international^{244 246 320} guidelines recommending the availability of intubation aids during emergency airway management.

To date, only Wedmore et al³¹⁶ have investigated the impact of intubating aids on improving intubation in a RCT whilst wearing CBRN-PPE. A limitation of this study, however, is that the participants did not wear CBRN-PPE gloves. Garner et al¹⁹² and MacDonald et al²⁰⁴ also provided intubation aids but in these studies there was no non-intubating aid control arm. This represents a gap in the available literature that Paper 6 is designed to explore, and represents a clinically relevant area for future CBRN-PPE research.

Paper 6 was designed to identify what intubating aids should be evaluated in a RCT, based on data obtained from interviewing clinicians who had previously taken part in the research reported in Papers 1 to 3. Data was collected during the same interviews that informed Papers 2, 3 and 5 with the recruitment strategy and the research methodology used to analyse these interviews discussed in detail in sections 4.10 and 4.11.

4.9 Data analysis and results of Paper 6

As noted in Paper 5, interviewees expressed strong opinions for and against particular intubation aids, with a number of participants expressing a particular dislike for stylets, which are rarely used during adult intubation in the UK. The bougie was recommended by 92% (23 out of 25) of interviewees in accordance with its status as the principle UK intubating aid (Table 19).^{242 243} These observations provide support for the findings in Paper 5 regarding the impact of individual experience, familiarity and personal opinion on which devices were recommended by interviewees for inclusion in a future RCT.

Although the bougie was a popular choice with the majority of interviewees, a number of clinicians indicated that its use may be adversely affected by the loss of dexterity and sensation associated with wearing CBRN gloves (Table 20, 21). Two interviewees

highlighted that the NHS CBRN-PPE gloves would make it difficult to picking up the bougie, with one consultant anaesthetist remarking that the bougie needed to be thicker if it was going to be used whilst wearing NHS CBRN-PPE. Currently, however, a thicker bougie is not commercially available.

In addition to commenting on the impact of loss of dexterity, two interviewees stated that the loss of sensation due to the gauge of the NHS CBRN-PPE gloves would prevent the wearer feeling the 'clicks' as the bougie passed over the tracheal rings, thus eliminating one of the ways a bougie helps to confirm that it has been correctly placed into the trachea.^{240 321} These are important observations, as the bougie has recently been incorporated into the mass casualty pods, plus the bougie is recommended for use during all prehospital intubations²⁴³ as well as for use during difficult or failed intubation attempts.²⁴²

Some clinicians also thought that the use of the ILMA might be affected by the loss of dexterity associated with wearing gloves, while others indicated that the ILMA would help overcome dexterity issues. Both opinions are actually valid. During the interviews, a consultant and a trainee anaesthetist postulated that the main issue would be removing the ILMA over the endotracheal tube once the patient had been intubated, describing this process as '*fiddly*'. These remarks resulted in the recommendation that the ILMA should be left in place once intubation had occurred, leaving the endotracheal tube positioned in the ILMA. Such an approach would allow the removal of the ILMA to be delayed until after the patient had been evacuated to a safe environment where CBRN-PPE could be removed, thus negating any issues regarding dexterity. These useful observations further demonstrate the benefit of conducting face-to-face interviews to explore opinions about the use of emergency equipment.

Whilst the stylet was disliked by the majority of UK clinicians, it was popular with clinicians who had received their intubation training outside of the UK, consistent with international variation that exists with regard to the use of intubating aids.^{50 245 246 320 322} There were some UK trained clinicians who felt that the unique properties of a stylet might improve intubation, in the context of a CBRN incident, (Table 20) by reducing the degree of dexterity required to complete intubation.

Table 21: Clinicians' description of wearing NHS CBRN-PPE

Device	Statement or sentence
PPE	'Hot' 'Clumsy' Restricting and uncomfortable'
Gloves	'They are too big or too small' 'It's like trying to tie shoe laces wearing ski gloves' 'You loss all fingertip sensation'
Vision	'Hood gets in the way when you lean forward' 'Visor does not move with your head' 'It's ok when looking forward' 'it is better than the military respirator'
Adapted from Castle et al. ^{44 45 52 53}	

The remaining devices, (Airtraq™ and McCoy laryngoscope) were recommended for evaluation as the interviewees felt that the design of these devices would optimise visualisation of the patient's epiglottis. With the exception of the Airtraq™, all of the devices identified during the interviews were established intubation aids. The Airtraq™, however, was a relatively new device, and at the time of the study it had been heavily marketed. It is feasible that this marketing may have influence the interviewees, adding an external bias.

A number of non-intubation aids were also identified, including making a second clinician available to assist the intubator and optimising the position of the patient prior to attempting intubation. The availability of an assistant trained to assist with intubation reflects UK prehospital intubation guidelines.²⁴³ In addition to the provision of an assistant and consideration to the correct positioning of patients, two clinicians thought that the packaging of the intubation aids would be difficult to open whilst wearing NHS CBRN-PPE, due to the loss of dexterity and sensation from the gloves. These two clinicians recommended that, ideally, the bougie and/or a stylet should be pre-positioned in the ETT as part of the packaging of these devices. Whilst such an arrangement is not commercially available, it nevertheless remains a valid point. These observations further demonstrate the benefit of conducting face-to-face interviews.

The positive impact of training, the type of training provided and its frequency were commented on by a number of interviewees. Training during simulated CBRN emergencies is likely to be an important factor in responding to real CBRN incidents as all of the participants in Papers 1, 3 and 4 were noted to improve skill performance with practice.

During the face-to-face interviews, a number of participants suggested that this was due to participants learning how to adapt to wearing CBRN-PPE, with one commenting ‘... *You have to learn to do things clumsily*’. Notably, skill improvement occurred in all professional groups. It was also observed to occur for those clinicians who had previously worn CBRN-PPE as part of PPE familiarisation training, but not skills based training. This latter finding highlights that clinicians need to practise skills, whilst wearing CBRN-PPE, if they are going to function effectively during a CBRN incident. The importance of realism is already well established in military CBRN training²⁰ and is integral to how the Israeli civilian emergency services prepare for responding to a CBRN incident.⁶⁸

4.10 Limitations, clinical applications and discussion

Limitations, clinical applications and discussion of both Paper 6 and 5 significantly overlap and are presented in section 4.16.

4.11 The benefit of interviews in generating research hypothesis

Face-to-face interviews have a specific role in hypothesis generation in new fields of academic enquiry.^{172 259 314 323 324} This is particularly pertinent to the development of our understandings of performing resuscitation skills whilst wearing the NHS CBRN-PPE as prior to the Papers presented in this thesis no other studies have addressed this question. All of the airway devices and intubating aids identified in Paper 5 and 6 are consistent with best practise guidelines^{242 243} and current UK practise (Table 19)³¹⁷⁻³¹⁹, thus highlighting the clinical creditability of the interviewees

Therefore the interviews contained in this thesis achieved a number of goals that include the generation of a list of supraglottic airway devices and intubation aids for further evaluation.³²⁴ They also provided insight into what the NHS CBRN-PPE felt like to wear, particularly when attempting to perform clinical skills and provide clinicians an opportunity to express why they thought a particular airway technique would, or would not work in the context of a CBRN incident. These insights can only be obtained by interacting with clinicians³¹⁴ who have worn the NHS CBRN-PPE whilst attempting to perform a range of skills and represents a key rationale for including interviews in this thesis.

4.12 Analytical process of the interviews contained in Papers 5 and 6.

No maximum number of interviewees was set, with interviews continuing until no new themes were forthcoming. The participants interviewed in Papers 5 and 6 represent a purposeful sample¹⁷², as they all had a minimum skill set (able to intubate, insert and LMA, perform intravenous cannulation and use the EZ-IO device) that would result in them having to treat patients following a CBRN incident and they all had experience of performing a range of skills whilst wearing CBRN-PPE.

To ensure that all recruited professional groups were represented in the interviews a minimum of two clinicians from each of the professional subgroups were recruited. The decision to recruit, a minimum of two clinicians from each professional group was based on the fact that this represented 50% (n =4) of the prehospital care doctors recruited into Papers 1 to 3. It was anticipated that recruiting more than two prehospital care doctors would be difficult as they were not based at the research site, but worked instead part-time for the local ambulance service or, the air ambulance service, as well as being local general practitioners. Two interviews were therefore judged to be sufficient as a minimum number to gain insight into the experiences of the prehospital care doctors.

The interviewing technique was based on focused, open-ended questions which allow interviewees an opportunity to expand on their answers whilst providing an opportunity for the interviewer to delve deeper into the interviewees responses.¹⁷² These are both essential elements of obtaining data through interviews.³²³

Analysis of the interviews was based on an inductive approach to data analysis, as recommended by Elo and Kyngäs²⁸⁹, since this is an ideal technique to employ when there is little available data regarding the research question. Interviews were analysed using content analysis²⁸⁸⁻²⁹⁰, which is ideally suited to analysing written data.^{288 324} The technique of manifest content analysis was utilised, which focused on counting the frequency with which a device was identified by an interviewee.²⁸⁹ Whilst it could be argued that the approach taken of counting content, is more indicative of quantitative analysis than qualitative analysis^{289 325} this approach to analysing quantitative data is supported by Morgan.²⁸⁸

Whilst accepting that manifest content analysis represents an unsophisticated and basic approach to data analysis, it nonetheless facilitated the identification of a range of devices and the frequency with which these devices were identified, and thereby helped us achieve the key aim of Papers 5 and 6. Data analysis was further supported by listing specific

comments about individual devices, highlighting why an interviewee felt a particular device would, or would not work when wearing CBRN-PPE. Direct quotes were also used to convey opinions of interviewees regarding what NHS CBRN-PPE felt like to wear and how it impacted on skill performance.

4.13 Ensuring data reliability

Face-to-face interviews contain an inherent risk of bias^{172 326}, especially if the interviewer is tempted to steer the interview in order to achieve a particular answer.³¹³ Safeguards were put in place to minimise this risk, which included, using checklist of key questions to ensure that the key questions were consistently asked across all interviews. All interviews were digitally recorded and were played back at the end of the interview, this ensured that no leading questions were asked and facilitated the early identification of developing themes. A reflective journal was also maintained during the interviews, which enabled the interviewer to remember the context of the interview, environmental issues (such as background noise or distractions) and specific issues outside of the original research question that represented potential new areas of research enquiry (e.g. triage). These techniques are all recognised approaches to optimise data accuracy.^{172 323 326}

4.14 Achieving balanced interview recruitment

The use of purposive sampling techniques^{172 327} ensured that participants from each subgroup of professionals took part in the interviews. Interviews continued until the minimum number of participants (n = 2) from each professional subgroup were recruited. However, due to protracted timelines in trying to recruit the prehospital care doctors, consideration was given to excluding them entirely from the interview process. In the end, this step was not taken as it could have biased the results towards the opinions of hospital-based clinicians as well as losing the unique point-of-view of the prehospital care doctors. The experiences of the prehospital doctors are particularly valid, as they have specific roles during major incidents, to include medical scene management, triage and treatment of critically ill/injured contaminated casualties. In addition one of the prehospital care doctors was a medical director of a national ambulance service who was also involved in the development of national CBRN policy and thus a key informant.

4.15 Discussion and implications for clinical practice

A key finding of both Papers 5 and 6 was how personal preference and prior experience influenced the frequency a device was recommended for use when treating contaminated patients. The development of personal preference is likely to be multifaceted but, previous exposure^{328 329}, brand loyalty^{330 331} and habit^{253 254} are well established contributing factors to the development of personal preference, as are ease and speed of use^{274 332 333}, whereas comfort and product effectiveness represent more generic reasons for the development of preference.^{329 334-339} However, these differences may be based on perception as opposed to fact.³⁴⁰ Regardless of how personal preference develops, Papers 5 and 6 clearly demonstrate that it can be an influential reason for a clinician choosing device for use when treating patients. Furthermore, it can also result in the development of local policy, as noted by comments from trainee anaesthetists (section 4.6) regarding the availability of the Igel at the research site. Notably, Papers 5 and 6 are the first CBRN-PPE based studies to consider what would influence a clinician's choice of skills to perform during a CBRN incident.

Although the impact of personal preference is not surprising, it is noteworthy that it was affected by day-to-day clinical practice beyond the experiences of wearing CBRN-PPE. In some instances, this resulted in a clear prejudice towards a particular device, with strong terms such as '*hate*' and '*never*' being utilised. Furthermore, personal preference and prior experience is likely to have impacted on the initial and subsequent re-equipping of the mass casualty pods, which was based on expert-generated, consensus-based opinion.^{92 93}

The findings contained in Papers 1 to 6 also demonstrate the importance of simulation-based skill training. As earlier noted, interviewees recount how they learned to adapt skills perform whilst wearing CBRN-PPE, with even experienced clinicians learning to perform skills faster with practise. From the findings of these six Papers it is possible to conclude that training provides clinicians with an important insight into the impact of CBRN-PPE on skill performance, enabling them to adapt skill performance in response to the complexities associated with wearing the NHS CBRN-PPE.

Another important finding of the interviews, which pertains to the positive impact of experience gained through wearing CBRN-PPE during skill-based training, is how clinicians can combine their experiences of attempting to perform skills whilst wearing CBRN-PPE with their knowledge about individual supraglottic airways and intubating aids. This resulted in a number of interviewees challenging the appropriateness of established devices (e.g. bougie) for use during a CBRN incident. Nonetheless, it would be reasonable to assume that experienced clinicians may be reluctant to accept at face value research findings that

challenge their established beliefs about the effectiveness of a particular device, especially if the device in question is widely recommended for clinical use. However, through the process of clinicians experiencing for themselves the specific difficulties of performing skills, it is hoped that clinicians will be more amenable to changing their clinical practice. These concepts of learning, relearning and maintaining skills through simulation have been adapted from the aviation industry, where critical skills are practised in simulators under 'peer' observation. Increasingly, these same concepts are being applied to healthcare education²⁵⁷³⁴¹⁻³⁴³ with simulation playing a particularly strong role in training anaesthetists³⁴⁴⁻³⁴⁶ and emergency physicians.^{258 347}

From the standpoint of responding to a CBRN incident and the provision of emergency equipment, identifying the impact of personal preference and the existence of preconceived ideas about the effectiveness of particular devices is an important consideration. This is particularly true in the case of mass casualty pods, which cannot possibly contain all conceivable makes of supraglottic airway devices or intubating aids. Therefore, the research contained in this thesis indicates that clinicians should have an opportunity to practice using the devices they will be expected to use during an actual CBRN incident during simulation-based CBRN training.

4.16 Limitations with this research

The face-to-face interviews achieved their primary role of providing a spring-board for further research⁵⁴⁻⁵⁶, and furthermore provided an understanding as to why skills are difficult to perform whilst wearing the NHS CBRN-PPE. The interviews also facilitated the identification of a range of supraglottic airway devices and intubation aids, without repeating the risk of selection bias that may have occurred in Papers 1 to 4.

Although purposive sampling^{172 327} ensured that a range of clinicians were recruited for interviews, more hospital clinicians (e.g. anaesthetists) were recruited than prehospital clinicians (paramedics and prehospital care doctors). Theoretically, this could have biased the results in favour of the opinions and experiences of in-hospital clinicians'. However, such a bias was not detected since the LMA, and the bougie were identified by all clinicians whereas the Combitube, the LTA and the stylet were equally identified by hospital and prehospital clinicians.

4.17 Conclusion

Papers 5 and 6 were designed to enable further research, which is presented in Papers 8 and 9. More specifically, Papers 5 and 6 were designed to ascertain what CBRN-PPE felt like to wear and why clinicians believed that a particular skill would be feasible or difficult to perform whilst wearing NHS CBRN-PPE. Across the interviews conducted for Paper 5 and 6, the impact of personal preference and prior experience on recommending devices for further evaluation was identified, with many clinicians expressing strong preconceived ideas about certain devices. Whilst this finding is not particularly surprising, it is nevertheless an important observation as it will influence how future training is structured and perhaps provide the rationale for why certain devices are chosen for use following a CBRN incident.

Papers 5 and 6 also highlighted that clinicians challenged these preconceived perceptions once they experience the restrictive nature of wearing CBRN-PPE, and that clinicians learnt to adapt skills, even established skills, with practice. This learning effect occurred across all grades of clinicians (from trainee to consultant) as well as across all professional groups. The ability of clinicians to rapidly learn to adapt skills and to challenged ideas about what will and will not work when wearing CBRN-PPE further demonstrates the importance of ensuring that CBRN simulation-training is as realistic as possible.

The interviews also raised interesting questions about specific devices such as the Igel, the LTA, PLMA, and also the bougie and the stylet, with these questions addressed in the research design of Paper 8 and 9. The data in Paper 5 raised another interesting question as to whether all the supraglottic airways recommended for evaluation are truly interchangeable, since the devices are likely to differ with regards to ease of insertion as well as offering differing ventilating properties.²⁶⁷

Chapter 5

Is there an optimal strategy for airway management whilst wearing CBRN-PPE?

5.1 Introduction

The final three Papers presented in this thesis focus on airway management whilst wearing the NHS CBRN-PPE and attempt to identify an optimal airway management strategy. Paper 7 builds on the findings of Paper 3 by investigating whether there is an optimal position to adopt when attempting to intubate on the floor in the context of a CBRN incident. Paper 8 evaluates a range of supraglottic airway devices to ascertain their ease and speed of insertions, and Paper 9 evaluates a number of intubating aids to see if these devices improve intubation whilst wearing NHS CBRN-PPE. All the devices evaluated in Papers 8 to 9 were identified during the interviews outlined in Papers 5 and 6. With the exception of the LMA^{166 168 169} and the ILMA³¹⁶, none of these devices have previously been evaluated for use whilst wearing CBRN-PPE demonstrating a gap in the published literature.

Papers 7 to 9 restricted recruitment to South African student paramedics. This change in recruitment strategy from mixed clinicians to a clinician-specific group of participants was undertaken to strengthen the internal validity of the results, as by recruiting student paramedics Paper 7 to 9 ensured similar levels of intubation experience and that participants had not previously worn NHS CBRN-PPE. Papers 7 to 9 therefore focus solely on the impact of the NHS CBRN-PPE on skill completion by excluding any variation in skill performance associated with professional background or clinical seniority. This more exclusive focus represents a change in research methods from those adopted in Papers 1 to 4 and is based on the subgroup analysis of Papers 1, 3 and 4.

5.2 Is there an optimal on floor intubating position?

Paper 7: Castle N, Pillay Y, Spencer N. What is the optimal position of an intubator wearing CBRN-PPE when intubating on the floor: A manikin study. *Resuscitation* 2011; 82: 588-592

Paper 3 concluded that attempting to intubate on the floor whilst wearing NHS CBRN-PPE represented a suboptimal airway management strategy. As part of Paper 3, 25 clinicians were interviewed to ascertain their experiences of intubating manikins on the floor whilst wearing CBRN-PPE. Three of the interviewees recommended delaying intubation until the patient was removed from the floor and positioned on an ambulance trolley, whereas 23 (92%) indicated that following a mass casualty CBRN incident, they would elect to use an LMA, citing ease and speed of use as the main rationale.

Paper 3 did not consider, however, whether any one of a number of different on-floor intubating positions would prove to be more effective at facilitating intubation than intubation performed on an ambulance trolley. Subsequently, Paper 7 was designed to explore this question by evaluating intubation performed in a sitting; kneeling and lying position compared to intubation with the manikin placed on an ambulance trolley elevated 60 cm from the ground. The on-floor intubating positions were based on observations made during Paper 3 and have also been described in the literature^{293 295 348-350}, whereas intubating on an ambulance trolley was based on the findings of Paper 6 and is additionally supported by Lockey et al.²⁴³

5.3 Methods

For Paper 7, a power calculation indicated that the minimum number of participants required to achieve statistical significance was 24. Forty-eight paramedic students were entered into a crossover RCT which included a non-CBRN-PPE control arm. Each aspect of the study was randomised, including which skill was performed in what order and whether CBRN-PPE was worn on the first or second attempt, thereby minimising any impact associated with a learning effect or fatigue. All data collection was completed in one day and participants were isolated from each other to prevent the sharing of tips on how to complete skills whilst wearing CBRN-PPE.

5.4 Data presentation and analysis

Paper 3 reported mean completion times for skill completion (section 3.18) and this data was further supported by interviews, whereas, Paper 7 reports mean intubation times and intubation completed in pre-determined timeframes. The rationale for using pre-determined cut-off times is based on the findings of Davies et al²³⁷, who noted that patients requiring prehospital intubation were already hypoxic and prolonged apnoea is known to worsen clinical hypoxia.^{238 239} Therefore, each timeframe represents an increasing period of apnoea, with the aim being for intubation to be completed in 60 seconds²³⁸ but, ideally, within 30 seconds in accordance with the 2005 ERC guidelines.²⁶⁴ A time limit of 30 seconds to complete intubation has previously been used by Coates et al¹⁹¹ as a measure of successful airway management whilst wearing CBRN-PPE.

When wearing ambulance uniform, the kneeling position resulted in the highest number of intubation attempts completed in 30 seconds (Table 22), which is to be expected as the kneeling intubating position is popular amongst paramedics.²⁹³ At 45 seconds, intubation on an ambulance trolley had surpassed kneeling in terms of completed intubation attempts, with both positions achieving parity at 60 seconds. When monitoring the mean intubation times for successful intubation attempts whilst wearing ambulance uniform (Table 23) all four positions achieve similar mean intubation times.

None of the intubating positions, with the participant wearing ambulance uniform, was 100% successful at the 120 seconds cut-off time. However, this finding was based on a single participant in each of the kneeling, sitting and intubation on the ambulance trolley groups failing to complete intubation by 120 seconds and two participants in the lying group. If these outliers are removed, then 100% of intubation attempts on a trolley or kneeling were completed in 60 seconds with the remaining positions being completed in 90 seconds.

Conversely, when intubation is attempted using the same four intubating positions whilst wearing the NHS CBRN-PPE a negative impact on success rate and intubation speed was observed across all four positions (Table 22). As highlighted in Table 22 this is most noticeable when measuring the number of intubation attempts completed in 30 seconds. However, intubation on an ambulance trolley demonstrated rapid improvement between 30 and 45 seconds, with a 100% successful intubation rate by 60 seconds. The kneeling and sitting groups also improved between 30 and 45 seconds, but by 60 seconds less than 80% of intubation attempts had been successfully completed. The sitting and lying positions prove even more difficult to master, as demonstrated by the 95% CI (Table 23) and associated outliers (Figure 3).

Table 22: Intubation success in predetermined time-bands

Position		Intubation completed – presented as a %				
		30s (%)	45s (%)	60s (%)	90s (%)	120s (%)
No	Trolley	56.2	95.8	97.9	97.9	97.9
	Lying	56.2	87.5	93.8	95.8	95.8
PPE	Kneeling	66.7	93.8	97.9	97.9	97.9
	Sitting	58.3	91.7	95.8	95.8	97.9
CBRN-	Trolley	14.6	72.9	100	100	100
PPE	Lying	0.0	22.9	43.8	60.4	62.5
	Kneeling	8.3	47.9	79.2	81.2	81.2
	Sitting	16.7	50.0	75	77.1	81.2

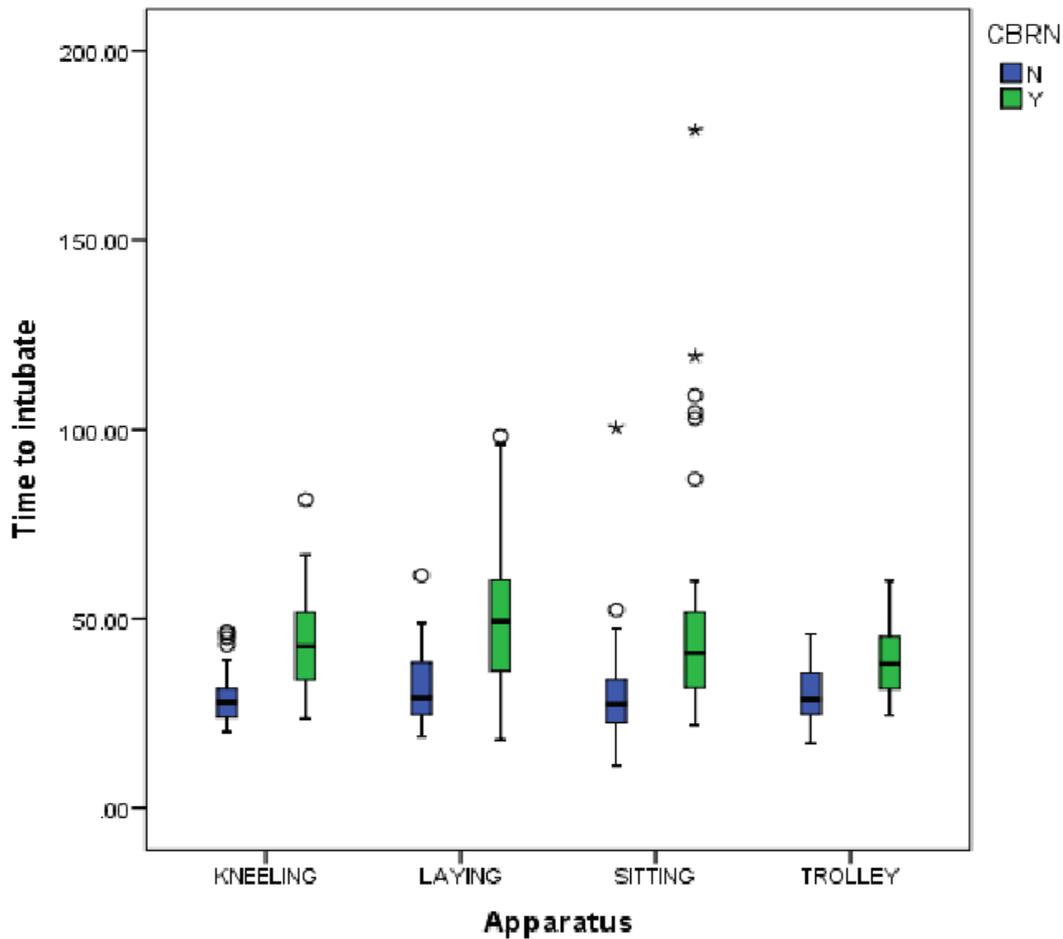
Castle et al.⁵⁴

Times needed to complete intubation, when performed on an ambulance trolley or in the kneeling position, whilst wearing CBRN-PPE, were similar with the mean difference being less than 4 seconds (Figure 3 and Table 23). However, we observed a clinically significant difference in success rate, with 100% of intubation attempts on the ambulance trolley being successful, compared to only 81% of attempts performed by the same cohort of participants in the kneeling position. Even though all four positions in Paper 7 had faster intubation times than those reported in Paper 3 (Table 23) there is still a detectable reversal in intubation performance when wearing CBRN-PPE. The resulting on floor intubation failure rate remained high, which confirms the negative impact of the NHS CBRN-PPE on intubation and further highlights the importance of confirming ETT placement. The movement of the visor and the resulting obstructed vision continued to be an issue when intubating on the floor, which is consistent with the findings of Papers 3 and 6.

Table 23: Time to complete intubation by position

Position	CBRN Suit Used?	Total successful attempts	Mean (secs)	SD	95% CI for mean	Total ETT resulting in oesophageal placement (as a %)
Trolley	No	47 (98%)	30.04	7.18	(27.95, 32.12)	Total 1 (2%)
	Yes	48 (100%)	39.42	9.44	(36.68, 42.16)	Total 0 (0%)
Lying	No	46 (96%)	31.37	9.10	(28.67, 34.07)	Total 1 (2%)
	Yes	30 (62.5%)	56.07	19.68	(48.72, 63.41)	Total 9 (18.7%)
Kneeling	No	47 (98%)	29.02	6.65	(27.06, 30.97)	Total 1 (2%)
	Yes	39 (81%)	42.56	11.52	(38.83, 46.29)	Total 5 (10.4)
Sitting	No	47 (98%)	30.14	13.41	(26.20, 34.08)	Total 1 (2%)
	Yes	40 (83%)	48.15	29.27	(38.79, 57.51)	Total 6 (12.5%)
Times from Paper 3: Only intubation times on the floor are reported as there was no prescribed on floor intubating position						
Floor various positions	Yes	55 (73.3%)	100.7	Not reported	(88.4, 113.0)	Total 9 (12%)
Adapted from Castle et al.^{45 54}						

Figure 3: Box plot demonstrating intubation outliers



5.5 Was the study adequately powered?

Regression analysis modelling³⁵¹ demonstrated that wearing CBRN-PPE was an independent factor affecting the likelihood of success when attempting to intubate in any of the four intubating positions (*p-value* 0.001). Due to the wide 95% CI for intubating in a sitting or lying positions (Table 23) Paper 7 appears to be under-powered to indicate which of these two techniques was the slowest to complete. Whereas a larger study could potentially narrow the 95% CI by balancing for the outliers observed in the kneeling, lying and sitting positions it is important to remember that Paper 7 was in fact a relatively large study since it recruited twice as many participants as were required by the power calculation.

Although speed of skill completion is important, so is successful intubation at the first attempt since multiple intubation attempts are associated with increased morbidity and mortality.²⁶⁰
²⁶¹ Therefore, the failure rate associated with the kneeling, lying and sitting intubating positions remains unacceptably high in comparison to intubating on an ambulance trolley indicating that there is a clear advantage to performing intubation with the manikin elevated off the floor. So, even if a large study successfully narrowed the 95% CI, it is unlikely to demonstrate that intubating either in the sitting or lying positions offers a viable alternative to intubation on an ambulance trolley

5.6 Identified confounding variable

The paramedic students recruited for Paper 7 were faster and more successful at intubating on the floor than the clinicians recruited for Paper 3. The reasons for this are likely to be multifactorial, but key confounders are that all the participants recruited for Paper 7 had frequently intubated manikins, including manikins positioned on the floor and they were allowed to use a stylet.^{240 244} The type of intubating manikin was not an issue as the Laerdal® Advanced Airway Trainer was used throughout all the Papers contained in this thesis, and has been consistently demonstrated to support intubation training.^{275 276}

The use of an intubation aid, a stylet, may have been partly responsible for the improved intubation performance noted between Paper 7 and Paper 3. Incorporating the use of an intubating stylet in Paper 7 was a conscious decision as it accords with standard paramedic intubation practice in South Africa.⁵⁰ It was therefore felt that preventing the paramedic students from using the stylet, would in itself, introduce a bias by disadvantaging them during the performance of intubation, regardless of the position of the manikin.

Notably, as each student acted as his/her own control, the deterioration in intubation performance when wearing NHS CBRN-PPE was independent of the participants using an intubating stylet. While it remains feasible that the use of a stylet may account for the improvement noted in Paper 7 when compared with Paper 3 it cannot account for the deterioration across all intubating positions evaluated in Paper 7. Furthermore, MacDonald et al²⁰⁴ recruited qualified paramedics and allowed the use of a stylet and yet reported slower intubation times than recorded in either Paper 1, 3 (standing-up) or 7 regardless of wearing CBRN-PPE. Considering that the research protocols are very similar between MacDonald et al²⁰⁴, and Paper 1 and 7 the impact that including the stylet had on the observed intubation performance in Paper 7, we believe to be minimal.

An unconsidered variable that exists in Paper 7, but not Paper 3, is that the participants in Paper 7 may have been physically fitter. This issue was not considered in the design of either study. Whilst accepting that this is a potential oversight, one mitigating factor is that the timing of the intubation attempts in the two studies did not start until the participant had adopted his/her chosen (Paper 3) or assigned intubating position (Paper 7). This step was taken to focus on the timing of intubation and not on the restricted mobility associated with wearing the NHS CBRN-PPE. Notwithstanding the fact that the impact of restricted mobility is a factor to consider when performing skills whilst wearing CBRN-PPE, the aim of both Paper 3 and 7 was to primarily focus on the impact of the position adopted by the intubator. Thus the approach taken when timing intubation is likely to have mitigated any impact associated with physical fitness by excluding the time required to adopt an intubating position.

5.7 Limitations

An accepted limitation of Paper 7 is that by recruiting only student paramedics, the external validity of the results are reduced by impairing the generalisability of the findings to other healthcare professionals. Mitigating this consideration is the fact that by narrowing participants to a single professional group, Paper 7 was able to more closely monitor the impact of CBRN-PPE on skill performance by removing the variable of differing levels of intubation experience of the participants. Consequently, the research methods adopted in Paper 7 actually improve the internal validity of the results.

5.8 Clinical implications of the results

Paper 7 demonstrates that the intubating performance of experienced on-floor intubators deteriorated when wearing the NHS CBRN-PPE, thus confirming the findings of Paper 3. This deterioration in performance occurred across all intubating positions (*p-value 0.001*) and was directly attributed to the design of the NHS CBRN-PPE as the movement of the NHS CBRN-PPE hood was noted to obscure the view of the intubator (Illustration 6). These observational findings further support the findings of Papers 3 and 6.

Paper 7 reaffirms the previous conclusion that intubating on the floor is at best suboptimal and further supports the argument advanced in Paper 6 that patients should be moved to a more suitable position before attempting intubation. The argument for performing intubation on an ambulance trolley goes beyond just intubation success; this is because it is also safer for the intubator (since gases such as chlorine will be more concentrated at floor level) and

for the patient, as an ambulance trolley can be tipped head-down allowing postural drainage of a patient's airway.²⁴⁰

When considering the combined results of Papers 3, 6 and 7, it is clear that intubation on the floor should not be performed whilst wearing the NHS CBRN-PPE and that a different strategy is required. During the face-to-face interviews, a number of clinicians recommended delaying intubation until the patient was in a more appropriate position, with two interviewees highlighting the role of the LMA as a bridging airway for use whilst extricating the patient to a more ideal intubating position. This approach of staging airway management has merit since LMA insertion was found to be unaffected by patient position in Paper 3. Although the LMA proved to be easy to insert with a manikin positioned on the floor, a number of other supraglottic airway devices were identified in Paper 5 that represent a potential alternative to the LMA. These additional supraglottic airway devices were subsequently evaluated with the results presented in Paper 8.

The impact of patient position on intubation performance is an important finding as it will allow clinicians to consider how best to manage a patient's airway during the initial phase of a CBRN incident. Any change in clinical practice will require clinicians to challenge established practice and therefore CBRN training should encourage clinicians to perform skills during simulated emergencies. The benefits of such simulations are diverse³⁴³ and include learning new skills in a complex environment^{303 352}, thus allowing a clinician to assess what does and does not work ultimately influencing a clinician's acceptance of new ways of treating patients.^{341 353-356}

5.9 Are all supraglottic airways the same with regards to ease and speed of insertion whilst wearing NHS CBRN-PPE?

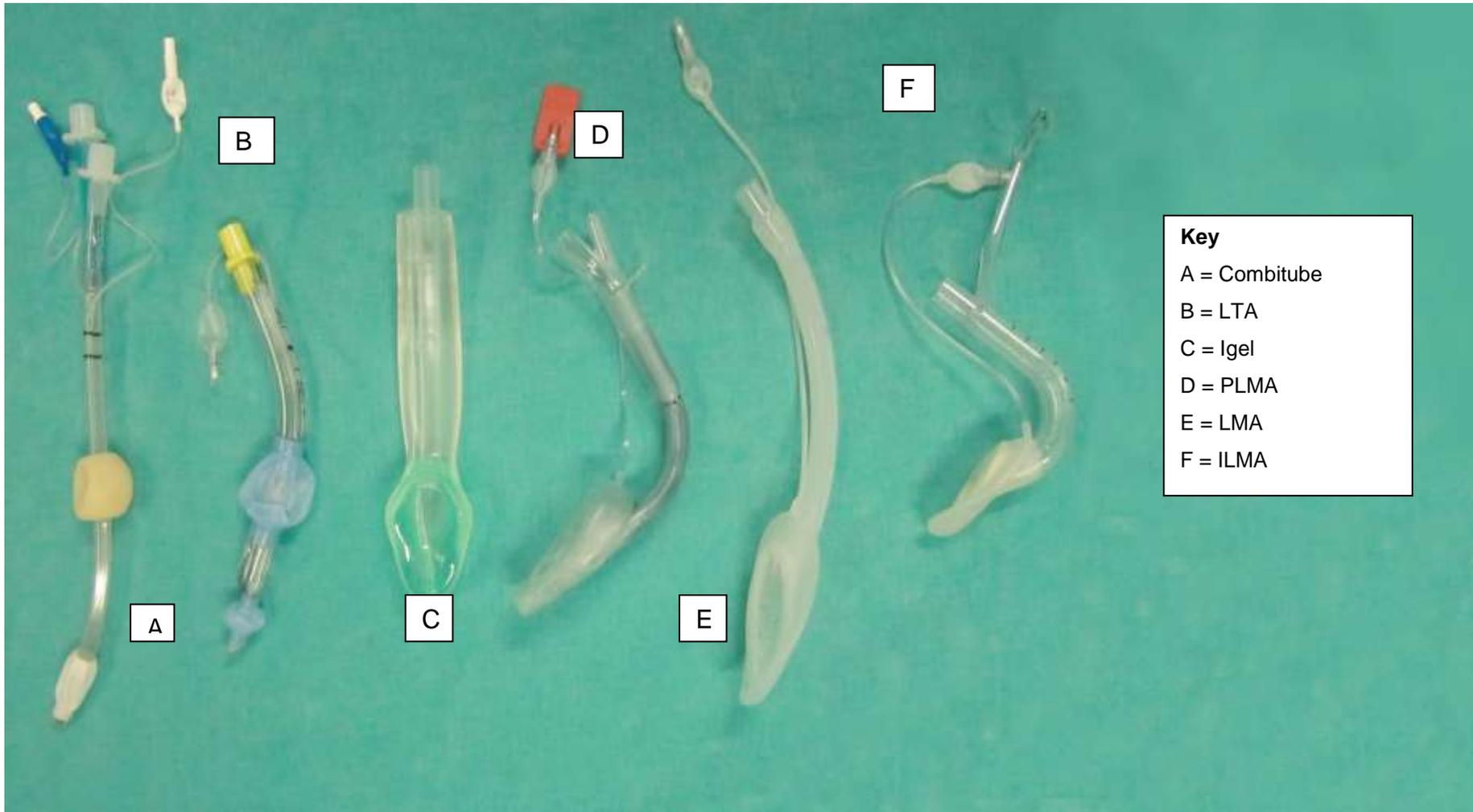
Paper 8: Castle N, Pillay Y, Spencer N. Insertion of six different supraglottic airway devices whilst wearing Chemical, Biological, Radiation, Nuclear Personal Protective Equipment: a manikin study. *Anaesthesia* 2011; 66: 983-988

Paper 8 was designed to evaluate a range of supraglottic airways devices that were identified during face-to-face interviews of clinicians who had previously performed skills whilst wearing NHS CBRN-PPE.⁵² The intended purpose of Paper 8 was to ascertain which of the devices was the easiest and fastest to insert, as these are some of the key properties identified by Hein et al³⁵⁷ for basing the selection of supraglottic airway devices for use during prehospital airway management by paramedics.

All six devices evaluated in Paper 8 are recommended for use during CPR by the ERC²²⁶, with each device offering varying features, including improved ventilation in the presences of high airway pressures all the way through to greater protection from gastric aspiration.²⁶⁷ Each device differs in its appearance (Illustration 7), although the LMA, ILMA and the PLMA are based on a similar design. The Combitube is somewhat distinctive as it is the only device designed to be placed into the oesophagus, creating a seal between the oesophagus and the oral pharynx.³⁵⁸

All supraglottic airways are known to improve ventilation^{187 267 290} and reduce the risk of aspiration³⁵⁹⁻³⁶³ in comparison to bag-valve-mask ventilation.^{226 364} This improved ventilation is an important factor as bag-valve-mask devices can deliver variable tidal volumes^{198 365 366} leading to hyper- or hypo-ventilation. For example, Wheatley et al³⁶⁷ demonstrated that a single-handed bag-valve-mask ventilation technique failed to achieve the minimum recommended tidal volume for effective ventilation when using supplementary oxygen²²⁶ (6-7 ml/kg). Although a two handed technique successfully delivered 6 ml/kg tidal volume, it failed to achieved the 10 ml/kg tidal volume required if supplementary oxygen was unavailable.²²⁶ This variable tidal volume delivery is particularly applicable to the management of a CBRN casualty, as the attachment of a CBRN filter further lowers the tidal volume delivered via a bag-valve-mask.^{181 184} Achieving optimal ventilation is vital aspect of patient management following a CBRN incident, as hypoxia and respiratory arrest are common modes of death.^{37 112 249}

Illustration 7: Supraglottic airway devices evaluated for use whilst wearing CBRN-PPE



Effective ventilation via a supraglottic airways is reportedly easier to achieve than ventilation just using a bag-valve-mask^{247 368}, training can be achievable via manikin-based training programmes^{369 370} and supraglottic airways devices are suitable for use by non-healthcare professional.³⁷⁰⁻³⁷³ And yet despite these clinical benefits to date only three devices^{166 168 169 185 316} have been evaluated for use whilst wearing CBRN-PPE. The optimal supraglottic airway for use during CBRN emergencies remains unknown.

5.10 Methods

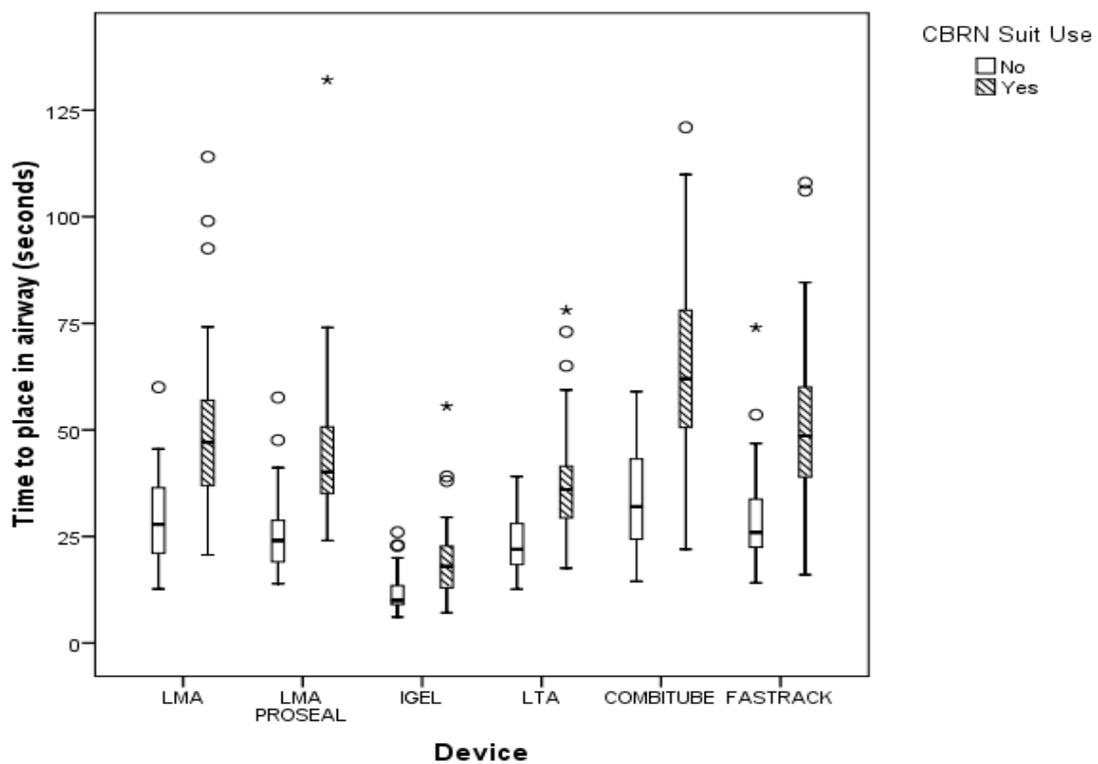
Fifty-eight paramedic students were recruited into a crossover RCT, which included a non-CBRN-PPE control group, thus exceeding the minimum number of participants identified by the pre-test power calculation (n = 52). All aspects of the study were randomised with regards to the order in which the skills were performed and the wearing of CBRN-PPE. Individual device preference and participant assessment of ease of insertion were measured against a 5-point Likert scale, which allowed participants to award a neutral score³⁷⁴ correlating to a score of three.

Paper 8 was based on the premise that supraglottic airway devices are faster, easier and more successful to insert than intubation^{198 247}, whilst also being more effective than bag-valve-mask ventilation.^{274 361 367 368 371 375 376} Additionally the immediate placement of a supraglottic airway, without prior ventilation with a bag-valve-mask, reduces the risk of aspiration^{359 375 377} and is supported by the ERC.²²⁶ However, currently no time limit is set for supraglottic airway insertion.²²⁶ Therefore 30 seconds was selected to represent the maximum recommended time for intubation during CPR^{349 264}, in part because a 30 second cut-off point has previously been used by Coates et al¹⁹¹ as a marker of successful intubation during their CBRN intubation study and by Müller et al³⁷⁸ for LTA insertion during CPR. However, as one of the principle arguments for supraglottic airway use is their faster speed of insertion, we included, a 15 seconds cut-off representing an optimal time for skill completion. Results are presented, using mean completion times and the percentage of completed supraglottic airway insertions against pre-determined timeframes, reassembling the methodology used in Paper 7 (section 5.4).

5.11 Data analysis

As demonstrated by Figure 4 and Table 24, there was a wide variation in insertion times across all six devices. Accepting that the 30 and 15 second target set for supraglottic airway insertion is based on an extrapolation of the time recommended for endotracheal intubation, Table 25 successfully demonstrates the superiority of both the Igel and the LTA over the other devices. The observed differences in insertion times of all six devices is due to the different insertion techniques required for the various supraglottic airway devices.²⁶⁷

Figure 4: Box plot of time to place airway by device and CBRN suit use.



Fastrack is the brand name of a single-use make of Intubating Laryngeal Mask Airway

Castle et al.⁵⁵ 95% CI are presented in Table 26.

The Igel was the fastest (Table 24, 25) and easiest device to insert as well as being the most popular with the participants. The design of the Igel enables it to be directly inserted into a patient's airway without pre-insertion preparation, whereas all the other devices require some varying degrees of pre-insertion preparation. A particular issue for all of the devices, with the exception of the Igel, is that before ventilation can be commenced, the clinician has to inflate the devices integral cuff.^{52 267} The need to inflate an integral cuff prolongs the insertion time and, furthermore, the need to attach a syringe to the inflation port requires the retention of fine motor skills which are impaired by NHS CBRN-PPE gloves.^{43 44 51 52}

The difference in insertion times between the LTA and the Combitube (Table 25) is of particular interest as both of these devices were infrequently referred to during interviews. The Combitube performed poorly, reflecting the comments of a small number of interviewees, whereas the time to insert the LTA was second only to the Igel. The speed of insertion of the LTA within a non-CBRN-PPE manikin study using a similar cohort of students has previously been noted.²⁷⁴ Neither the LTA nor the Combitube are widely used in the UK during emergency airway management³¹⁷⁻³¹⁹ which is likely to reflect their limited, if any, use by UK anaesthetists during routine anaesthesia. The inclusion of the LTA and the Combitube is a direct result of the interviews reaffirming the benefit of qualitative data in hypothesis generation.

The impact of CBRN-PPE on inserting the Combitube is particularly noteworthy as the mean insertion time (65.08 seconds) is slower than for intubation whilst wearing CBRN-PPE, for example in Paper 1 (63.3 seconds), as well as being slower than intubation performed on an ambulance trolley in Paper 7 (39.42) or in Paper 9 (standard intubation no stylet 49.6 seconds). The Combitubes complex insertion technique³⁵⁸ was directly responsible for its protracted insertion time. During Paper 8, the Combitube was inserted into the manikin without the aid of a laryngoscope, which is a commonly recommended insertion technique of the Combitube.²²⁶ However, this approach can result in tracheal or oesophageal trauma³⁷⁹⁻³⁸² and therefore Krafft and Schebesta³⁵⁸ recommend using a laryngoscope to minimise the risk of airway trauma.

Table 24: Time to place airway by device and CBRN suit use

Device	CBRN Suit Used?	Mean (secs)	Std. Deviation	95% CI for mean	Participant preference	Ease of use
						1 = hardest to insert 5 = easiest to insert
LMA	No	28.8 (33.8) ^a	9.43	26.32, 31.28 (30.9, 36.7) ^a	6.1%	% scoring 1 = 2%
	Yes	48.46	17.58	43.84, 53.08		% scoring 5 = 24%
PLMA	No	25.07	8.27	22.90, 27.25	14.3%	% scoring 1 = 14.3%
	Yes	44.22	16.15	39.97, 48.47		% scoring 5 = 38%
Igel	No	11.63 (12.3) ^a	4.45	10.46, 12.80 (11.5, 13.1) ^a	59.2%	% scoring 1 = 0%
	Yes	19.26	8.36	17.06, 21.46		% scoring 5 = 94%
LTA	No	22.75 (22.4) ^a	6.03	21.17, 24.34 (20.3, 24.5) ^a	6.1%	% scoring 1 = 2%
	Yes	38.22	12.67	34.89, 41.55		% scoring 5 = 28%
Combitube	No	34.54	11.86	31.43, 37.66	6.1%	% scoring 1 = 6.1%
	Yes	65.08	22.62	59.13, 71.02		% scoring 5 = 16%
Fastrack/ILMA	No	29.17	10.45	26.42, 31.92	8.2%	% scoring 1 = 8.2%
	Yes	50.54	17.64	45.90, 55.18		% scoring 5 = 24%
<p>Participant preference was measured as a percentage whereas ease of use was measured against a questionnaire using a 5-point Likert scale (1 = hardest and 5 easiest) Castle et al.⁵⁵</p> <p>^a Data drawn from a non-CBRN-PPE study looking at Igel, LTA and LMA by Castle et al²⁷⁴ using a similar cohort of South African paramedic students.</p>						

An additional issue affecting the suitability of the Combitube for use following a CBRN incident is that its design allows it to be placed into either the trachea or the oesophagus.²²⁶
^{267 358} During Paper 8, trachea placement of the Combitube occurred twice (3% of insertions) in each arm of the study. Although this is a lower rate of occurrence than has been reported in other studies^{201 204}, it mandates that Combitube placement is confirmed along the same lines as intubation.³⁸³ The combination of slow insertion speed, complexity of insertion technique and the possible need to use a laryngoscope, coupled with the potential of placement of the Combitube into the trachea, makes the Combitube a sub-optimal airway device for use during a CBRN incident.

Table 25: Placement of supraglottic airway devices in predefined timings by devices and CBRN-PPE use

CBRN-PPE worn	Device	Completion of insertion (measured in seconds)					
		15s	30s	45s	60s	90s	120s
NO	LMA	1.7%	56.9%	94.8%	98.3%	100%	100%
	PLMA	5.2%	79.3%	96.6%	100%	100%	100%
	Igel	81.0%	100%	100%	100%	100%	100%
	LTA	8.6%	91.4%	100 %	100%	100%	100%
	Combitube	1.7%	37.9%	72.4%	96.6%	96.6%	96.6%
	Fastrack*/ILMA	3.4%	58.6%	94.8%	98.3%	100%	100%
YES	LMA	0.0%	10.3%	46.6%	81.0%	94.8%	100%
	PLMA	0.0%	6.9%	65.5%	89.7%	98.3%	98.3%
	Igel	32.8%	94.8%	98.3%	100%	100%	100%
	LTA	0.0%	27.6%	79.3%	94.8%	100%	100%
	Combitube	0.0%	3.4%	19.0%	43.1%	81.0%	94.8%
	Fastrack*/ILMA	0.0%	3.4%	44.8%	74.1%	96.6%	100%

*Fastrack is the brand name of a single-use make of the intubating laryngeal mask airway (ILMA)
 Adapted from Castle et al.⁵⁵

The insertion times whilst not wearing CBRN-PPE presented in Table 24 differ from the data presented by Wahlen et al¹⁹⁸, who reported that the LMA, PLMA, ILMA, LTA and the Combitube were all at least 10 seconds faster to insert than reported in Paper 8. Wahlen et al¹⁹⁸ did identify that in other studies these devices took longer to insert, indicating that their data may have been affected by the fact that they recruited participants from a range of clinical backgrounds (to include anaesthetist). This is likely to be the case as a study by Castle et al²⁷⁴, using a similar cohort of student paramedics, reported similar insertion times for the LMA, Igel and the LTA as were reported in Paper 8 (Table 24). Notably, Hüter et al³⁸⁴ and Dörjes et al³⁸⁵ both recorded insertion times for the Combitube that were at least 30 seconds longer than reported by Wahlen et al.¹⁹⁸

5.12 Ease of use and personal preference

The Igel was deemed to be the easiest device to insert (Table 26) and proved to be the most popular device with the paramedic students. The Combitube was regarded as being the hardest device to insert and shared the same popularity rating as the LMA, LTA and the ILMA, despite these devices being considered easier to use (Table 26). Although at face value, a measurement of ease of insertion and clinician preference may appear to be subjective, personal preference can impact on the type of supraglottic airway a clinician selects to use when treating patients.^{328 329} Whereas the opinions of subject matter-experts, such as anaesthetists (section 4.15), can dictate hospital policy affecting the availability of supraglottic airway devices, as was demonstrated in Paper 5 (Chapter 4).

Table 26: Ease of use and personal preference of the six supraglottic airways

	Preference	1	2	3	4	5
LMA	6%	2%	0%	30%	44%	24%
PLMA	14%	2%	0%	8%	52%	38%
Igel	59%	0%	0%	2%	4%	94%
LTA	6%	2%	4%	22%	44%	28%
Combitube	6%	26%	20%	34%	24%	16%
ILMA	8%	6%	8%	20%	42%	24%
Score of 1 = hardest whereas a score of 5 = easiest. Total number of participants = 58 Modified from Castle. ⁵⁵						

The popularity rating of the Combitube shown in Table 26 is explained by a small number of South African Defence Medical Service soldiers (soldiers trained to administer advanced first aid) who were attending the university to complete paramedic training. This is because at the time of data collection, the Combitube was the standard supraglottic airway used by the South African Defence Medical Service. And further serves to demonstrate, how prior exposure to a particular device influences clinician's choice as to what device to use in an emergency. The popularity of the Igel reflects its ease and speed of insertion. Yet, whilst these are valid reasons for selecting a supraglottic airway, the ability of an airway device to permit ventilation against high airway pressures and reduce the risk of pulmonary aspiration are also compelling clinical arguments.

5.13 Study power

There was a marked device-based variation in insertion times (Figure 4) and although the speed of insertion varied between devices, the 95% CI for the LMA, LTA, ILMA and the PLMA (Table 24) did not exceed 10 seconds in either arm of the study. However, as the fastest device to insert the 95% CI for the Igel (17.06, 21.46 seconds) is narrow demonstrating that wearing NHS CBRN-PPE had a limited, if any, impact on Igel insertion. In contrast, the 95% CI for the slowest device, the Combitube (59.13, 71.02 seconds), is wide, further demonstrating the negative impact of NHS CBRN-PPE on Combitube insertion. It is of addition note that with the exception of the Igel, the standard deviation of the mean typically doubled between the CBRN-PPE and non-CBRN-PPE groups. This is similar to the impact of the NHS CBRN-PPE on other techniques evaluated in this thesis. Therefore, whilst a larger study may have narrowed the 95% CI for some of these devices, the impact of CBRN-PPE across this thesis indicates that skills take upwards of twice as long to complete when wearing the NHS CBRN-PPE.

5.14 Comparisons with Paper 1

Participants in Paper 8 were over 20 seconds slower at inserting the LMA than the combined times for all the clinicians taking part in Paper 1 (mean 26.5 vs. 48 seconds). This difference persisted even when comparing LMA insertion times achieved by the paramedic students with the paramedic/resuscitation officers (48 vs. 31.6 seconds).⁴³ The reason for the difference in LMA insertion times is likely to reflect the frequency with which South African student paramedics undertake supraglottic airway insertion, as South African paramedics typically prefer to perform endotracheal intubation.⁵⁰

5.15 Limitations

The main limitation of Paper 8 is that in an attempt to optimise internal validity, the external validity of the data was arguably compromised. Similar issues occurred in Paper 7 and are discussed in section 5.7. The potential lack of generalisability of the results reported in Paper 8 to other healthcare professionals is supported by the slower insertion times reported for the LMA when compared with either Paper 1 or 3. These slower insertion times reflected the lower levels of experience that the South African student paramedics had with regards to supraglottic airway insertion and occurred despite their attendance at an airway workshop held prior to data collection. This workshop provided instruction and practice in all of the supraglottic airway devices included in Paper 8. Whilst accepting that the lack of generalisability is a limitation of the study, the impact that CBRN-PPE had on skill completion is clearly apparent from the data presented in Paper 8 and so represents a valuable contribution to this ongoing area of research.

5.16 Clinical implications of results

Paper 8 indicates that the Igel can be inserted in 30 seconds, making it a viable alternative to bag-valve-mask ventilation, whereas the Combitube is a sub-optimal airway device for use during a CBRN incident. By comparing the mean insertion time of 19.2 seconds for the Igel with the mean 39.4 second insertion time for intubation on a trolley (as reported in Paper 7), a reduction in apnoea time of 20 seconds is achievable. More strikingly, this correlates to 94% of patients receiving their first resuscitation breath in 30 seconds of commencing airway management with the Igel compared to 14.6% of patients being intubated in the same timeframe. The speed at which the Igel can be inserted further strengthens the argument for staged airway management as it confirms that the immediate insertion of a supraglottic airway is achievable.

A number of authors³⁷⁰⁻³⁷³ have demonstrated that a range of non-medical rescue personnel can be trained to insert a variety of supraglottic airways. Accepting that this was not an intended outcome of this thesis the speed and ease of insertion of an Igel would suggest that its use could be extended to non-medical rescue personnel. The role of non-medical rescue personnel delivering first aid in the confines of a CBRN incident is supported by the International Committee of the Red Cross and Red Crescent Societies.¹⁷

In the UK a potential group of non-medical rescuers would be the fire service. Currently the levels of first aid training provided by the various UK fire services differs³⁸⁶ but, all UK fire

services train their personnel to perform CPR and to use oxygen.^{386 387} Increasing fire services are expanding the first aid training they provide to incorporate the use of a bag-valve-mask device, hand operated suction devices, advisory defibrillators and tourniquets for haemorrhage control.³⁸⁶⁻³⁸⁸ Theoretically, then, training fire personnel to undertake additional emergency interventions is feasible. Although it is accepted that specialist ambulance teams^{7 95} are better trained than fire service personnel to treat CBRN casualties, their availability is limited.⁹² Nonetheless, the findings of Paper 8 do highlight that the wider use of devices, such as the Igel, warrant further research as part as an organised response to a mass casualty CBRN incident.

Paper 8 successfully highlights issues with the Combitube and demonstrates the benefits offered by the Igel, but, it cannot detract from the effectiveness of the other supraglottic airway devices. As although speed and ease of insertion are important factors the LTA, the PLMA and the ILMA all have unique features that offer improved airway management compared to the Igel.^{52 267 362 363} Nonetheless, Paper 8 does provide important data to inform clinicians balancing the need for speed of insertion against improved ventilation properties when choosing a supraglottic airway for use following a CBRN incident.

Paper 8 has also informed the development of a research project designed to investigate the ventilation performance of a range of supraglottic airway devices, which might be used during a CBRN incident. This study is currently in its early developmental phase but it is envisaged that by replicating the pulmonary oedema, bronchospasm and increased upper airway secretions associated with a range of chemical agents the ventilating properties of the supraglottic airway devices (minus the Combitube) reviewed in Paper 8 can be evaluated.

5.17 What is the impact of intubation aids on skill completion whilst wearing NHS CBRN-PPE?

Paper 9: Castle N, Pillay Y, Spencer N. Comparison of six different intubation aids for use while wearing CBRN-PPE: A manikin study. *Resuscitation* 2011; 82: 1548-1552

The research methodology of Papers 1 and 3 purposefully excluded the use of any intubating aids, as at the time of data collection the mass casualty treatment pods did not stock any type of intubation aid.⁹¹ However, the potential benefit of an intubating aid to improve the success of intubation is a clinically relevant question, as wearing CBRN-PPE is known to adversely affect intubation performance.^{43 45 54 166 168 204} Therefore, Paper 9 was designed to ascertain the impact of a range of intubating aids (Illustration 8) that were identified during face-to-face interviews of clinicians recruited for Papers 1 to 3. Paper 9 is the first study, to date, to evaluate the effectiveness of intubating aid whilst wearing CBRN-PPE.

Since the publication of Paper 9, mass casualty treatment pods have been up-dated and now include the bougie, LMA or the Igel, Thomas™ Tube Holder and devices for monitoring end-tidal carbon dioxide. The new equipment was selected via a Delphi study^{93 92}, with the inclusion of the bougie and devices for measuring end-tidal carbon dioxide reflecting prehospital intubation guidelines.²⁴³

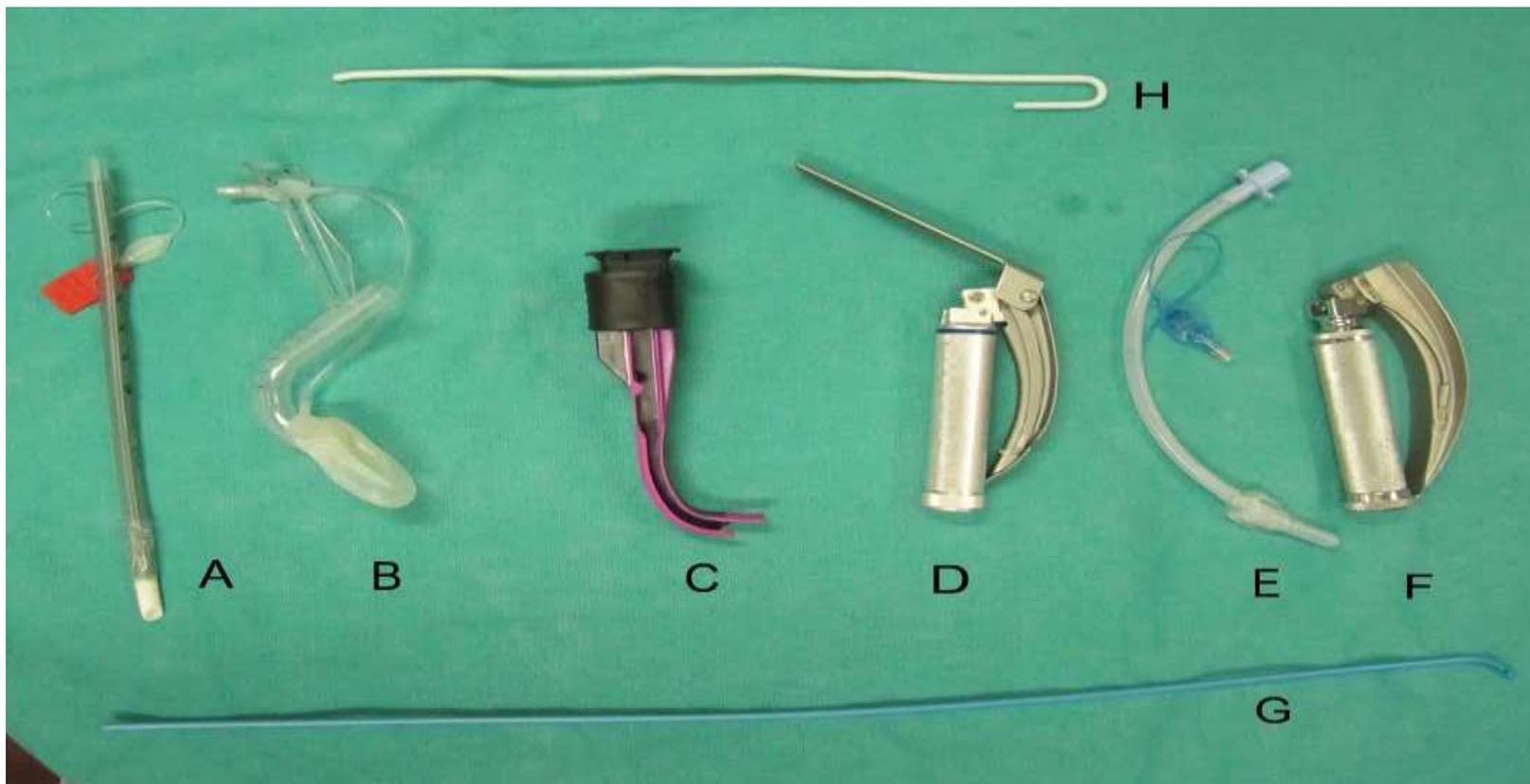
5.18 Methods

Sixty-six paramedic students were recruited into a crossover RCT with each participant acting as their own control. The order in which each device was used, wearing of CBRN-PPE, and intubation using an intubating aid was randomised.

In Paper 9, completion times for intubation were measured against pre-determined timeframes where each timeframe represented an increasing period of apnoea. The aim was for intubation to take no longer than 60 seconds to complete but for it ideally to be completed within 30 seconds.²⁶⁴ This methodology has been previously explained in section 5.4. Participants were also requested to rate each device with regard to ease of use against a 5-point Likert scale, with a neutral score equating to a score of 3 (1 = very easy and 5 = very hard).

Illustration 8: Intubating aids and associated accessories evaluated for use whilst wearing NHS CBRN-PPE.

A) Flexible endotracheal tube used for intubation via Intubating LMA, **B)** Intubating LMA, **C)** Airtraq™, **D)** McCoy™, **E)** standard endotracheal tube used for all intubations except via the *intubating* LMA, **F)** standard laryngoscope used as part of standard intubation, intubation using a bougie and intubation using a stylet, **G)** bougie and **H)** malleable intubating stylet.



Certain aspects of the methods used in Paper 9 differed from those used in earlier CBRN based intubation studies^{43 45 54 166 168 204}, as an assistant was provided to assist the bougie arm of Paper 9. The need for an assistant occurred as the standard technique for using a bougie requires two clinicians²⁴⁰, however, assistance was limited to placing the ETT over the bougie once the intubator had inserted the bougie into the trachea. The assistant wore NHS CBRN-PPE as per the same randomisation schedule as the intubator. Although Hendler et al⁹⁰ had also included an assistant during their intubation study both participants wore tactile preserving gloves (gauge of 0.3 mm), as opposed to the butyl rubber CBRN gloves incorporated into the NHS CBRN-PPE (minimum gauge at the fingertips of 0.9 mm). The potential positive impact of an assistant on skill performance was highlighted in Paper 6.

In Paper 6, a number of the interviewees had pointed out that the bougie and the stylet would only be faster to use if they came pre-inserted in the ETT. As this option is not commercially available, participants were required to assemble the intubation aids along with all of the equipment required for intubation as part of the intubation attempt. MacDonald et al²⁰⁴ also used a similar methodology.

5.19 Data analysis

Regardless of which intubating aids were used, intubation performance was adversely affected by CBRN-PPE. This effect was particularly noticeable at the 30, 45 and 60 second timeframes (Table 27). Even at 150 seconds none of the attempts at intubation had achieved a 100% success rate. Standard intubation and intubation using a stylet were the fastest intubating techniques, but at the 60 second timeframe 25% of these attempts had still not been successfully completed, a finding that compared unfavourably with the non-CBRN control group.

Table 27: Numbers and percentage of successfully completed intubation attempts at various times by device and CBRN suit use

CBRN-PPE worn?	Device	30 Seconds	45 seconds	60 seconds	90 seconds	120 seconds	150 seconds	Eventually
NO	Standard	34 (52%)	64 (97%)	65 (98%)	66 (100%)	66 (100%)	66 (100%)	66 (100%)
	Stylet	21 (32%)	59 (89%)	63 (95%)	66 (100%)	66 (100%)	66 (100%)	66 (100%)
	Bougie	6 (9%)	46 (70%)	61 (92%)	65 (98%)	65 (98%)	65 (98%)	65 (98%)
	ILMA	12 (18%)	48 (73%)	61 (92%)	65 (98%)	66 (100%)	66 (100%)	66 (100%)
	Airtraq™	7 (11%)	36 (55%)	53 (80%)	61 (92%)	62 (94%)	62 (94%)	62 (94%)
	McCoy™	19 (29%)	57 (86%)	61 (92%)	65 (98%)	65 (98%)	65 (98%)	65 (98%)
YES	Standard	4 (6%)	33 (50%)	50 (76%)	57 (86%)	60 (91%)	61 (92%)	61 (92%)
	Stylet	1 (2%)	28 (42%)	48 (73%)	58 (88%)	61 (92%)	61 (92%)	61 (92%)
	Bougie	0 (0%)	15 (23%)	38 (58%)	55 (83%)	60 (91%)	61 (92%)	61 (92%)
	ILMA	0 (0%)	10 (15%)	39 (59%)	58 (88%)	63 (95%)	64 (97%)	64 (97%)
	Airtraq™	1 (2%)	18 (27%)	33 (50%)	50 (76%)	53 (80%)	56 (85%)	60 (91%)
	McCoy™	0 (0%)	21 (32%)	46 (70%)	52 (79%)	53 (80%)	54 (82%)	54 (82%)

Adapted from Castle et al.⁵⁶

Standard intubation and intubation using a stylet were the fastest intubating techniques but the ILMA had the highest overall success rate (Table 27). Intubation using either the bougie or the ILMA achieved parity with standard intubation and intubation using a stylet by the 90 second time-point. At 60 seconds, the McCoy™ laryngoscope was the third fastest device. However, participant improvement reached a plateau after 90 seconds resulting in the McCoy™ laryngoscope recording the lowest overall successful intubation rate (Table 27). Overall the Airtraq™ was the slowest device to insert but it recorded a higher successful intubation rate than the McCoy™ laryngoscope.

It is generally accepted that the principle role of intubation aids, such as the bougie, is to increase the success of intubation and not intubation speed^{240 242 389}, and yet the failed intubation rate detected in Paper 9 is the same for standard intubation, intubation using a stylet and intubation using a bougie (Table 28). The failed intubation rate was even higher when intubation was performed using either the McCoy™ laryngoscope or the Airtraq™. These findings demonstrate a number of points meriting further examination, most importantly the performance of the bougie, stylet, standard intubation and the potential role of the ILMA.

Le et al²⁴⁵ reported that paramedics were able to master the use of the bougie with limited training, achieving the same success rate with a bougie as they achieved using a stylet. These findings were further validated by Phelan et al³²², whereas Gregory et al²⁴¹ reported that paramedics performed intubation faster using a stylet compared to a bougie, thus corroborating the data presented in Table 27 & 28.

Gregory et al²⁴¹ suggested a number of reasons for the poor performance of the bougie. These included the high ambient temperature, in which the study was undertaken, resulting in the bougies being too soft to use, poor quality of the selected bougies³³⁸, and the participant's experience of using either device. Gregory et al²⁴¹ dismissed prior experience as a contributing factor during their study, but this appears to be at odds with their data as 71% of their participants had experience of using a stylet compared to only 30% having experience with the bougie.

Table 28: Time to successfully complete intubation by device and CBRN suit use

Device	CBRN suit used?	Number of abandoned intubations	Number of oesophageal intubations	Number of successful intubations	For successful intubations only		
					Mean (seconds)	Standard Deviation	95% CI for mean
Standard	No	0 (0.0%)	0 (0.0%)	66 (100.0%)	30.8	8.5	(28.7, 32.9)
	Yes	0 (0.0%)	5 (7.6%)	61 (92.4%)	49.6	20.9	(44.2, 54.9)
Stylet	No	0 (0.0%)	0 (0.0%)	66 (100.0%)	34.4	9.9	(32.0, 36.9)
	Yes	0 (0.0%)	5 (7.6%)	61 (92.4%)	50.9	17.0	(46.6, 55.3)
Bougie	No	1 (1.5%)	0 (0.0%)	65 (98.5%)	41.9	11.0	(39.1, 44.6)
	Yes	2 (3.0%)	3 (4.5%)	61 (92.4%)	58.4	20.0	(53.3, 63.5)
ILMA	No	0 (0.0%)	0 (0.0%)	66 (100.0%)	41.6	13.9	(38.2, 45.1)
	Yes	1 (1.5%)	1 (1.5%)	64 (97.0%)	61.0	19.6	(56.1, 65.9)
Airtraq™	No	0 (0.0%)	4 (6.1%)	62 (93.9%)	44.9	15.2	(41.0, 48.7)
	Yes	2 (3.0%)	4 (6.1%)	60 (90.9%)	69.4	38.4	(59.5, 79.3)
McCoy™	No	1 (1.5%)	0 (0.0%)	65 (98.5%)	36.1	12.2	(33.1, 39.2)
	Yes	4 (6.1%)	8 (12.1%)	54 (81.8%)	50.8	15.6	(46.6, 55.1)

ILMA = Intubating laryngeal mask airway
Adapted from Castle et al.⁵⁶

The majority of the issues identified by Gregory et al ²⁴¹ were controlled for during Paper 9 as data collection occurred in an air conditioned skill laboratory to minimise participant fatigue ²⁰, and a multiple-use bougie was selected because of the superiority of this model.^{390 391} Nevertheless, it is not possible to exclude experience as a factor affecting skill performance. This is because student paramedics regularly use a stylet, and despite, attending an airway workshop that involved all the intubation aids evaluated within Paper 9 paramedic students were relatively unfamiliar with the bougie. Therefore, participants' prior experience of using a stylet does represent a confounding variable in Paper 9.

During Paper 6, two of the interviewee's highlighted potential issues with picking-up and handling the bougie whilst wearing CBRN-PPE. During Paper 9, this was observed to be an issue as the high gauge of the gloves made grabbing hold of the bougie and releasing it difficult. This difficulty was further exacerbated if the gloves were too big for the operator as fingertip sensation and grip were further reduced if the gloves were too large, consistent with the findings of Bensei.¹⁸⁷

Despite being initially one of the slowest devices to insert, the ILMA achieved parity with standard intubation and intubation using a stylet at 90 seconds before demonstrating continued improvement at the 120 and 150 second points (Table 25 & 27). The ILMA achieved the highest overall intubating success rate and was also viewed as being the easiest device to use by the participants.

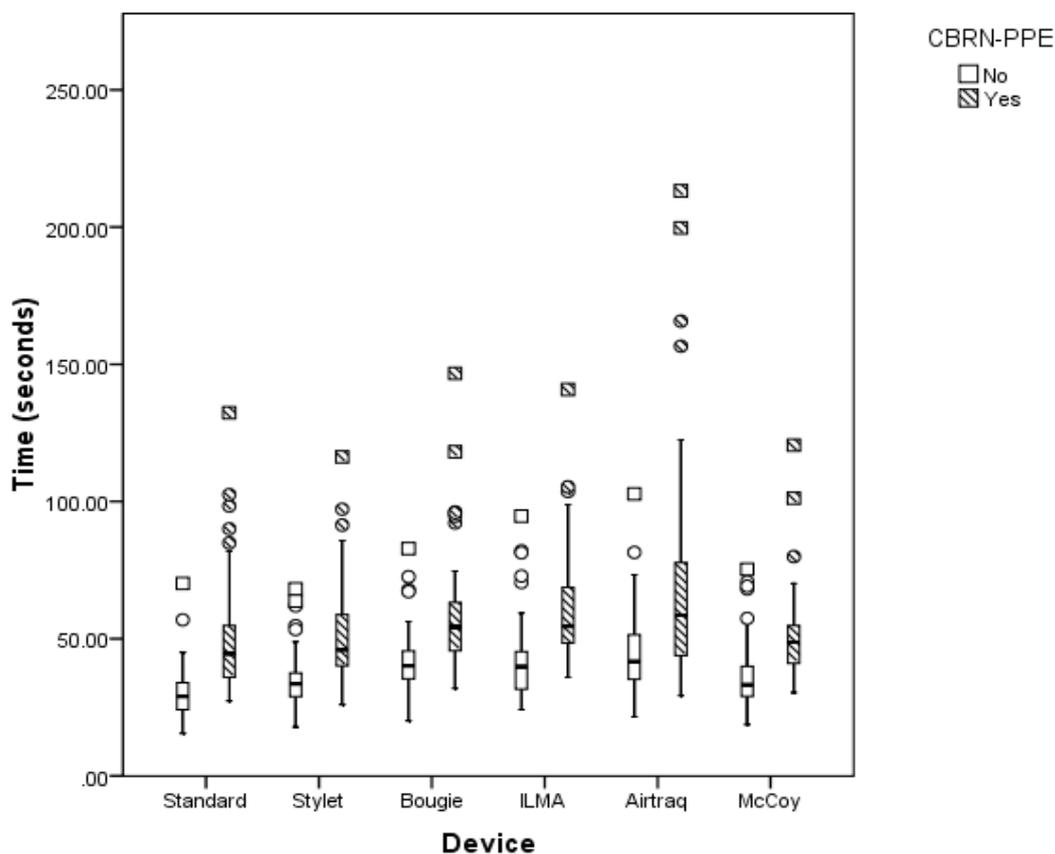
The insertion times reported in Paper 9 for the ILMA are slower than those noted by Wedmore et al ³¹⁶ (61.0 vs. 24.6 seconds). However, there are numerous differences between these two studies. For example participants in Wedmore et al ³¹⁶ study only wore a CBRN respirator and no CBRN gloves. Furthermore, the syringe for inflating the ILMA cuff was pre-attached prior to insertion in Wedmore et al ³¹⁶ study, but not during Paper 9. The need to attach the syringe to the inflation port of the ILMA in Paper 9 was observed to be fiddly further demonstrating the impact that wearing CBRN-PPE gloves has on performing dextrous skills. Notably, the difference in completion times for the insertion of the ILMA as reported by Wedmore et al ³¹⁶, when compared to Paper 9 gives further credence to the observations made by interviewees in Paper 6.

Considering that prior to inserting the range of LMA devices (LMA, PLMA and the ILMA) the clinician is required to inflate and then deflate the device's integral cuff ²⁴⁰, it might be advantageous to leave the syringe attached in order to speed up the delivery of the first breath post-insertion. A similar argument could also be made for the LTA. While accepting that it is not possible to estimate the potential time-savings that may occur on the basis of the data presented in Paper 9 or from Wedmore et al ³¹⁶ et al, this observation is intuitively correct and warrants further evaluation.

Standard intubation and intubation using a stylet were both faster than intubating via the ILMA, but they resulted in a higher incidence of oesophageal intubation (Table 28). The mean intubation time recorded in Paper 9 for the ILMA was 61 seconds (95% CI 56.1, 65.9) whereas the mean insertion time for the ILMA in Table 8, when used as a supraglottic airway, was 50.54 seconds (95% CI 49.9-55.18), findings which highlight the benefits of the ILMA both as supraglottic airway and as a conduit for intubation.²⁶⁷ The twin role offered by the ILMA would allow a period of ventilation when used as a supraglottic device, thus removing the risk of aspiration associated with using a bag-valve-mask device ^{359 362}, before proceeding to intubation. This dual-purpose function would minimise the complications associated with protracted or repeated intubation attempts.^{260 261} The feasibility of this approach has been demonstrated ³⁹²⁻³⁹⁶ during other airway emergencies and, was highlighted as potential role for the ILMA during Paper 6, as well as by Greenland et al ⁷⁵ when treating contagious patients (e.g. pandemic influenza).

The Airtraq™ and the McCoy™ laryngoscope both performed poorly with regards to time to complete intubation and successful intubation attempts. Despite being marginally more successful than the McCoy™ laryngoscope, the Airtraq™ proved to be the most difficult device for the students to master as demonstrated by its 95% CI (Table 28) and the outlying attempts (Figure 5). This reflects both the participants' lower level of familiarity with the Airtraq™ and the different intubation technique required when using this device.³⁹⁷

Figure 5: Box plot of time to successfully complete intubation by device and CBRN suit use



Adapted from Castle et al.⁵⁶

5.20 Does preparing the equipment prior to intubation slow down the intubation attempt?

Standard intubation, without the use of an intubating aid, resulted in the fastest intubation times as there was minimal equipment assembly prior to commencing intubation. This can be demonstrated by comparing the intubations times recorded in Paper 7 (intubation on trolley) with Paper 9, where a 4.4 second difference (30.04 vs. 34.4 seconds) was reported whilst not wearing CBRN-PPE, increasing to a difference of 11.5 seconds when wearing CBRN-PPE. The principle difference is that in Paper 7 the stylet was pre-inserted before data collection, whereas during Paper 9 the intubator had to insert the stylet before proceeding to intubate.

The impact of having to assemble equipment provides an explanation for the converging of intubation times when using a stylet, the ILMA and the bougie that occurs after 60 seconds, reflecting the time required to assemble equipment. The potential impact of preparing equipment whilst wearing the NHS CBRN-PPE was identified during the face-to-face interviews, as reported in Papers 5 and 6. Similar issues were also noted during the intravenous access study by Suyama et al.¹⁸⁶, and the impact of preparing equipment prior to performing intubation, whilst wearing CBRN-PPE, has recently been confirmed by Chung-Cheng et al.³⁹⁸ At face value, this finding may appear to be a methodological flaw but the research design of Paper 9 reflects real life, as intubation aids are separately supplied from endotracheal tubes and therefore require time to insert. However, the negative impact of preparing equipment whilst wearing CBRN-PPE has been further illustrated by Paper 9, reaffirming the findings of early^{189 252} and more recent studies.³⁹⁸ This aspect of skill difficulty should form part of simulation-training, as clinicians are likely to 'take for granted' the ease at which they prepare equipment prior to use, thereby potentially underestimating the impact of loss of hand dexterity.¹⁸⁷

5.21 Study power

As with Papers 7 and 8, a number of participants in Paper 9 had difficulty with skill completion. This occurred with all intubation aids (Figure 5) but the 95% CI variance remains in a range of 10 seconds for all the intubation aids except the Airtraq™. Therefore, whilst a larger study might narrow the 95% CI, it is doubtful the performance of the evaluated devices would improve to the point that they would demonstrate a clear benefit with regards to improving either the speed or success of intubation of a particular device whilst wearing NHS CBRN-PPE.

5.22 Limitations

The chosen research method concentrates on the impact of CBRN-PPE on use of intubating aids and no attempt was made to increase the difficulty of intubation.²⁴¹ This may have reduced any benefit to be gained from utilising intubation aids which are designed to improve intubation success and not intubation speed. Nonetheless, considering the failed intubation rate was equal to or higher when using all the evaluated intubation aids, except the ILMA, making the overall intubation technique more difficult is unlikely to have revealed that any particular intubation aid was better than standard intubation. Rather, any increase in intubation difficulty would, most likely, have reduced the overall intubation success rate for all the evaluated intubation aids. The issue of intubation difficulty and its impact on intubation whilst wearing CBRN-PPE warrants further consideration, whilst keeping in mind that numerous additional factors such as the skill of the clinician or environmental factors (e.g. patient position) are also important variables impacting on intubation success.

The choice of intubating aids evaluated in Paper 9, were selected by a range of clinicians who had both experience of performing intubation during the management of non-CBRN emergencies, such as during cardiopulmonary resuscitation, as well as having performed airway skills whilst wearing the NHS CBRN-PPE. The rationale for using interviews was to reduce the risk of selection bias that might have occurred during Papers 1 to 4, and to gain an understanding of what the issues were when performing skills whilst wearing NHS CBRN-PPE. Despite this a number of relatively new video assisting intubation devices³⁹⁹, which are increasingly being used during difficult airway management were not identified for evaluation in Paper 9.

5.23 Clinical implications of results

The results of Paper 8 and 9 demonstrate that no particular airway device provides the ideal solution to airway management when treating a patient exposed to a CBRN agent. In Paper 9, the ILMA had the highest successful intubation rate but in Paper 8 the ILMA was slower to insert than the Igel, LTA or the PLMA.

Despite the inconsistency in the findings noted above, the ILMA may confer a clinical benefit beyond intubation, with the results of Papers 8 and 9 also indicate a potential benefit of using the ILMA to pre-oxygenate^{75 238 400} a patient before proceeding to intubation. This approach could be adopted for a single or multiple critically ill patients, with the ILMA bridging the gap between immediate airway management, decontamination and intubation

whilst wearing CBRN-PPE. Similarly, the Igel (as the fastest device to insert), LTA or PLMA could also be used in the initial phase of an emergency, allowing the clinician time to position the patient and prepare the equipment ahead of intubation. However, the ILMA remains the only supraglottic airway device specifically designed to facilitate intubation^{75 392-396} whilst also providing the option of pre-intubation ventilation, or immediate ventilation (via the ILMA as a supraglottic airway), should the initial intubation attempt fail.³⁹⁵

Despite the allocation of an assistant, the CBRN-PPE gloves made handling and inserting the bougie difficult. This was due to the loss of finger-thumb dexterity and fingertip sensation which interfered with picking-up, inserting and releasing the bougie. These observations correlate with the opinions of a number of interviewees who were interviewed for Paper 6. The Airtraq™ and the McCoy™ laryngoscope appeared to offer no benefit during a CBRN incident.

Despite these issues surrounding the use of the bougie the recently up-dated mass casualty pods have been re-equipped with bougies, supraglottic airway devices (typically the LMA or the Igel), commercial endotracheal tube holders (typically the Thomas™ Tube Holder) and portable end-tidal CO₂ monitors. Considering that the mass casualty pods are intended for use following any major incident, the inclusion of bougies is understandable. Nonetheless, the availability of bougies may provide a clinician, who is inexperienced at performing skills whilst wearing CBRN-PPE, with a level of reassurance that the bougie will assist with a difficult intubation whilst wearing CBRN-PPE. This is a level of reassurance that is not supported by the evidence as presented in Paper 9.

A version of the ILMA not evaluated in Paper 9 was the CTrach™ ILMA. This version of the ILMA incorporates a video screen, designed to facilitate visualisation of the vocal cords in an attempt to improve intubation success.^{401 402} The CTrach™ LMA incorporates all the benefits of the more basic ILMA, although Gerstein et al⁴⁰³ indicate that the intubation success rate is not improved by the availability of the video screen.

Despite, the findings of Gerstein et al⁴⁰³ the use of video assisted intubation, to improve intubation success rate whilst wearing NHS CBRN-PPE, theoretically has benefit. Although, during the initial literature review (Chapter 2 and appendix 2) no studies using a video assisting intubation device were identified, a recently published study by Shin et al⁴⁰⁴ has compared the Pentax-AWS (video-assisted laryngoscope) with a traditional laryngoscope whilst wearing CBRN-PPE, demonstrating improved performance with the Pentax-AWS.

Paper 9 raises a number of issues that will need to be addressed in subsequent studies to provide a full understanding of any benefit to be gained from using intubation aids during a CBRN incident. These include the following:

- 1) What is the impact of practise and greater familiarity of using intubation aids on speed and success of intubation whilst wearing NHS CBRN-PPE?
- 2) Does altering the degree of intubation difficulty introduce a clinical need for intubation aids compared with standard intubation?
- 3) Do video-assisting intubation devices improve intubation success and speed whilst wearing NHS CBRN-PPE?

Currently, the first of these questions is being examined as part of a RCT in South Africa. This study is being run over 12 months, with the skills outlined in Paper 9 being repeated every four months. This study is designed to ascertain whether clinicians, who have had no previous experience of wearing NHS CBRN-PPE, and limited experience of using a range of intubation aids, improve their intubation performance following increased exposure to performing these skills whilst wearing CBRN-PPE.

Chapter 6

Conclusion

6.1 Introduction

The research presented within this thesis sets out to achieve two key aims, the first to identify what airway and vascular access skills can be performed whilst wearing the NHS CBRN-PPE and the second to develop a CBRN based simulation-training programme to enable staff to respond to a CBRN incident. In 2007, when this research journey started, ascertaining what skills could be completed whilst wearing the NHS CBRN-PPE was a clinical priority, as there was no evidence-based guidance indicating what skills could be implemented whilst wearing the NHS CBRN-PPE.

The CBRN-PPE issued to the NHS provides a high level of protection, requires minimal training to wear, enables staff to wear their own glasses and is not affected by beards (Appendix 1). Nonetheless, as confirmed by this research, it is hot, bulky, cumbersome, restricting and can be claustrophobic to wear. Yet, following a CBRN incident there is an expectation that medical personnel will treat patients in an attempt to preserve life, requiring these healthcare personnel to wear CBRN-PPE to prevent self-contamination. The research in this thesis clearly demonstrates that the NHS CBRN-PPE impairs the performance of clinical skills. This is, in part, due to the 0.9 mm gauge of the integral gloves reducing dexterity and sensation, which is further compromised if the gloves are too big or too small. Another problem is that the integral visor can move independently of the clinician's head, obscuring the clinician's vision. Although the research contained in this thesis identifies the design of the NHS CBRN-PPE as a factor in reducing skill performance, replacement of the currently issued CBRN-PPE is unlikely to be economically viable in the current financial climate, especially as the NHS CBRN-PPE adequately serves its primary function of protecting the wearer from contamination.

Following the nine Papers contained in this thesis, we now have a better understanding of what airway and vascular access skills can be performed whilst wearing NHS CBRN-PPE. The key themes in this thesis are outlined in Table 29 and recommendations are presented in Table 30 with future research questions outlined in section 6.8. This new knowledge will support the delivery of CBRN training programmes and the selection of equipment for use during a CBRN incident, both of which will help to optimise the treatment of patients with

time-critical injuries or illness following exposure to a CBRN agent and thus help to reduce the mortality associated with treatment delays.^{8 32 37}

6.2 The importance of prior experience and the presence of a learning effect

By recruiting a range of healthcare professionals (nurses, doctors and paramedics) with varying levels of experience, the research in this thesis successfully demonstrated that the impact of prior experience is not profession-dependant (Paper 1, 3, and 4). It is, however, dependent on the frequency with which a clinician is exposed to performing a skill during his or her daily clinical practice.

At face value, these findings support the assertion that the most skilled clinician should perform all clinical interventions whilst wearing CBRN-PPE; a view consistent with World Health Organisation advice for intubating a patient with pandemic influenza.⁷⁵ Whilst this proposal is intuitive and supported by the literature, it is also idealistic and unrealistic as the 'ideal' clinician may not be immediately available, or the number of clinicians available may be inadequate to meet the needs of the number of patients requiring treatment.²⁷⁷ The research also demonstrates that clinicians can learn to adapt skills whilst wearing CBRN-PPE, which indicates that the provision of simulation skill-based training will optimise the performance of clinicians who may be expected to treat patients following a CBRN incident.

6.3 Meeting the training needs of clinicians with a simulation-based CBRN training programme

Simulation-based training is central to anaesthetic training^{345 346 356 405}, emergency medicine²⁵⁸ and obstetrics³⁵⁵, as well as in the development of resuscitation skills.³⁴³ Simulation has also been used for prehospital emergency care education³⁰³, during specialist training scenarios for aeromedical evacuation³⁴¹ and in military medical training prior to deployment to Afghanistan.³⁵² The reasons for using simulation are numerous, but include patient safety^{257 345}, learning to perform new skills^{258 303 406 407}, maintaining competence^{303 354 408}, practising infrequently performed skills where poor performance may result in patient harm^{355 356 408 409}, as well as skills surrounding decision-making and team working in complex environments.^{341 342 346} Simulation-based training allows clinicians to learn through making mistakes in a safe environment supported by peer-feedback and educator led debriefing.^{258 410-412} An additional important aspect of simulation-training is the provision of a realistic scenario^{20 257 346} which, equally, requires access to equipment that staff would be expected to use during actual clinical emergencies.

Table 29: Key themes in this thesis

Finding	Comment	Paper
The impact of prior experience on skill performance	This is a generic finding that occurred for all clinicians and across all skills such as when anaesthetists performed intubation or emergency nurses aspirated drugs. Thus wherever feasible, the most experienced clinician should perform the required skills. (Illustration 9).	Paper s1, 3, 4 and subgroup analysis.
The importance of patient positioning on airway management whilst wearing CBRN-PPE.	The research demonstrates a direct correlation between patient positioning and intubation success which is attributed to the design of the NHS CBRN-PPE.	Paper s 3, 6 and 7.
The impact of prior experience and personal preference on deciding what skills/equipment to use in a CBRN environment	During the interviews, the impact of personal preference was seen to influence what devices were recommended for evaluation. This is likely to explain the initial contents and also the subsequent re-equipping of the mass casualty pods. However, clinicians were also observed to apply their clinical knowledge and experiences of wearing the NHS CBRN-PPE to make pertinent recommendations.	Papers 5 and 6
The presence of a learning effect associated with repeating skills whilst wearing CBRN-PPE.	This is a generic finding noted across all skills regardless of their level of dexterity. It was not clinician centric as it occurred across all participants from expert to novice. However, more expert clinicians were noted to learn faster than less expert clinicians.	Paper 1.
The degree of dexterity required to complete a skill affects the ease/speed at which the skill is performed.	This finding applied across a range of skills, including airway management, securing an endotracheal tube in situ, vascular access and drug administration. Whilst the high dexterity skills were noted to improve the most (e.g. intravenous cannulation), an improvement was also noted in the lower dexterity skills (e.g. LMA insertion).	Papers 1-6, 8 and 9.
The movement of the NHS CBRN-PPE hood/visor impedes intubation on the floor.	When attempting to intubate on the floor the movement of the hood/visor was an independent factor in intubation skill failure but did not affect the insertion of the LMA. This was directly due to the design of the NHS CBRN-PPE.	Papers 3, 6 and 7
The treatment of airway, breathing and obtaining vascular access are achievable whilst wearing CBRN-PPE.	With training and the provision of appropriate equipment, life-saving airway, breathing and vascular access interventions are achievable whilst wearing CBRN-PPE. The dexterity required to perform the chosen skill is, however, one of the key factors predicting the effectiveness of the selected intervention (Illustration 9).	All 9 papers.

Simulation-based training is also well established in medical education with its effectiveness having been confirmed by McGaghie et al⁴⁰⁸, in a meta-analysis of published studies linking simulation to improved patient outcomes. Similar benefits in skill performance, clinical knowledge and professional behaviour have been reported by Cook et al.⁴¹³ With two very recently published (on line ahead of print publications) systematic reviews by Gjeraa et al⁴¹⁴ and Boet et al⁴¹⁵ demonstrating the role of simulation-training in the improvement of non-technical skills.

6.4 The role of CBRN simulation-training to improve skill performance and change clinical behaviour

With regards to CBRN training, the literature review by Taylor and Orlansky²⁰ identifies the importance of training whilst wearing CBRN-PPE as part of non-medical military CBRN preparation, these findings have been echoed by Arad et al¹⁷⁸ with regards to training military medical personnel. These lessons have been transferred to civilian CBRN preparations, most nobly in Israel.^{68 189 206} Whereas Watson et al⁴¹⁶, recently demonstrated that simulation-based training improved the clinical performance of experienced paediatricians, as well as team working skills and adherence to PPE guidelines during preparations for pandemic influenza.

The research contained in this thesis highlighted a number of important factors, specifically related to the development of a CBRN based simulation-training programme. A fundamental finding in Papers 1 and 3 was that any learning effect only occurs when skills are practised whilst wearing CBRN-PPE and did not develop with CBRN-PPE familiarisation training. This finding therefore mandates that clinicians need to practise performing skills whilst wearing the NHS CBRN-PPE. In addition to learning how to adapt skills, clinicians need to experience the claustrophobic and restricting nature of the CBRN-PPE, as well as learning to appreciate the impact that the CBRN-PPE has on communication. These represent important non-technical skills that can be equally achieved through simulation-training.^{414 415}

Furthermore, Papers 5 and 6 also demonstrated that clinicians can have strong preconceived ideas about what skills can be performed whilst wearing CBRN-PPE. These preconceived ideas typically mirror accepted practices and/or skills developed whilst wearing normal uniform (e.g. theatre scrubs). Regardless of how these perceptions are developed, they represent clear barriers to learning.^{417 418} However, clinicians were also noted to change their opinions after attempting to perform clinical skills whilst wearing CBRN-PPE.

To date, 20 simulation courses have been run at three different hospital venues, primarily during preparations for the 2012 London Olympics.^{46 419} Participants have mainly been drawn from anaesthesia, emergency medicine and emergency nursing and so comprise those clinicians most likely to be involved in the treatment of CBRN casualties. All participants have been deemed competent at performing a range of skills, such as intubation, with a number of participants being considered experts (e.g. consultants).⁴²⁰ None of the participants had any previous experience of wearing NHS CBRN-PPE and therefore by definition they were all classed as novices.⁴²⁰

Each CBRN simulation course included instruction in how to don the CBRN-PPE, CBRN-PPE safety issues and, an introduction to CBRN triage sieve. The course instructors also asked clinicians to perform a range of skills during simulated emergencies whilst wearing NHS CBRN-PPE. The skills practised during each training session were adjusted to meet the needs of the participants and local practise.

To optimise learning, all simulation-training initially concentrated on clinicians experiencing the loss of dexterity, vision and the restricted movement associated with wearing CBRN-PPE whilst performing established clinical interventions. These established interventions, such as using a cotton tie to secure an ETT, were selected locally. Participants were then introduced to new techniques (e.g. Thomas™ Tube Holder) or were shown different ways to accomplish established clinical interventions whilst wearing CBRN-PPE. Participants then repeated the clinical interventions and discussed with their peers the difficulties they experienced, thereby allowing clinicians to make their own comparisons between established skills and new techniques (e.g. cotton tie vs. Thomas™ Tube Holder).

This approach to training, is reflective of enhanced discovery-based-learning, where students receive some instruction but also learn through doing.⁴²¹ It was envisaged that by combining enhanced-discovery-based teaching techniques with simulation-based training and peer-debriefing, preconceived ideas regarding skill performance, whilst wearing CBRN-PPE, could be overcome. This is because simulation-based training has been shown to successfully support changes in clinical practice.^{346 356 416 422 423} For example, Hubert et al³⁵⁶ noted that the attendance at failed airway simulation-training, not only improved the technical performance of anaesthetists but also their adherence to difficult airway guidelines. These improvements were still apparent at 12 months. Whereas, Weller et al⁴²² noted that after completing anaesthetic crisis management training, anaesthetists not only felt more confident in managing a range of emergencies but were more willing to call for help early.

Similarly, Hallikainen et al⁴²⁴ noted that medical students were more likely to wear gloves (p -value = <0.012), and give clear instructions regarding the monitoring of a range of vital signs (blood pressure p -value = <0.01, heart rate p -value = <0.002) to an anaesthetic team after completing simulation-training, when compared with more traditional theatre-based training. Whereas Hunt et al⁴²⁵, Marzano et al⁴²³ and Parsons et al⁴²⁶ have all demonstrated improved adherence to trauma protocols following simulation-training. With both Marzano et al⁴²³ and Parsons et al⁴²⁶ using simulation to develop and monitor team adherence to newly introduced clinical guidelines.

Therefore, simulation-training is essential to both the development of technical and non-technical skill performance whilst wearing NHS CBRN-PPE. Finally, simulation-based training allows clinicians to practice infrequently performed skills^{355 356 409}, under-supervision and supported by peer-group feedback, whereas from a logistical point-of-view it enables the training of larger number of clinicians.⁴²⁴

6.4.1 The role of verisimilitude and the validity of simulation-training

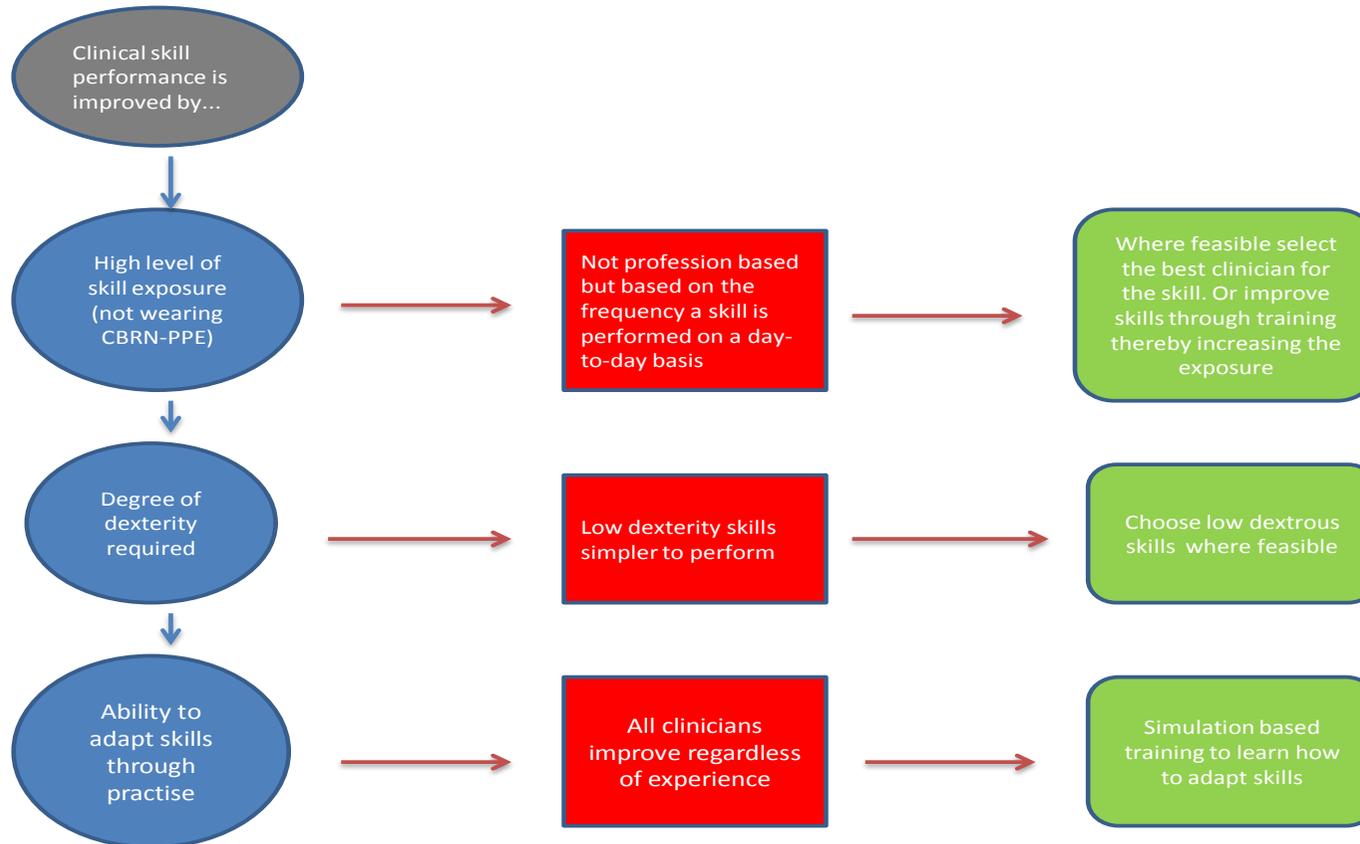
An additional element that needs to be considered during simulation-training is the realistic nature of the training as the use of realistic manikins and/or equipment increases the validity of the experiences gain.^{20 346 427 428} Therefore all clinicians wore CBRN-PPE when performing clinical skills, thereby, combining PPE familiarisation with skill-based performance training. For safety, ethical and practical reasons manikins were used as patient simulators, however, the use of manikins is well established in simulation-training.^{257 343 406 424}

Although McGaghie et al⁴⁰⁸, Gjeraa et al⁴¹⁴ and Boet et al⁴¹⁵ have all put forward strong arguments indicating that simulation-training is now well proven. However it is, the literature review by Boulet et al⁴⁰⁶ that identifies how to ensure simulation-based training is valid by identifying the importance of using standardised patients so that each student is exposed to the same patient, scripted clinical scenarios, checklists of performance indicators for technical (e.g. turning on oxygen) and non-technical skills (e.g. calling for help). The research presented in this thesis, has not attempted to validate simulation as an educational technique for improving skill performance whilst wearing NHS CBRN-PPE. This is partly, because, simulation-training is now so well established in medical education and because Berkenstadt et al¹⁸⁹ has previously identified that anaesthetists value simulation-training over traditional approaches to CBRN training.

Whilst accepting that specific research that addresses the validity of simulation, as a method of skill training whilst wearing CBRN-PPE is limited, it appears reasonable to extrapolate the positive findings of the non-CBRN research to indicate that clinicians will benefit from CBRN simulation-training. Especially, if we combine the findings of Berkenstadt et al¹⁸⁹ to the findings presented in this thesis. Berkenstadt et al¹⁸⁹ demonstrated that 100% of anaesthetists found that simulation-based CBRN training was superior to traditional training methods. Whereas, as discussed in this thesis, clinicians can learn to adapt technical skill through repetition, gain a better understanding of the impact of NHS CBRN-PPE on non-technical skills, and that by performing skills whilst wearing CBRN-PPE clinicians can change their opinions as to what interventions will, or will not work in specific environments.

Finally, the choice of clinical intervention (low-dexterity skills vs. high-dexterity skills) and the background of the clinicians are equally important factors in skill completion that needed to be addressed during the development of simulation-training. In summary, the essential elements to achieve in a simulation-based CBRN training programme are, consideration of the prior experience of the participants and, realistic skill-based training obtained through simulation which allows clinicians to learn to adapt skills supported by careful choice of clinical interventions (Illustration 9).

Illustration 9: Elements associated with improving skill performance whilst wearing CBRN-PPE



6.5 What are the implications of this research on current CBRN treatment strategies?

In addition to informing how best to deliver a CBRN-based simulation programme, the research presented in this thesis was designed to evaluate a range of airway and vascular access skills to ascertain which of these could be performed whilst wearing the NHS CBRN-PPE. The finding resulted in a number of recommendations which are outlined in Table 30.

6.5.1 Airway management

Notwithstanding the fact that the optimal supraglottic airway for use during a CBRN incident is unknown, the research in this thesis presents data on a range of supraglottic airway devices, enabling clinicians to select the device/devices that best meet their specific needs. A significant benefit of a supraglottic airway is in its immediate use during the initial ventilation of a patient, as opposed to using a bag-valve-mask device on an unprotected airway.^{226 359 375 378 429 430} Whilst accepting that intubation provides the optimal protection from aspiration of gastric contents, a supraglottic airway can provide an effective alternative.

Based on speed and ease of insertion, the research presented in this thesis supports the Igel as being the ideal supraglottic airway for immediate use following a CBRN incident. Albeit slower to insert than the Igel, the LTA is also an alternative to the immediate use of a bag-valve-mask device.^{370 378} Furthermore, the design of LTA should offer improved ventilation against high airway pressures and protection from aspiration.^{267 362 363}

Whilst this thesis supports the use of supraglottic airway devices during the management of a CBRN incident, endotracheal intubation still offers clinical benefits to patients exposed to a CBRN agent.^{74 82 148 249} Papers 1, 3, 7 and 9 demonstrate that intubation whilst wearing CBRN-PPE is achievable, with Papers 1 and 3 highlighting that clinicians improve with practise. However, intubation is adversely affected when performed on the floor and this is directly due to the design of the NHS CBRN-PPE. Consequently, if intubation is to be considered, whilst wearing CBRN-PPE, it should be performed in the optimal position (i.e. raised off the floor) by a clinician who has had an opportunity to practice intubation whilst wearing CBRN-PPE and, that all intubation attempts should be supported by techniques to confirm ETT placement that can be used whilst wearing CBRN-PPE. If a competent clinician is not available, or if the patient is positioned on the floor, then intubation should be replaced by the use of a supraglottic airway.

Table 30: Key recommendations for clinical practise

Recommendation	Supporting Papers	Comments
Intraosseous access should be the preferred option for vascular access.	Paper 1	Where a patient needs immediate vascular access, the intraosseous route offers a reliable and effective alternative to intravenous cannulation.
The Thomas™ Tube Holder (TTH) is the preferred device to secure endotracheal tube in situ.	Paper 2	Whilst the TTH is a popular device in the prehospital arena the use of cotton ties remains a commonly used technique in hospitals. Therefore, CBRN-based training programmes should provide clinicians with the opportunity to practice and compare various techniques for securing the ETT in situ.
Aspirating drugs – wherever possible avoid using glass ampoules	Paper 4	Prefilled syringes are faster, more accurate and offer a lower risk of user injury while plastic ampoules represent a cheaper option for stockpiling drugs.
Optimise patient positioning prior to intubation – staged airway management.	Papers 3, 6 and 7	Intubation on the floor should be replaced with the immediate use of a supraglottic airway supported by prompt evacuation of the patient to a more suitable area where the patient’s ongoing airway needs can be re-evaluated.
CBRN familiarisation training to learn how to adapt skills and experience the complexities of skill performance whilst wearing CBRN-PPE.	Papers 1 to 9	Clinicians need to experience the restrictions on skill performance first hand to learn how to adapt skills as well as learning what skills can/cannot be successfully performed whilst wearing CBRN-PPE. CBRN training should incorporate an element of skill practise that is appropriate to the healthcare professional’s background.
Introduce staged airway management with supraglottic airways used as a bridging measure until optimal intubating conditions are feasible.	Papers 3, 7 to 9	Supraglottic airway devices offer a reliable, easy to use and faster alternative to intubation during the initial phase of a CBRN incident. The use of a supraglottic airway would result in faster airway management allowing the greatest number of patients to be treated when resources are limited. This could be further supplemented by combining immediate use of supraglottic airways and intraosseous drug administration.
During the treatment of mass casualties intramuscular drugs, via a CBRN auto-injector, offer an option in patient management.	Literature review	Although speed of therapeutic onset via intramuscular drugs is variable the ease and speed of use associated with CBRN auto-injectors makes these devices ideal for mass casualty management. The combination of auto-injectors and Igel would represent a rapid treatment strategy for responding to mass casualties following a CBRN incident.
Where immediate airway management is required the Igel should be considered as the ideal emergency airway adjunct.	Paper 8	Whilst the Igel is the fastest device to insert the optimal supraglottic airway device, with regards to ventilation in the confines of a CBRN incident, remains unknown.
Confirmation of ETT is essential when wearing CBRN-PPE.	Papers 1, 3, 7 and 9	Incidents of oesophageal intubation occurred across all four Papers in which intubation was evaluated whilst wearing CBRN-PPE. Therefore an effective strategy for ensuring correct placement of ETT, what can be performed whilst wearing the NHS CBRN-PPE is a clinical priority.
Consider preparing equipment outside of the hot/warm zone.	Observation and literature review	Regardless of the skill, CBRN-PPE had an adverse impact on skill completion. An aspect of any skill is preparation and therefore, wherever feasible, preparation in the cold zone and transferring the prepared item e.g. aspirated drugs into the hot/warm zone would be advisable.

These recommendations are consistent with the 2005²⁶⁴ and 2010 ERC resuscitation guidelines²²⁶ and are equally applicable to intubation in a CBRN environment, as this thesis confirms that CBRN-PPE further complicates the performance of intubation.

When presented with a potentially difficult intubation attempt, the UK^{242 243} and international guidelines²⁷⁹⁻²⁸¹ recommend using an intubation aid. However, there currently exist no guidelines or recommendations as to how to intubate a patient whilst wearing CBRN-PPE, nor had the impact of CBRN-PPE on using intubation aids been fully evaluated. The findings in this thesis demonstrate that all of the evaluated devices were adversely affected by the NHS CBRN-PPE. Nevertheless, Papers 8 to 9 did indicate a potential role for the intubating LMA (ILMA), as the design of the ILMA will allow it to be used in stages, first as a supraglottic airway and then as a device to facilitate intubation. This approach could minimise any impact of a prolonged intubation²³⁹ attempt and should the intubation attempt fail, the presence of the ILMA will allow immediate ventilation.

Throughout this thesis, the Positube™ and a colorimetric end-tidal CO₂ device were used in combination to simulate the process of confirming ETT placement. However, an issue highlighted in Paper 1 was the incidence of right bronchus intubation, which neither the Positube™ nor colorimetric end-tidal CO₂ devices are designed to detect. Right bronchus intubation is normally diagnosed by chest auscultation and by observing how the patient chest rises.²²⁶ However, the NHS CBRN-PPE prevents the use of a stethoscope to perform auscultation to confirm ETT placement, whereas, techniques such as observing the chest raising are prone to misdiagnosing a misplaced ETT.²⁶⁵ The research in this thesis demonstrates that the combination of a Positube™ and a colorimetric end-tidal CO₂ device is achievable whilst wearing CBRN-PPE. It also confirms that oesophageal intubation remains a realistic risk, and that clinicians need to carefully observe for right bronchus tube placement.

The research presented in this thesis confirms that the cotton tie provides poor airway security when compared to the Thomas™ Tube Holder (TTH). Despite the TTH being more effective than the cotton tie, changing clinical practice will be difficult due to the low cost of cotton ties, their established role in securing an ETT in situ^{284 286}, the absence of any international recommendations on securing an endotracheal tube in situ, either during standard anaesthetic practice, emergency airway management or in the context of a CBRN will make clinicians reluctant to change deep rooted clinical practice. This can be demonstrated by the fact that mechanical tube holders have been available for a number of years, and yet the frequency of their use remains low during hospital emergency airway

management.^{284 286} The use of the TTH during simulated CBRN training will thus be an important factor if mechanical securing devices are to gain traction in CBRN clinical practice.

6.5.2 Vascular access and drug administration

The literature review in this thesis supports the continued use of CBRN auto-injector as they are easy to use when wearing CBRN-PPE gloves.^{68 102 431} Nevertheless, not all emergency drugs can be administered via the intramuscular route²²² and patients may require large doses of some drugs, such as atropine^{17 82 102 153}, mandating the need for intravascular access.

Paper 1 demonstrates that intravenous cannulation has no role in obtaining intravascular access whilst wearing the NHS CBRN-PPE, whereas intraosseous access offers a viable alternative. Intraosseous devices are easily inserted and drugs administered via this route have an onset of therapeutic action comparable to intravenous drug administration.^{210 230} An additional benefit of intraosseous access, particularly pertinent for use during a CBRN incident, is that an intraosseous device 'self-secures' through the periosteum and into the cortex of the bone. This makes accidental removal difficult. Therefore this thesis supports the replacing of intravenous cannulation with intraosseous access when immediate administration of drug therapy is required.

Once intravascular access is secured, clinicians need to consider how best to administer drug therapy. Paper 4 demonstrated a clear benefit for using prefilled syringes which were easier, faster, safer and more accurate when compared with ampoules. The increased speed and accuracy offered by the prefilled syringes confers a clinical benefit to the critically ill patient, by ensuring that treatment is given in a timely manner with the correct drug dose. Moreover, prefilled syringes offer safety benefits for responding healthcare professionals with a reduced risk of needle stick injuries and damage to the CBRN-PPE. The UK's mass casualty treatment pods have recently been up-dated and now contain a mixture of glass and plastic ampoules as well as prefilled syringes. However, the stockpiling of major incident drugs is still based on a balanced consideration of cost versus the need for immediate availability.²²²

Glass ampoules represent the cheapest option for mass storage but remain a poor choice for use if clinicians are wearing CBRN-PPE. Plastic ampoules are easier and safer to use than glass ampoules but whereas the prefilled syringe maybe the optimal drug preparation, it is more expensive and the current range of drugs offered in a prefilled syringe is limited. However, where drug administration is time dependent, such as with the administration of atropine following nerve gas exposure¹⁰², the use of prefilled syringes is ideal.

During the research reported in Paper 4, emergency department nurses were noted to be the fastest at aspirating drugs from glass ampoules, although all participants demonstrated a generic learning effect across the various drug preparations. Consequently, the results of Paper 4 suggest that simulation-training may help to reduce the impact of CBRN-PPE on aspirating drugs. On a more fundamental level, simulation-training may encourage clinicians to think more laterally electing to prepare drugs in the clean zone and then transporting them into the hot or warm zones for subsequent administration. This would be a simple, cheap and effective approach to drug administration.

6.5.3 Staged airway management

The patient requiring immediate airway management following a CBRN incident presents a clinical challenge. The patient is likely to be clinically hypoxic and positioned on the floor, and the attending clinician will be wearing CBRN-PPE. With the exception of Papers 3 and 7, all CBRN-PPE research to date has failed to consider the position of the patient or the complexities of treating a hypoxic patient. This gap in the literature has resulted in airway research being undertaken in the optimal intubating position, typically at waist height, and devised around a single skill such as intubation or LMA insertion.

By combining the results from this thesis; the potential of performing different airway interventions at varying stages of the patient's treatment can be considered. This staged approach to airway management would involve changing the intervention to either meet the patient's need, the needs of the situation, as well as the level of competence of the clinician or to reflect what is achievable whilst wearing the NHS CBRN-PPE.

Staged airway management would initial involve the use of a supraglottic airway in the hot zone, with the patient being extricated to the warm zone, where he/she can be reassessed. At this point, the supraglottic airway might be retained whilst the patient is decontaminated, the patient could be intubated, or the patient might no longer require airway management. The idea of staged airway management is reflective of TOXALS™³² and is supported by

Byers.⁹⁸ Based purely on ease and speed of insertion, the research in this thesis indicates that the Igel is the obvious supraglottic airway for immediate use during the treatment phase and subsequent evacuation of an unconscious patient.

Staged airway management is not just applicable to multiple casualties but maybe appropriate when managing a single critically ill patient. As using a supraglottic airway in the immediate treatment of a hypoxic patient, instead of using a bag-valve-mask device, will reduce the risk of aspiration and hypoventilation. The choice of supraglottic airway best suited to treating the single contaminated casualty is debatable, although the Igel offers ease and speed of insertion, the ILMA equally offers its own unique benefits.

Apart from airway management, the use of intraosseous access supported by the use of prefilled resuscitation syringes also confers significant time-savings. By combining the early use of a supraglottic airway, securing intravascular access via the intraosseous route and administering drugs (if required) via prefilled syringes, valuable time can be saved when treating casualties with time critical airway, breathing or circulatory collapse. This approach has recently been successfully evaluated by Reiter et al⁴²⁹ in the simulated management of non-CBRN cardiac arrests.

The approach of staging or escalating patient care following a mass casualty incident may at first appear to be at odds with CBRN triage sieve, particularly as during the initial phase of a mass casualty CBRN incident, it may not be feasible to instigate treatment on large numbers of casualties. However, as highlighted in Chapter 1, many of patients following CBRN incidents are likely to have minor, non-life threatening contamination with a small number of patients being critically ill. Focusing immediate treatment on the critically ill patients can save lives as demonstrated by the response to the Tokyo sarin gas attack and numerous case studies (Table 2, section 1.4.1 and 1.6).

6.6 Robustness of the research

The research presented in this thesis, represents the largest body of research, to date, looking at selected skills performance whilst wearing the NHS CBRN-PPE. Unlike a more traditional thesis submitted as part of a period of study aiming towards the award of an academic degree, this research grew out of an observed clinical need and therefore the nine papers presented in this thesis represent three phases of research, the first four papers grew out of a need to ascertain what skills could be performed whilst wearing the NHS CBRN-PPE and were devised through action research techniques to answer clinically imperative

questions. However, as the research story grew the research methods changed to optimise the integrity of the research. To this end, Papers 5 and 6 were designed to link together Papers 1 to 3 with 7 to 9 with the intention of removing potential biases observed within Papers 1 to 4. Papers 5 and 6 also allowed clinicians to document their experiences of wearing the NHS CBRN-PPE whilst performing clinical skills. This approach allowed Papers 7 to 9 expand on Papers 1 to 3 whilst avoiding a number of variables, which are discussed below in section 6.6.1.

6.6.1 Achieving robustness of the research

As Papers 1 to 4 and 7 to 9 were designed to monitor the impact of skill performance whilst wearing the NHS CBRN-PPE an intention-to-treat-model was adopted, whereby all skills were performed by all participants on the same make of manikin. The use of an intention-to-treat-model allowed for the analysis of any impact associated with wearing CBRN-PPE on skill performance, in as a realistic way as possible. However, the use of an intention-to-treat-model prevents the use of blinding of participant to the study outcomes. The lack of blinding is not felt to have affected the results, as all interventions performed whilst wearing NHS CBRN-PPE were preselected and participants had no influence over the skills to be completed.

The nine Papers presented in this thesis did not involve any long-term follow up looking at repeat skill performance. Therefore there were no issues regarding protocol violation; however, two participants recruited into Paper 4 had to withdraw due to claustrophobia. The data from these two participants was incomplete and was subsequently excluded from data analysis. Potential issues with regards to claustrophobia were not considered in the recruitment strategy employed for Papers 1 to 4. This was subsequently changed. The identification of claustrophobia as a problem affecting the NHS CBRN-PPE highlights the benefits of using an intention-to-treat-model by identifying an important consideration for both simulation-training and future research.

On reflection, the fear of being claustrophobic may have affected recruitment for Papers 1 to 4, as it has since been noted to be an issue during CBRN simulation-training, as it might have prevented eligible clinicians from volunteering for the research project. However, the fear of being claustrophobic did not appear to affect recruitment, as Papers 1 to 4, either met, or exceeded the minimum number of participants required by their power calculation. It does, however, reflect a potential operational issue that would need to be considered in hospital and emergency services major incident preparations. It also serves to highlight a

non-technical benefit to be gained from CBRN-based simulation-training. Nonetheless as the ability to wear CBRN-PPE is not central to the employment of NHS personnel, as it is in the military, there is no immediate solution to the issue of claustrophobia, apart, from continued exposure to wearing CBRN-PPE as part of tolerance training. From an ongoing research protocol standpoint, this problem was controlled for, in subsequent Papers, by selecting South African student paramedics, who as part of their selection for paramedic training are screened for claustrophobia.⁵⁰

Papers 1 to 4 and 7 to 9 all incorporated a power calculation, thereby optimising the likelihood of achieving statistical significance with 80% power using a 5% significance level (p -value = 0.05). As discussed in section 3.24, the power calculation used to inform Paper 4 was, in part, based on a pilot study, which highlighted the possibility that a Type 1 error could occur when comparing the two different prefilled syringes and the two different presentations of ampoules. Therefore, to minimise the impact of a potential Type 1 error, and to further reduce the risk of a spurious result a significance level of 1% (p -value = 0.01), rather than the traditional 5% (p -value = 0.05%) was used. An additional finding of the pilot study was the importance of choosing drugs that did not effervesce when injected into a measuring beaker to ensure accurate measuring of the injected drug volume.

Therefore Papers 1 to 4 and 7 to 9 differed in this regard, to the majority of other published studies addressing skill performance whilst wearing CBRN-PPE, since only two out of the 14 studies included in the literature review (Chapter 2) incorporated a power calculation. Papers 2 to 4 and 7 to 9 actually exceeded the minimum number of participants required, as identified by their power calculations. This was opportunistic in Papers 2 and 3, as data collection occurred during time-tabled CBRN training, whereas over-recruitment occurred during Papers 4, 7, 8 and 9 due to the sizeable numbers of participants volunteering for these studies. Over-recruitment did not occur in Paper 1, due to the complex nature of the studies randomisation schedule, which required multiples of 16 participants, so as to balance for possible interactions between individual skills, the order the skill was performed, and prior familiarity with wearing the CBRN-PPE. Over-recruitment ensured that all p -values achieved significance, and this was particularly advantageous in Papers 7 to 9 as skill performance by some of the participants were protracted, and whilst this resulted in a number of outliers, the results of these studies were still able to demonstrate the negative impact associated with wearing the NHS CBRN-PPE.

Papers 1 to 4 and 7 to 9, present results using a combination of 95% confidence intervals, p -value, standard deviations, ranges of time to complete skills, and overall success rate. This

combination allowed meaningful comparisons between the studies, highlighting which skills were the most successful and the fastest to complete, consistent with the purpose of the studies. However, the data presented in these papers were not normally distributed due to variations between individuals performing the various interventions as well as between the different skills being evaluated. For this reason non-parametric tests were used.³⁵¹ This approach confirmed that prior exposure of wearing CBRN-PPE had no impact on skill performance, nor did the order in which clinicians were randomised, but that clinician background had a positive impact on skill performance. The complex nature of the statistical designs, and the associated statistical models used to analyse the data in Papers 1 to 4 and 7 to 9 required the support of senior and experienced statisticians (Appendix 4).

The participants in Papers 1 to 4 comprised a wide range of clinicians from different professional backgrounds and with varying levels of clinical seniority. With the exception of the nurse lecturers (Paper 4), these clinicians were employed in roles which could lead to them treat patients following a CBRN incident, thereby ensuring that the results contained in Papers 1 to 4 are generalisable to the healthcare professionals who may respond to a CBRN incident.

Nonetheless, as demonstrated by subgroup analysis, professional background and clinical seniority (e.g. consultant vs. trainee) impacted on skill performance with certain professional groups (i.e. anaesthetists) performing certain skills (i.e. intubation) faster than other clinicians. This was attributed to the day-to-day exposure clinicians had at performing skills, and whilst this was a useful finding to support the development of simulation-training and the operational response to a CBRN incident, from a research methods stand-point it represented a confounding variable in the data. This is because, theoretically, any improvement or failure in skill performance might be due to the participant's clinical background, and level of training as opposed to any impact associated with wearing NHS CBRN-PPE.

Therefore to control for both the clinical background and the clinical seniority of participants in subsequent studies (Papers 7 to 9) a single professional group of clinicians were recruited (i.e. student paramedics). This approach ensured similar levels of experience and training, and was undertaken to improve the internal validity of the results, by concentrating on the impact of CBRN-PPE on skill performance, while excluding the confounding factor of inter-professional variation in skill completion. It is accepted that this approach equally reduces the generalisability of the results, but it provides a better answer to the research question

'What airway and vascular access skills can be performed whilst wearing the NHS issued chemical, biological, radiation, and nuclear personal protective equipment'?

Data collection for Papers 7 to 9 was moved from the UK to a South African University. The South African university was selected for numerous reasons, which included a vested interest in CBRN research, access to a large pool of students and an established research partnership.^{274 292 432} This approach, not only ensured that all participants had similar level of intubation experience; it also ensured similar levels of experience of intubating manikins placed on the floor, whilst also ensuring that participants had not previously worn the NHS CBRN-PPE. Therefore the recruitment of South African paramedic students successfully minimised the impact of varying intubation experience as well as excluding any benefit from having previously worn NHS CBRN-PPE on subsequent data collection.

All nine Papers submitted in this thesis were peer reviewed prior to publication. As part of this peer-review process the use of manikins was challenged as lacking validity and generalisability compared with human volunteer-based studies. The use of human volunteers for CBRN research, especially research involving airway management, is challenging as it represents a risk to the volunteer by prolonging the period required to complete the evaluated skill. Therefore, to minimise this risk, researchers have to recruit participants deemed to have a low anaesthetic risk and have to recruit a different volunteer for each arm of their study, reducing the generalisability and the validity of the results. This can be demonstrated by looking at the research protocol employed by Flaishon et al¹⁶⁸ (section 2.8.1), who, for safety reasons had to exclude all patients deemed potentially difficult to intubate, selecting only low risk anaesthetic patients, thereby reducing the generalisability of the results to the general public. Furthermore, each participant had to perform each skill twice (in/out of CBRN-PPE) which required a different volunteer for each arm of their study. This study design could, theoretically have resulted in a participant initially intubating a 42 kg female, whilst wearing standard theatre clothing, before repeating the same skill on a 105kg male (Table 8) whilst wearing CBRN-PPE. This change in intubating conditions reduces the face validity of the data.

Such safety issues are not a concern when using a manikin. Furthermore, manikin-based research is well established in the field of resuscitation research, with 19 manikin-based studies published in the *Journal of Resuscitation* during 2013. Whilst accepting that the use of human volunteers is traditionally seen as ideal, it can also be argued that the use of manikins strengthened the validity of Papers 1, 3 and 7 to 9 by ensuring that all participants experienced the same 'patient', as the same make of manikin was used across all data

collection (section 5.6). Finally, as an additional aim of this research was to develop a CBRN skill-based training programme, confirming the effectiveness of manikins for CBRN simulation is a supplementary finding of this thesis.

The clinical skills and devices (i.e. LMA and EZ-IO drill) evaluated in Papers 1 to 4 were primarily selected by the lead author. The choice of these skills and devices was a direct result of using action research and reflective practice in an attempt to answer the clinical question *'What airway and vascular access skills can be performed whilst wearing the NHS issued chemical, biological, radiation, and nuclear personal protective equipment?'* as they reflect locally available equipment. Whilst the choice of these clinical skills and devices was valid, this approach is subjective and potentially prone to selection bias.¹⁷² Therefore Papers 5 and 6 were designed to avoid selection bias by interviewing an expert group of clinicians, so as to identify what airway devices should be subsequently evaluated in Papers 8 to 9.

In addition to Papers 5 and 6, interviews were also incorporated into Papers 2 and 3 providing insight as to why securing an endotracheal tube in situ and intubation on the floor were complicated by wearing CBRN-PPE. Papers 2, 3, 5 and 6 are the only studies to date that have combined quantitative and qualitative techniques to address this area of CBRN-PPE research. The analysis of all interview data (Papers 2, 3, 5 and 6) was based on manifest content analysis²⁸⁹, which allowed for the analysis of a large amount of data and the population of a list of devices for further evaluation. Whilst also gaining an insight into what the NHS CBRN-PPE felt like to wear.

The above benefits notwithstanding, the interviews represent an area of this thesis that was not completed to its full potential. This was because as the research project progressed, and I reflected on the data collected, the wider opportunities afforded by the interviews became increasingly apparent. This limitation has been addressed in a subsequent research project, by working more closely with an established qualitative researcher on a re-running of Paper 1 over a 12 month period. Interview data has also been used in this study to further gauge clinicians' experiences.⁴³³

A number of unanticipated observations arose in Paper 3, which included the negative impact of the NHS CBRN-PPE design when attempting to intubate on the floor. The negative impact of the NHS CBRN-PPE was noted to affected both experienced and inexperienced intubators. This occurred regardless of any one of a range of different intubating positions clinicians adopted when attempting to intubate on the floor. Subsequently, these observed intubating positions were incorporated into the design of Paper 7. Papers 1, 3 and 4 also

demonstrated a learning effect with skill repetition, which has led to the devising of two longitudinal studies being undertaken, which are now nearing completion.

6.7 Putting the results of this thesis into practice

From an operational stand-point, the research in this thesis has resulted in a change in practice in three hospitals that now incorporate the Igel, EZ-IO and the use of the Thomas™ Tube Holder in their treatment plans for managing contaminated casualties. Clinicians at two of these hospitals now regularly practice treating casualties whilst wearing the NHS CBRN-PPE. Furthermore, an overseas ambulance service is incorporating the lessons learnt regarding staging patient management by adopting the use of the Igel, lightweight ventilators incorporating CBRN filters and nerve agent auto-injectors in the hot zone, which are then supported by rapid extrication and re-triage in the warm zone.

The results of this thesis have been shared with the Health Protection Agency (HPA) resulting in the production of a CBRN training DVD⁴⁷, and a number of the recommendations presented in Table 27 are incorporated into the HPA publication *Essentials of Toxicology for Health Protection*.⁴⁸ On a national level, I am currently working with NHS England on the development of CBRN-PPE and relevant guidelines for hospitals, which has resulted in a further two hospitals contacting me to discuss developing their own local simulation-training. Since the publication of the first Paper presented in this thesis, the UK approach to treating CBRN contaminated casualties has grown and developed. Part of this growth has seen the introduction of specialist ambulance rescue teams^{94 95}, who are trained to work in hostile environments, training that enables them to work in the hot and warm zones following a CBRN incident.⁹² These teams have introduced the EZ-IO intraosseous device and the Igel as their preferred treatment options in managing contaminated casualties⁹⁵, reflecting the research findings contained in this thesis.

6.8 Future research

During the data collection and analysis of Papers 1 to 9 a number of additional research questions were identified. These include the following:

1. What is the impact of practising skills whilst wearing CBRN-PPE?
2. How often should refresher training be undertaken to maintain and optimal skill level?
3. Does the learning effect plateau over time?
4. What is the impact of a two-person versus a single-person ventilation strategy when using a bag-valve-mask device with a CBRN filter attached?

5. What is the optimal intraosseous device for use whilst wearing CBRN-PPE?
6. Do video-assisting intubation devices improve intubation success and speed whilst wearing NHS CBRN-PPE?
7. What is the optimal supraglottic airway for use when ventilating a patient who has been exposed to a nerve agent?

The first three research questions address the issue of how frequently clinicians should complete CBRN-based simulation-training. These questions originated from the interviews conducted in Paper 6 and from the observation of a learning effect in Papers 1, 3 and 4. All three questions are operationally pertinent questions, affecting both specialist rescue teams who need to achieve and maintain a high skill level, as well as hospital staff who may have to treat contaminated casualties. Training always represents a balance between meeting operational need and ensuring optimal performance. This is particularly true when training non-specialist hospital-based teams, and therefore identifying the optimal frequency of training will maximise CBRN response with the least impact on service delivery.

Turning to questions four, five and six, the best technique when using a bag-valve-mask device, with a CBRN filter attached remains undetermined^{181 184}, while currently the optimal intraosseous device remains unknown, even though a number of different intraosseous devices are commercially available.^{233 434} Similarly, any benefit to be gained from using a video-assisted intubating device (e.g. CTrach™ LMA) still needs to be fully evaluated. It is envisaged that these three questions can be addressed in a RCT, with participants wearing CBRN-PPE, using a similar research design to Paper 1.

Finally, with regards to question seven, the research presented in this thesis has continuously demonstrated the ease with which supraglottic airways can be inserted and with a higher success rate than endotracheal intubation. However, none of the studies contained in this thesis were designed to determine which supraglottic airway provides optimal ventilation following a CBRN incident. This is an important question if supraglottic airways are to be more widely used during CBRN emergencies, but to fully explore this question a complex and expensive animal based study will be required. Currently overseas funding is being sought for this project.

Studies addressing the first three research questions are approaching completion, continuing the research partnership developed in association with a UK (Paper 4) and a South African university (Papers 7 to 9). Data collection regarding bag-valve-mask ventilation is planned to start in 2015 and funding is currently being sought to commence the research to answer questions 5, 6 and 7.

6.9 Developing as a researcher

Prior to starting the nine Papers contained in this thesis, I had a wide publication portfolio. However, the Papers submitted as part of this thesis reflect my journey from being part of a research team to leading a research team, undertaking protracted and complex data collection, as well as analysing results to present research-informed opinion regarding skill performance whilst wearing CBRN-PPE. This journey has culminated in the nine peer-reviewed research-based Papers presented in this thesis as well as other academic output (Appendix 4). In addition to publications and presentations to various bodies, I have been invited to act as a peer reviewer on the subject of CBRN-PPE and simulation-training for the *Journal of Ergonomics*, and the *European Journal of Emergency Medicine*.

An additional element of this research journey has been the need to obtain research funding (Appendix 5) and infrastructure support. This has primarily come from the medical devices industry, pharmaceutical companies and charitable groups. Securing this funding has been an important and necessary aspect of my future ambition to continue with a number of additional and CBRN-related research topics.

6.10 Final reflections

This thesis grew out of a clinical need to address a local question, which ultimately grew into a series of interlocking publications. It has identified the need to stop, think and address the unique nature of caring for patients following a CBRN incident, regardless of the cause. Furthermore, it has highlighted that there are differences between military incidents involving mass casualties within a war zone and a civilian incident, particularly a civilian incident in which the agent involved is derived from a chemical weapon.

Appendices

Appendix 1

The NHS CBRN PPE and mass casualty treatment pods

A.1 Types of chemical, biological, radiation and nuclear personal protective equipment.

There are four levels of PPE^{8 25 26 94} (A, B, C and D) with levels A, B and C providing varying degrees of protection from CBRN agents. However, as the level of protection increases so does the need for specialist training and a higher level of physical fitness.^{8 209 210} Level C PPE requires less training to wear than Level A or B CBRN-PPE and provides adequate protection for healthcare professionals.^{25 48}

Level A (Illustration 10) is commonly referred to as a gas tight suit because it is fully encapsulating, with integral butyl gloves, boots and self-contained air supply. Level A CBRN-PPE offers the greatest level of protection, but requires the highest level of training and physical fitness to wear. Within the UK emergency services, Level A CBRN-PPE is only available to the fire service and specialist ambulance rescue teams.^{8 29 94}

Level B CBRN-PPE consists of a chemically resistant suit with gloves, and boots, and contains its own integral air supply. This type of PPE offers the same degree of respiratory protection as Level A PPE but with less protection from corrosive substances.

Level C CBRN-PPE (Illustration 11) is the level of CBRN protection issued to the NHS, the police and the military.^{8 25 26} It includes a chemical-resistant splash suit, butyl rubber gloves, boots and a respirator. Level C PPE provides adequate protection from the majority of chemical agents but it is not suitable for use in heavily contaminated areas or where the oxygen content is lower than atmospheric air.^{8 25 26 48}

Illustration 10:

Level A CBRN-PPE

Fire service level A CBRN-PPE with breathing apparatus. Whilst providing maximum mobility this approach has limited air supply and requires a high degree of physical fitness



Level A CBRN-PPE with an airline. This type of PPE reduces mobility but offers prolonged air supply . Commonly used within high risk industry



Illustration 11: Level C CBRN-PPE

NHS ambulance personnel wearing the NHS issued CBRN-PPE with its C1 respiratory and panoramic visor



British soldiers wearing C2 respirators and bifocal visor



The NHS issued Level-C suit is designed to be ‘stepped into’ as it is fully encapsulating with integral boots and gloves.²²² Externally, it resembles a Type A suit minus the independent air supply. The suit provides a minimum of two layers of protective gloves (an optional pair of cotton under-gloves are also provided for comfort) with a minimum gauge at the fingertips of 0.9mm (Illustration 12).²² The gauge of the gloves reduces finger-thumb dexterity and sensation, which is further reduced by the ‘one size fits all’ sizing of the integral gloves which results in the gloves often fitting poorly.¹⁸⁷

Illustration 12: NHS CBRN-PPE integral gloves

Personal Protective Equipment (gloves)

UK CBRN gloves are 0.9mm thick reducing dexterity, sensation but are less likely to become damaged by debris

The loss of finger-thumb dexterity makes skill like handling syringes more difficult.



Despite its limitations, the NHS issued CBRN-PPE is designed to enable staff to function with minimal training, and the provision of a battery-powered respirator allows the wearer to breathe normally without any increase in respiratory workload.^{180 183 435} These are important design features when considering that the NHS workforce is varied, physical fitness is not a factor in continued employment, staff may need to wear glasses or elect to have beards (prohibited in the military) and training in the use of CBRN-PPE is not considered a priority outside of specialist teams.⁹⁴

Types of respirator (Illustration 13): There are two types of respirators, these being either the air-supplying respirator, via cylinder or air-line, which is used as part of a Level A or B PPE, or an air-purifying respirator. Air-purifying respirators filter air via a CBRN filter and can be further sub-divided into negative-pressure respirators or powered air-purifying respirators.

Negative pressure respirators require the wearer to generate adequate pressure to draw air through a filter increasing the effort required to breathe.^{20 21 435} Whereas powered air-purifying respirators draws air through a filter via a battery-powered motor reducing the effort of breathing.¹⁸³ The NHS CBRN-PPE incorporates a powered air-purifying respirator which allows staff with chronic medical conditions and varying levels of physical fitness to wear CBRN-PPE.

Illustration 13: Types of respirator



negative pressure air-purifying respirator



powered air-purifying respirators

Level D (Illustration 14) is based on the normal day-to-day uniform supplemented with tactile preserving gloves and a water proof apron.⁴⁸ This can be further enhanced by wearing a mask to provide protection from respiratory infection e.g. pandemic flu or an air-purifying respirator to provide protection from respiratory irritants such as tear gas. Level D PPE supplemented by an air-purifying respirator would not provide adequate protection from chemical agents such as mustard gas or VX.

Illustration 14: Level D PPE

Personal Protective Equipment

This level of PPE affords protection from diseases spread by airway droplets such as flu and meningitis but this level of PPE provided no protection following the Tokyo Sarin gas. Level-D PPE is inadequate for use following a CBRN incident



A.1.2 Mass treatment pods

The mass treatment pods were devised to support ambulance services and emergency departments in the treatment of mass casualties from a range of emergencies including a CBRN incident. The pods were designed for ease of transfer to an incident site but are centrally held and stocked according to a generic contents list.⁹² The centralisation of mass casualty equipment ensures a minimum national reserve stock of equipment at a lower cost than local stockpiled equipment.²²² The mass treatment pods do not remove the need for locally mass casualty equipment as there can be a significant time delay between requesting centrally held equipment and its arrival at an incident site.

Initially, the equipment contained in these pods reflected standard resuscitation equipment carried by ambulance services and included intravenous cannula, equipment for intubation and drugs in glass ampoules. The supplied equipment therefore required the retention of finger-thumb dexterity and unimpaired vision, both of which are adversely affected by wearing CBRN-PPE. In addition, the pods did not initially contain equipment for confirming the correct placement of endotracheal tubes, nor did they contain intubating aids to support difficult airway management. The contents of these pods have since been reviewed^{92 93} and now include bougies and end tidal CO₂ monitoring, reflecting best practice guidelines regarding intubation equipment.²⁴³ The up-dated pods also contain supraglottic airways, intraosseous drills and a number of drugs presented in prefilled syringes.³¹⁰ Furthermore, the introduction of specialist ambulance rescue teams has resulted in the provision of light weight CBRN ventilators and the availability of the Igel as part of a specific CBRN response.⁹⁵

A.1.3 Summary

Level C CBRN-PPE is the most commonly issued CBRN-PPE throughout the world.²⁵ The main difference with the NHS CBRN-PPE is that it has been designed to be worn by healthcare professionals with limited training, as well as staff with chronic medical conditions, beards or those who wear glasses. However, the NHS CBRN-PPE hampers skill performance^{43 44 51-53} and the design of the NHS CBRN-PPE prevents clinicians from electing to wear thinner gloves to preserve tactile sensation.

Appendix 2

Literature review

A.2 Search strategy, inclusion and exclusion criteria

The literature search was undertaken using key words and MeSH terms (Table 31) with only English language used as a limitation. Papers were reviewed in full if the abstract was not available or if the abstract indicated that the study met the inclusion criteria. A separate keyword search using the terms CBRN and nuclear, biological and chemical was performed in journals which regularly publish articles relating to CBRN-PPE. A similar strategy was applied using the names of author's who frequently publish in the field of CBRN. The reference lists of all identified publications were hand-searched, resulting in a study by Luria et al ²⁵⁰ being identified which had been missed during the literature search that informed the research design of Paper 2, as well as the literature search strategy employed for this thesis.

A.2.1 Inclusion and exclusion criteria

An essential inclusion criterion for the literature review was that participants must have performed a clinically based skill whilst wearing a respirator and chemical protective gloves. The type of skill was not prescribed as long as it was considered to be a clinically relevant intervention such as intubation or the application of a pressure dressing.

An attempt to limit this search strategy solely to skills performed whilst wearing NHS CBRN-PPE was abandoned, as with the exception of the studies submitted as part of this thesis and a single-case report ¹⁵⁶ no studies were identified. A further attempt to limit the inclusion criteria solely to gloves with a thickness that reflected the NHS CBRN-PPE gloves ($\geq 0.9\text{mm}$) was also abandoned as the majority of studies either did not state glove gauge or used lower-gauged gloves.

Table 31: Search strategy MEDLINE and MeSH terms

A MEDLINE (1950 to 1st August 2012), CINAHL (1981 to 1st August 2012) and Cochrane Central Register search was performed using the NHS evidence search engine.

Key word	Result	Selected MeSH term
CBRN.ti.ab	79	1) terrorism, 2) disaster, planning, 3) occupation, exposure, 4) warfare, 5) respiratory protective devices and 6) protective clothing
chemical AND biological AND radiation AND nuclear.ti.ab	73	Same MeSH terms as for CBRN
NBC.ti.ab	545	Same MeSH terms as for CBRN
nuclear AND biological AND chemical.ti.ab	1210	Same MeSH terms as for CBRN
decontamination.ti.ab	6747	Unable to map
'mass casualties'ti.ab	451	1) mass casualties, incident, 2) triage, 3) emergency medical services and 4) military medicine
'gas mask'.ti.ab	73	1) masks and 2) military personnel
respirator.ti.ab	1010	1) ventilation, mechanical
gloves.ti.ab	5072	1) gloves, protective
'glov\$.ti.ab'	7911	As above
airway.ti.ab	106401	1) airway, management
intubat\$.ti.ab	40025	Unable to map
intubation.ti.ab	32741	1) intubation and 2) intubation, intracheal
bag AND valve AND mask	317	1) respiration, artificial
intravenous.ti.ab	228992	1) administration, intravenous, 2) infusion, intravenous and 3) injection, intravenous
intramuscular.ti.ab	32953	1) injections, intramuscular
intraosseous.ti.ab	4326	1) intraosseous, infusion
resuscit\$.ti.ab	43301	Unable to map
resuscitation.ti.ab	37917	1) cardiopulmonary resuscitation
dexterity.ti.ab	2842	1) motor skill, 2) psychomotor performance, 3) hand and 4) hand strength
dexterous.ti.ab	276	MeSH terms as for dexterity
'hand AND eye'ti.ab	101	Unable to map

A.2.2 Grey material and corresponding authors

An attempt was made to contact all corresponding authors of the selected studies to ascertain that no published studies, studies in press or unpublished data had been missed. Where no contact details were available, a Google search was used to locate an email address. This approach successfully secured contact details for Luria.²⁵⁰ Replies were obtained from Schumacher¹⁸⁰⁻¹⁸⁴, Suyama¹⁸⁶, and Luria.²⁵⁰ Schumacher was able to confirm the research protocol used during his joint studies with Brinker^{180 181} supporting the exclusion of these studies from the literature review. Luria was asked to provide information regarding the gauge of the gloves used and for additional data relating the skill repetition when securing an endotracheal tube in situ; however, this data was no longer available.

In addition to searching published literature the makers of the NHS CBRN-PPE²², civilian⁹² and military¹⁹⁰ CBRN experts were also contacted to ascertain the presence of any missed research. No new research was forthcoming but useful product information²², operational and training protocols were provided. A Google scholar alert tracking the terms CBRN and Nuclear, Biological and Chemical was also created providing numerous related studies and policies but no additional research relating to the research question was identified.

A.2.3 Identified Papers for review

In total, 266 studies were selected for initial review, with no meta-analysis, Cochrane or other systematic literature reviews being identified that related to the literature review question. A literature review²⁰ and a Cochrane review⁴³⁶ on related topics were identified but as they did not address the research question they were excluded from the literature review.

A total of 20 studies fulfilled the inclusion criteria (Figure 6) and were selected for appraisal using the Critical Appraisal Skills Program (CASP) tools (<http://www.casp-uk.net>). The CASP tool was selected as it is an established critical appraisal tool suitable for appraising studies with different methodologies.¹⁷⁷ This is an important consideration in this thesis as the studies selected for review utilised a range of research methods. In addition, CASP is readily accessible and can be amended to meet the researcher's needs.¹⁷⁷ Six studies were excluded by CASP, due to methodological flaws, resulting in a total of 14 studies being included in the final literature review (Figure 6). An overview of the selected studies is presented in Table 32.

Figure 6: Application of exclusion criteria on literature strategy

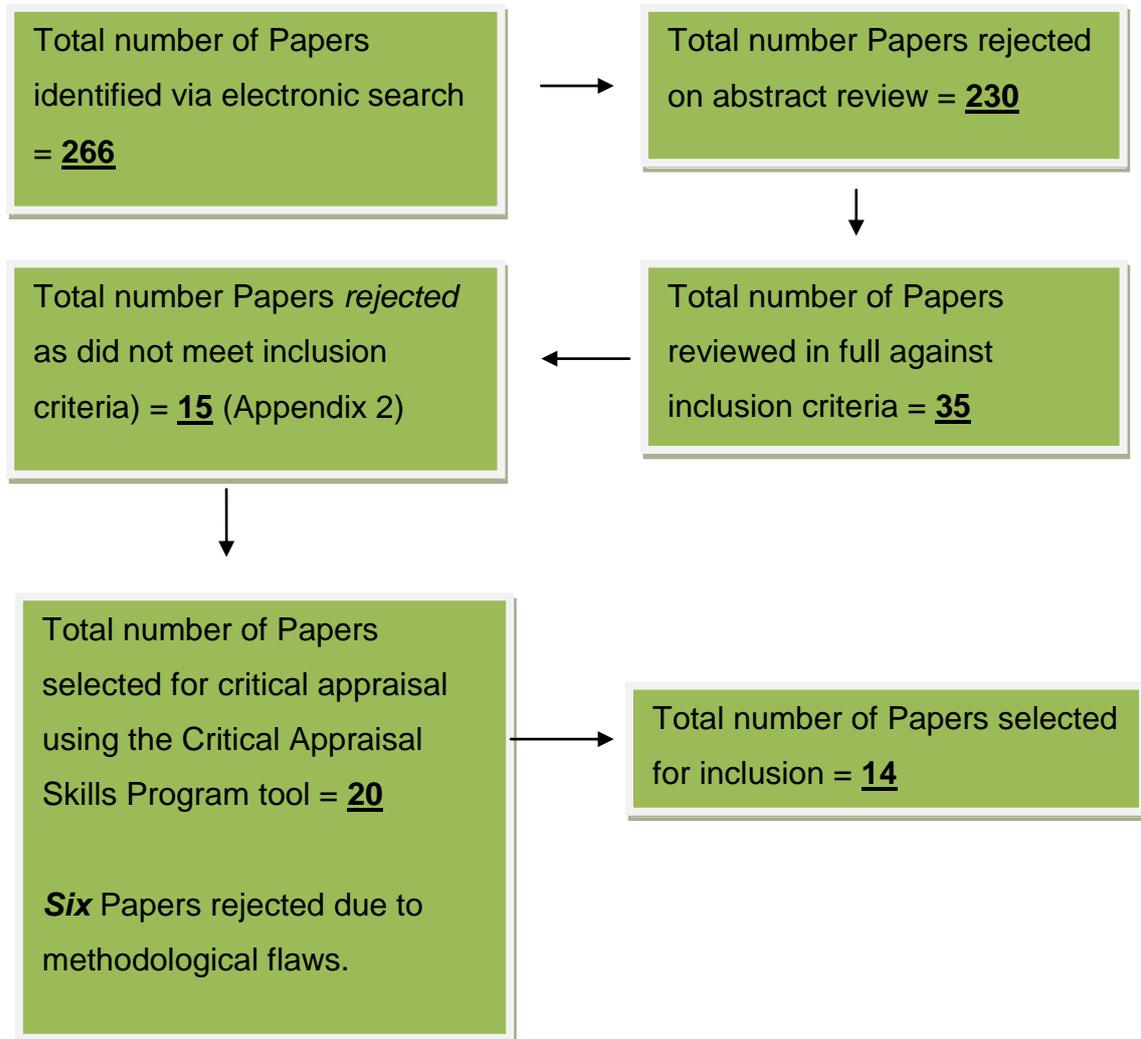


Table 32: Studies included in the literature review following the application of a critical appraisal tool.

King J and Frelin A.¹⁷⁰ A manikin and human volunteer based study

Longitudinal (6 consecutive days) crossover RCT comparing the performance of 8 basic medical tasks complete whilst wearing CBRN-PPE with varying types of gloves compared to military uniform. Tasks were completed by medically trained soldiers. Butyl rubber gloves (similar to NHS CBRN-PPE) and tactile preserving gloves were compared. Skill performance was judged by observers against established criteria. All skills and clothing were randomised and the gloves were examined for damage on day 3 and day 6. The total number of recruits was small (n = 9) and the results are poorly presented. However, a negative impact of CBRN-PPE on medical skill performance was detected. This is an important study as a number of subsequent studies adopted tactile preserving gloves based on the results of this study and were subsequently excluded from this literature review.

The above study used American military CBRN-PPE, with standard thickness butyl rubber gloves or thinner tactile preserving gloves. Actual gauge of the gloves is not stated, however, Arad et al¹⁷⁸ refer to tactile preserving gloves as having a gauge of 0.3mm compared to the NHS CBRN-PPE with a glove gauge (at the finger tips) of 0.9mm.²² Attempts to contact authors and/or the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Luria S et al.²⁵⁰ A manikin based study

A mixed method study that evaluate four endotracheal tube securing techniques, using a crossover RCT supported by questionnaire and qualitative observational data in order to ascertain the fastest device as well as the device preferred by the participants. Questionnaire data assessed the degree of security of the endotracheal tube securing device, the suitability of its use in a CBRN environment, ease of use/learning and which device was believed to be superior. Participants were randomised to perform skills in/out of CBRN-PPE, with the results demonstrating a statistically significant difference in speed of skill completion, as well as ease of use, quality of security and general preference in favour of the Thomas™ Tube Holder. This was a small study (n = 12) with an additional 7 observers contributing to the questionnaire data. A retrospectively applied power calculation based on the published results demonstrates that 12 participants is adequate to detect a ≥ 5 second difference between the devices to a significance of *p-value* 0.05 (>80% power). The statistical difference is reflected in the results but a 5 second difference would not be clinically significant; the degree of security, however, is a clinically significant finding.

The above study used Israeli military CBRN-PPE, but the gauge of the gloves is not stated. Attempts to contact the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful and although contact was made with Luria (author) he was unable to recall the gauge of the CBRN gloves used.

Goldik Z et al.¹⁶⁶ Animal based study

This is a crossover RCT involving anaesthetists (n = 20) and non-anaesthetists (n = 20) performing intubation and LMA insertion (on simians) whilst wearing CBRN-PPE. There was no non-CBRN-PPE control arm. No power calculation was presented but a retrospectively applied power calculation demonstrates that this study was adequately powered (>80% power) to detect ≥ 5 second difference between each arm to a *p-value* of 0.05. A failed airway attempt occurred if the skill took >45 seconds to complete, if the simian had signs of respiratory distress or if either device was inappropriately placed. The eventual reason for skill failure was not stated in the results, which is an oversight and would have provided useful data. A 5 second difference between the two airway devices would not be clinically significant but the high percentage of failed intubation attempts is. The absence of a non-CBRN arm affects the robustness of the results. The results of this study show superiority for LMA insertion over intubation.

The above study used Israeli military CBRN-PPE, but the gauge of the gloves is not stated. Attempts to contact authors and/or the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Ben-Abraham R et al.¹⁶⁷ Tissue based study (cooked turkey bone)

This is a crossover RCT comparing doctors gaining intraosseous access using the Bone Injection Gun in/out of CBRN-PPE (n = 20). No power calculation was presented; however, a retrospective power calculation demonstrated that this study is adequately powered (>80%) to detect a 10 second difference with a *p-value* of 0.05. The authors stopped timing insertion attempts once the needle was in the bone. No drug therapy was administered as this role would be delegated to an attending assistant. The study demonstrated a statistically significant difference in insertion of the intraosseous needle between the CBRN-PPE and non-CBRN-PPE arms (CBRN-PPE slower), but the observed time difference would not represent a clinically significant difference. However, the increased failure rate plus safety issues noted whilst wearing CBRN-PPE are important factors that would affect clinical care. The main issue identified in this study was the loss of dexterity due to the gloves and visual impairment due to respirator.

The above study used Israeli military CBRN-PPE, but gauge of gloves is not stated. Attempts to contact authors and/or the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Berkenstadt H et al.¹⁸⁹ Manikin-based.

This was an observational study (n = 22) supported by questionnaires (100% return rate), based around the completion of patient management during CBRN-based simulation-training. The intended purpose of the study was to ascertain the effectiveness of simulation as a form of CBRN training. Additional data, described as subjective, was presented regarding individual participants perceptions of difficulties with skill performance. This study provides useful insight into difficulties with regards to skill performance despite its primary aim of validating simulation as a mode of CBRN training.

The above study used Israeli military CBRN-PPE, but the gauge of gloves is not stated. Attempts to contact authors and/or the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Flaishon R et al.¹⁶⁸ Human volunteer based study.

This is a crossover RCT involving anaesthetists (n = 15) who performed intubation and LMA insertion on human volunteers. It included both a CBRN-PPE and non-CBRN-PPE arm. No power calculation was presented but a retrospectively applied power calculation demonstrates that this study was adequately powered (>80%) to detect a ≥ 10 second difference between each study arm to a *p-value* of 0.05. For safety reasons, each skill was performed only once on each volunteer, which meant that a total of 60 volunteers (patients undergoing anaesthesia) were required to complete this study. No attempt was made to control for inter-volunteer variables such as age, weight or gender, but the study clearly identifies the adverse effect of CBRN-PPE on skill performance.

The above study used Israeli military CBRN-PPE, but gauge of gloves is not stated. Attempts to contact authors and/or the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Flaishon R et al.¹⁶⁹ Human volunteer based study.

This is a crossover involving trainee anaesthetists (n = 20), surgical trainees with some airway training (n = 22), and 6 airway novices with no airway training who inserted LMA's on human volunteers. It included both a CBRN-PPE and non-CBRN-PPE arm. No power calculation was presented, however, the part of the study comparing speed of skill completion between the anaesthetists and surgeons was adequately powered (>80%) to detect a 10 second difference between devices with a *p-value* 0.05. The novice arm was under-powered. A learning effect associated with skill repetition was identified and, although the novice data was poorly presented, it does highlight the impact of butyl gloves on tying in an endotracheal tube with an associated learning effect regarding skill performance.

The above study used Israeli military CBRN-PPE, but gauge of gloves is not stated. Attempts to contact authors and/or the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Vardi A et al.²⁰⁶ Manikin based study.

This was a RCT recruiting mixed clinicians (n = 94) into age (adult/child) appropriate clinical simulations, which compared drug administration via the intramuscular or the intraosseous route. Randomisation was done 'per day of week' as this optimised the provision of the correct equipment as per the randomisation schedule (either intraosseous or intramuscular). This study predicted patient survival based on time to complete the clinical scenario but the formula used to predict patient survival was not presented, but it was based on previously published data. Questionnaires were used to assess each participant's perceptions of the Bone Injection Gun. No power calculation was provided and there was insufficient data in the results section to retrospectively calculate a power calculation. However this is a large study which achieved statistical (*p-value* 0.001) and clinical significance.

The above study used Israeli military CBRN-PPE, but gauge of gloves is not stated. Attempts to contact authors and/or the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Stacey R et al.¹⁵⁶ Case report.

This is a case report following an attempted suicide by ingesting an organophosphate insecticide, where the NHS CBRN-PPE was worn during patient treatment. The data are observational in nature. However, with the exception of the Papers presented within this thesis, this is the only other study demonstrating the use of the NHS CBRN-PPE and, as such, provides useful insight with regard to observed difficulties whilst performing time-critical skills.

Although not stated by make the description of the CBRN-PPE appears to resemble the NHS issued CBRN-PPE hence the inclusion of this clinical case report within the literature review.

MacDonald R et al.²⁰⁴ Manikin based study.

This is a paramedic based (n = 16) crossover RCT evaluating a range of clinical skills. This study used a Latin-square randomisation design to minimise data contamination between skill performances (a similar design was used in Paper 1). A power calculation was provided and demonstrated that 16 participants was an adequately powered sample to detect one standard deviation (against a mean of 2.3 seconds for intravenous cannulation) to a significance of *p-value* 0.01. Although the power calculation included in the study indicated that the study was adequately powered, the 95% CI (for intubation) demonstrate a 10 second difference, which at the upper end of 95% CI may be of clinical significance. It is feasible that a larger study might have produced different results with regard to intubation and intravenous cannulation.

The above study used civilian CBRN-PPE, but the gauge of gloves is not stated and attempts to contact authors and/or the makers of the CBRN-PPE/gloves, to verify the gauge of the gloves were unsuccessful.

Suyama J et al.¹⁸⁶ Manikin based study.

This is a case control study involving a mixed cohort of student and qualified paramedics. The study was based on a quasi-experimental pre-/post-test design comparing the placement of an intravenous and intraosseous cannula in/out of CBRN-PPE. There was no randomisation regarding skill performance, with all participants completing all skills in a predetermined order. This study did not control for any impact associated with a learning effect and/or fatigue, nor did it control for the varying skill level of the participants. Data were recorded from the start of the procedure until an intravenous infusion was commenced, with individual timings provided. This is the only study that has measured total time to complete both vascular access and time to commence intravenous fluids. No power calculation was presented; however, a retrospectively applied power calculations, to the IV vs. IO arm in/out of CBRN-PPE, confirms that this study is adequately powered (>80%) to detect a 10 second difference with a *p-value* of 0.05.

The above study used civilian CBRN-PPE, but the gauge of gloves is not stated. Suyama (author) was successfully contact to enquire about the gauge of the gloves used but this information was unavailable, whereas, attempts to contact the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Ben-Abraham R et al.¹⁸⁵ Human volunteer study

This is a crossover RCT involving anaesthetists (n = 12) inserting the COPA into anaesthetised human volunteers (n = 24) whilst wearing either CBRN-PPE or theatre scrubs. A power calculation was presented which was based on an unpublished pilot study. The study was powered to detect a 10 second difference (90%) to a *p-value* of 0.05. The study monitored overall insertion time as well as time needed to secure the COPA in situ, and demonstrated an adverse impact associated with wearing CBRN-PPE. The reported time for the insertion of the COPA was slower than Flaishon (a co-author) had previously detected with a similar cohort of anaesthetists who inserted an LMA whilst wearing CBRN-PPE.

The above study used Israeli military CBRN-PPE, but gauge of gloves is not stated. Attempts to contact authors and/or the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Rebmann T et al.²⁰⁵ Manikin based study

This is a RCT using a mixed group of clinicians who were allocated to perform one of 3 skills either in/out of CBRN-PPE. Participants only performed a skill once, with the unsuited clinicians acting as a control group for each skill. The quantitative data was supplemented by a questionnaire designed to assess prior experience, preferred modes of future training, and perceived ease of device use. Participants had varying experience using the three devices, which was not controlled for and may have adversely impacted on the results. The authors claim that CBRN-PPE does not impact on the use of the auto-injectors, but they elected to only present the data for the CBRN-PPE arm and not the control arm preventing a closer review of their results. This study would have been statistically more robust and clinically more useful if a randomised cross-over design had been used. Furthermore, the needle/syringe group only administered a single drug compared to the auto-injectors who administered two drugs, thus further weakening the results of the study.

The above study used American military CBRN but gauge of gloves is not stated. Attempts to contact authors and/or the makers of the CBRN-PPE/gloves to verify the gauge of the gloves were unsuccessful.

Lamhaut L et al.²⁰⁷ Manikin based study.

This is a crossover RCT enrolling a mixed group of clinicians (nurses n = 9 and emergency physicians n = 16), none of whom had previously used an intraosseous device. Participants performed intravenous cannulation in/out of CBRN-PPE compared to intraosseous access in/out of CBRN-PPE. Clinicians were expected to open all packaging as part of the process. No power calculation was presented; however, a retrospectively applied power calculation confirms that this study is adequately powered (>80%) to detect a 10 second difference with a *p-value* of >0.05. The reported standard deviation for intravenous cannulation regardless of wearing CBRN-PPE was higher than for intraosseous access (+/- 30 seconds), thus indicating a number of potential outliers in this subgroup.

The French ambulance service provided their standard CBRN-PPE for this study. The gauge of gloves is not stated; therefore Lamhaut (author) was contacted via emailed. However, he was unable to furnish information regarding the gauge of the gloves used in the research and attempts to contact the makers of the CBRN-PPE to ascertain the gauge of the gloves were equally unsuccessful.

A.2.4 Selected studies

Fourteen studies were selected for inclusion in the literature review and a summary of these studies is presented in Table 32. A number of studies did not include a power calculation but where the available data allowed it, a retrospective power calculation was performed using a tool provided by the Institute of child health (www.ucl.ac.uk/stats-courses).⁴³⁷ A number of themes were identified (Table 33) with a number of studies including more than one clinical skill.

Table 33: Literature review themes

Themes
Basic medical skills
Vascular access and drug administration Intramuscular and intravenous access/drug administration. Intraosseous and intravenous access/drug administration. Types of intraosseous devices
Airway management Intubation only studies. Intubation and supraglottic airway devices. Supraglottic airway only studies
Securing airway devices in situ post insertion
Patient simulators and environmental factors The potential impact of patient simulators The role of realism during data collection

A.2.5 Excluded studies

Fifteen studies were excluded after a review of their methods sections as they did not fulfil the minimum PPE criteria. Among those excluded were a series of co-authored studies by Schumacher¹⁸⁰⁻¹⁸⁴, commonly in association with Brinker^{180 181}, in which skills were either performed without wearing CBRN-PPE or only one aspect of CBRN-PPE was worn (e.g. respirator only). Whereas studies by Arad et al¹⁷⁸, Berkenstadt et al¹⁷⁹ and Hendler⁹⁰ were excluded as they used tactile preserving gloves in keeping with the published evidence that wearing lower gauge gloves improves skill performance.^{170 187} The exclusion of these studies was an important element of this literature review because it helped to ensure that we

reviewed only studies in which the conditions associated with skill performance resembled, as closely as possible, those of the NHS CBRN-PPE.

A.2.5.1 Studies excluded following application of Critical Appraisal Skills Program (CASP)

Six studies by, Rissanen et al ²⁵², Borron et al ⁴³⁸, Garner et al ¹⁹², Udayasiri et al ²⁴⁸, Grugle and Kleiner ¹⁹³ as well as a study by Coates et al ¹⁹¹ were rejected following the application of a methodologically appropriate CASP tool. No studies were excluded on the basis of being under-powered during the initial literature review as this would have resulted in the exclusion of the majority of the identified studies.

Rissanen et al ²⁵² was excluded as the research protocol for the ventilation arm provided participants with a 'breath-per-breath' visual feed-back of the effectiveness of their ventilation technique. This allowed participants to adjust their ventilation technique, thereby introducing a measurement ³¹² bias that may have overestimated the effectiveness of the bag-valve-mask ventilation.

Overestimation of bag-valve-mask effectiveness may have been further compounded as Rissanen et al ²⁵² did not state whether a CBRN filter was attached to the bag-valve-mask device. This is a significant omission as CBRN filters negatively impact tidal volumes ^{181 184} and bag-valve-mask devices deliver varying tidal volumes based on the ventilation technique used.³⁶⁵⁻³⁶⁷ Tidal volume also varies between different makes of bag-valve-mask device.³⁶⁶ The clinical impact of reduced tidal volumes is variable but includes hypoventilation, resulting in worsening hypoxia.^{439 440} In addition to the identified issues regarding ventilation techniques employed, Rissanen et al ²⁵² elected also to exclude a participant from the intravenous access arm of their RCT, describing this participant as an 'outlier'. The impact of a single participant indicates that this study was under-powered further challenging the validity of the study's results.

Borron et al ⁴³⁸ study was poorly designed, as within the CBRN experienced group there were marked variations in the levels of CBRN training of the participants (range 1-10 training sessions). Participants were sub-divided into 'experienced' (had training) and novices (no training), but there were marked differences in the individuals allocated to these two arms. For example, two of the experienced participants had received training in all the types of PPE being evaluated, three of the experienced participants had only previously worn one type of PPE, and one participant had worn two of the types of PPE being evaluated.

Additionally, half of the participants in the novice group had received some CBRN-PPE training, with one novice having attended at least one CBRN incident. It was possible, therefore, that some of the novices may have had similar experience as participant allocated to the experienced group, thus reducing the face-validity¹⁷² of the results. Borron et al⁴³⁸ also elected not to present *p-values* or CI, stating that their study failed to achieve statistical significance and thus indicating it was underpowered.

The two arms of Borron et al study were also poorly balanced, with six experienced clinicians performing intraosseous insertion whilst wearing four different types of CBRN-PPE, as compared to the novice group (n = 12) who only performed the skills twice. This allowed the experienced group greater practice at skill performance but also concurrently exposed them to a higher risk of fatigue due to extended periods of wearing PPE.^{20 441} In addition, participants came from differing clinical backgrounds with varying experience of obtaining intraosseous access (0 vs. >10 clinical uses). This study therefore failed to control for the impact of experience of having previously worn CBRN-PPE, the impact of either the development of a learning effect gain through skill repetition or fatigue, as well as failing to control for the varying experience each clinician had with regards to intraosseous insertion.

Similar issues regarding poor control of participant experience level is noted in studies by Garner et al¹⁹² and Udayasiri et al.²⁴⁸ Garner et al¹⁹² recruited emergency physicians (n = 3), anaesthetists (n = 2) and paramedics (n = 3) but assessed skills that are commonly performed by anaesthetists (e.g. intubation). Furthermore, Garner et al¹⁹² did not use any randomisation, thereby failing to control for the impact of either a learning effect or fatigue that could have occur during data collection. Garner et al¹⁹² described their research as a pilot study, thus explaining why they elected not to perform a power calculation. As anticipated, then their results fail to achieve statistical or clinical significance. As no larger study, by Garner or his co-authors was identified during the literature review attempts were made to ascertain whether a larger study is planned. However, these attempts were unsuccessful as no active email address was identified.

Udayasiri et al²⁴⁸ recruited a mixture of emergency physicians (n = 7) and emergency department nurses (n = 11) with varying levels of experience of having previously worn CBRN-PPE. In fact, one participant had previously received training in how to perform skills whilst wearing CBRN-PPE. Participants were instructed to perform a range of skills, with a power calculation being provided only for intubation. Due to the recruitment of insufficient doctors (to achieve the minimum number identified in their power calculation) five nurse intubators were included in the intubating arm of this study. The results combine doctor and

nurse intubation times and thus introduced a potential skill performance bias between the nurses and the doctors. Udayasiri et al elected not to include any randomisation, failing to control for the impact of either a learning effect or fatigue.

Grugle and Kleiner¹⁹³ used a non-randomised correlation study and timed simulations to measure the impact of CBRN-PPE on team dynamics. This study included five 2-man teams who completed set simulations in and out of CBRN-PPE, with none of the participants having previously worn CBRN-PPE. Six of the ten participants, however, had previously worn fire-fighting clothing which is similar in some respect to CBRN-PPE (e.g. high gauge protective gloves and respirators). Sixty percent of the candidates thus had some prior understanding of the impact of CBRN-PPE on skill performance.

Grugle and Kleiner¹⁹³ elected to limit the reporting of *p-values* as being either ≤ 0.05 or ≥ 0.05 , with the majority of *p-values* failing to achieve statistical significance. The main weakness of this particular study is the degree to which the simulations differed between the two arms. The rationale given for changing each simulation was theoretically sound (i.e. to minimise learning effect), but the degree to which the simulations differ raises the question of whether a true like-for-like skill performance was measured.

Coates et al¹⁹¹ utilised an observational study design to detect the impact of CBRN-PPE on skill performance. Successful intubation was judged against correct tube placement and completion of intubation in 30 seconds, consistent with standard recommendations for intubation performance during resuscitation.^{264 349} The intubation process was poorly described. For the other remaining skills, participants were required to gauge skill difficulty whilst wearing CBRN-PPE, against historical control as no non-CBRN-PPE control arm was incorporated in the study. The lead researcher acted as the sole observer, scoring all skills and thus introduces the potential of a reviewer bias.³¹² This study would have achieved greater statistical power and potential clinical significance if a crossover RCT incorporating a non-CBRN-PPE control group had been used. This would have allowed the participants to more accurately assess the impact of skill performance as opposed to participants having to relying on historical controls.

The study designs of Rissanen et al ²⁵², Borron et al ⁴³⁸, Garner et al ¹⁹², Udayasiri et al ²⁴⁸, Grugle and Kleiner ¹⁹³ as well as Coates et al ¹⁹¹ all failed to ensure internal consistency of their data, affecting the reliability of these studies. Despite these concerns regarding reliability the data collected in these studies provide useful insight into skill difficulty whilst wearing CBRN-PPE and support future study development. For example, results from Garner et al ¹⁹² were used to inform the power calculation for Paper 1 and Udayasiri et al ²⁴⁸ for Paper 4.

Appendix 3

Supplementary CBRN publications

A number of additional publications, chapters in books and presentations to academic bodies have resulted from the Papers and associated research contained in this thesis.

A.3 Abstracts:

Bowen J and **Castle N**. Learning effect of repeat clinical skill performance in a CBRN suit. *Emerg Med J* 2011; 28: e1. Abstract.

Castle N, Owen R, Shaikh L, Hann M, Reeves D, Kuybida Y. Are prehospital clinicians faster at intubation on the floor whilst wearing CBRN-PPE than hospital clinicians? *Intensive Care Medicine* 2010; 36 (2) S302. Abstract.

Williams J, **Castle N**, Bowen J. Ambulance staff's experiences of delivering patient care whilst wearing a chemical, biological, radiological or nuclear (CBRN) suit: An exploratory study. *International Journal of Qualitative Methods*; 2011: 10 (4): 451. Abstract.

A.3.1 Published reply letters defending research findings:

Castle N, Clarke S and Owen R. Reply to Letter: Impact of chemical, biological, radiation, and nuclear personal protective equipment on the performance of low- and high-dexterity airway and vascular access skills. *Resuscitation* 2010; 81: 363–364

A.3.2 Chapters in books and DVD:

Clarke S and **Castle N**. Medical management of chemical incidents. In Barker et al (eds). *Essentials of Toxicology for Health Protection: A handbook for field professionals* (2nd Ed). Chap 2; 67-84. Oxford University Press; Oxford 2012.

What if...? CBRN training for Emergency Department Staff (DVD). Health Protection Agency. Department of Health. Produced by www.dependableproductions.tv

A.3.3 Presentations:

Hann M, **Castle N** and Owen R. A Balanced Factorial Experiment of Clinicians' Performance in treating victims of a Chemical Weapons Attack whilst wearing Level C Personal Protective Equipment. 2008 Northern Region 'Society for Academic Primary Care' Conference. 2008.

Bowen J and **Castle N**. CBRN-PPE and drug administration. University of Hertfordshire 'Research day' (July 2009) presented initial findings of CBRN research involving skill performance whilst wearing CBRN-PPE.

Castle N. 'Impact of CBRN PPE on resuscitation skill performance'. Bi-annual Emergency Medical Conference (Nov 2009) sponsored by the Emergency Medical Journal/College of Emergency Medicine.

Castle N. So what skills can you do whilst wearing NHS CBRN-PPE? Hospital Grand Round (preparation for Olympics). February 2012

Castle N. So what skills can you do whilst wearing the NHS CBRN-PPE? Durban University of Technology 'Research day' (October 2012) presented over-view of all nine CBRN papers.

Appendix 4

Verification letters from co-authors

As this thesis is based around prior publications, the institutional rules of City University require co-authors to confirm the involvement of the student in all activities associated with the research. This is required to demonstrate originality of the publications and to confirm the contribution of the student to the academic process.

Dr D Reeves: Senior Research Fellow in Statistics. Statistician at the University of Manchester.

Mr Yugan Pillay: Consultant Paramedic Ambulance Service Hamad Medical Corporation, Qatar. Formerly lecturer at the Durban University of Technology.

Dr M Hann: Statistician at the University of Manchester.

Dr N Spencer: Principle lecturer statistical studies (now Reader in Statistics): University of Hertfordshire.

Dr R Owen: Executive officer and Hon: Research Fellow Durban University of Technology Ambulance Service Hamad Medical Corporation, Qatar. Formerly Clinical Director of Surrey Ambulance service.

Dr S Clarke: Consultant Emergency Physician Frimley Park Hospital and Hon. Consultant Toxicologist Health Protection Agency

Appendix 5

Research funding

The research studies contained in this thesis received funding from a number of different avenues.

Supporter	Funding
UBC Pharma	£5000 to fund Paper 4 and Paper 7
Margaret Harrison fund	£7000 to fund transcribing costs of Papers 2-3 and 5-6 as well paying for statistical analysis for Papers 8 to 9
Durban University of Technology	Provided support for Papers 7-9 by covering costs of in-country living expenses such as accommodation
Resuscitation Training and Research Trust Fund Frimley Park Hospital	£3000 for overseas travel for Papers 7 to 9
Birmingham Hospital Airway Research Group	£5000 to support ongoing research in South Africa looking at skill development whilst wearing CBRN-PPE

Appendix 6

PDF of the nine peer-reviewed submitted as part of the this thesis

Paper 1: Castle N, Owen R, Hann M, Clarke S, Reeves D and Gurney I. Impact of Chemical, Biological, Radiation, and Nuclear Personal Protective Equipment on the performance of low- and high-dexterity airway and vascular skills. *Resuscitation* 2009; 80: 1290-1295.

Paper 2: Castle N, Owen R, Clark S, Hann M, Reeves D, Gurney I. Comparison of technique for securing the endotracheal tube while wearing chemical, biological, radiological, or nuclear protection: A manikin study. *Prehospital Disaster Medicine* 2010; 25 (6): 589–594.

Paper 3: Castle N, Owen R, Clarke SFJ, Hann M, Reeves D, Gurney I. Does position of the patient adversely affect successful intubation whilst wearing CBRN-PPE? *Resuscitation* 2010;81(9):1166-71

Paper 4: Castle N, Bowen J, Spencer N. Does wearing CBRN-PPE adversely affect the ability for clinicians to accurately, safely, and speedily draw up drugs? *Clin Toxicol* 2010;48(6):522-27.

Paper 5: Castle N. Care after chemical, biological, radiation or nuclear events. *Emergency Nurse* 2010; 18 (7): 26-36.

Paper 6: Castle N. A qualitative interview based study of clinician's opinions of what intubation aids should be used following a CBRN incident? *Journal of Paramedic Practice* 2012; 4 (4): 226-234.

Paper 7: Castle N, Pillay Y, Spencer N. What is the optimal position of an intubator wearing CBRN-PPE when intubating on the floor: A manikin study. *Resuscitation* 2011; 82: 588-592

Paper 8: Castle N, Pillay Y, Spencer N. Insertion of six different supraglottic airway devices whilst wearing chemical, biological, radiation, nuclear-personal protective equipment: a manikin study. *Anaesthesia* 2011;66(1):983-88.

Paper 9: Castle N, Pillay Y, Spencer N. Comparison of six different intubation aids for use while wearing CBRN-PPE: A manikin study. *Resuscitation* 2011; 82: 1548-1552

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