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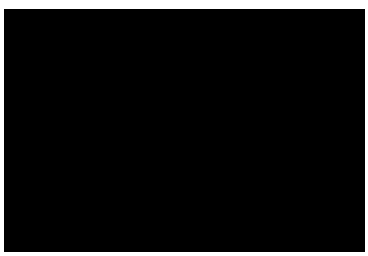
I, Kate Crewdson confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.



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Abstract

Poor airway management in severely injured patients is a source of significant morbidity and mortality and frequently identified as a cause of preventable death in this group of patients. Traditionally the majority of patients have not received definitive airway management until arrival at hospital and those patients who were sufficiently obtunded on scene to tolerate tracheal intubation without the use of drugs had a universally poor outcome.

Pre-hospital Emergency Medicine (PHEM) is now a recognised medical subspecialty and is usually delivered by doctors and paramedics with specific training in this field. The development of this subspecialty has increased the practice of Pre-Hospital Emergency Anaesthesia (PHEA). Despite improvements in the delivery of PHEM and consequently of PHEA, controversy surrounding this intervention exists and it has failed to demonstrate an obvious survival benefit.

This thesis sets out to further examine the practice of PHEA and attempt to establish why this intervention does not appear to be reducing mortality in patients who have sustained major trauma. I designed and developed studies to address a number of key questions including whether there is a requirement for PHEA, the potential benefit of it, and to identify areas of practice that can be improved. Through studies conducted at a local and national level I have been able to provide evidence that not only is PHEA an essential and beneficial intervention for a subset of major trauma patients, but also that there is a demand for this intervention which is not met by the current prehospital practice and infrastructure in the UK.

Impact Statement

The evidence-base for PHEA remains relatively poor and to date, it has been difficult to demonstrate a significant survival benefit for this intervention. The complex nature of PHEA means that the are many different components of the intervention which can potentially be further analysed and modified in order to improve patient safety and outcome. The rationale for this thesis came from deconstructing the PHEA process into three component parts; pre-induction, induction, and post induction of anaesthesia. From here, I developed studies focussing on specific problems encountered in these three individual areas. Analysis of the pre-induction component includes an assessment of the demand for PHEA and whether the current pre-hospital infrastructure in the UK can meet this demand, as well as the identification of appropriate patients for PHEA. In terms of the induction process, specific areas addressed were questions around who should provide PHEA and advanced airway management, the use of apnoeic oxygenation as part of a pre-oxygenation strategy, and the design and use of checklists. Post-intubation ventilation was also reviewed. Information derived from the studies was fed into consensus processes and contributed to the development of local, national and international guidelines. The dissemination of the study findings and subsequent development of guidelines has the ability to change and guide future clinical practice as well as improve patient safety and outcome associated with PHEA.

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Glossary of Abbreviations

ED	Emergency Department
ICU	Intensive Care Unit
RCS	Royal College of Surgeons
NCEPOD	National Confidential Enquiry into Patient Outcome and Death
PHEM	Pre-hospital emergency medicine
PHEA	Pre-hospital emergency anaesthesia
ISS	Injury Severity Score
US	United States
UK	United Kingdom
TARN	Trauma Audit and Research Network
MTC	Major Trauma Centre
TU	Trauma Unit
BVM	Bag valve mask (ventilation)
GCS	Glasgow Coma Score
AIS	Abbreviated Injury Score
$EtCO_2$	End tidal carbon dioxide
SaO_2	Arterial oxygen saturation
EMBASE	Excerpta Medica database
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
CI	Confidence interval
RSI	Rapid sequence induction (of anaesthesia)
BASICS	British Association of Immediate Care
IQR	Interquartile range
PHI	Pre-hospital intubation
EDI	Emergency Department intubation
PHNTIAI	Pre-hospital non-tracheal intubation airway intervention
REBOA	Resuscitative endovascular balloon occlusion of the aorta
MAP	Mean arterial pressure
EHAC	European HEMS and Air Ambulance Committee
MWG	Medical Working Group
NGT	Nominal group technique

EMS	Emergency Medical Service
KPI	Key Performance Indicator
MILS	Manual In Line Stabilisation
PALM	Pharmacologically assisted laryngeal mask insertion

Published papers related to this thesis:

1. **Crewdson K**, Fragoso-Iniguez M, Lockey DJ. Requirement for urgent tracheal intubation after traumatic injury: a retrospective analysis of 11,010 patients in the Trauma Audit Research Network database. *Anaesthesia* April 2019

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10. Lockey DJ, **Crewdson K**, Lossius HM. Prehospital Anaesthesia: The Same But Different. *British Journal of Anaesthesia* 2014;113(2): 211-219

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12. **Crewdson K,** Lockey D. Adequacy of Ventilation for Patients Undergoing Pre-hospital Emergency Anaesthesia (awaiting submission to *Journal of Trauma and Acute Care Surgery*)

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Chapter 1: Defining the problem

1.1 The Major Trauma Epidemic

Traumatic injury accounts for 10% of the global burden of disease. (1) It accounts for the deaths of approximately 5 million people each year, and it is the leading cause of death in patients under the age of 40. (2) Whilst the traditional trauma demographic has been males under the age of 40, (3) there has been a significant recent increase in the proportion of major trauma patients who are aged 75 years and over, termed 'silver trauma'. This is undoubtedly a direct consequence of an aging population with the associated problems of frailty, poor physiological reserve and limited rehabilitation potential. (4) Trauma admissions within England are dominated by low level falls, which is the most common mechanism of injury in the elderly trauma population. (3) Traumatic brain injury is also one of the major causes of morbidity and mortality following severe injury – data from 2018 suggest that 69 million people worldwide sustained a traumatic brain injury. The incidence of traumatic brain injury in developed countries, is more than 1000 people per 100,000 of the population, falling to 800-900 per 100,000 of the population in lower income countries. (5)

In 2007 the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report exclusively evaluated the early management of severely injured patients, finding that nearly 60% received suboptimal care. This was felt to be due to both organisational and clinical deficiencies throughout the patient pathway, both in the pre-hospital and in-hospital settings. (6)

1.2 Trauma Airway Management

The 2007 NCEPOD report remarked on the challenge of airway management in major trauma patients and commented that 'the current structure of prehospital management is insufficient to meet the needs of the severely injured patient'. It also commented on the high incidence of failed intubation

and a high incidence of patients arriving at hospital with a partially or completely obstructed airway, and highlighted the fact that change is urgently required. This is a familiar concept with Prehospital Emergency Medicine (PHEM) and for several decades, airway compromise, or poor or ineffective airway management were first identified as preventable causes of morbidity and mortality in the 1980s (7), with multiple similar reports since (8), most recently by Oliver et al. (9)

Until recently, severely injured patients have been attended by paramedics who do not administer drugs to facilitate endotracheal intubation or the delivery of any other advanced airway intervention on scene. Any patient who can tolerate such interventions without drugs is, by definition, completely obtunded and unlikely to survive. The outcome from non-drug assisted tracheal intubation thus typically was, and still is, universally poor. (10,11) Further, the majority of paramedics in the UK rarely encounter major trauma and intubation skill is likely to fade with time, like any other advanced clinical skill. In recognition of the fact that intubation without the use of drugs is generally futile, the UK Joint Royal Colleges Ambulance Liaison Committee no longer recommends training paramedics in tracheal intubation, but recommend the use of supraglottic airway devices for advanced airway management. (12)

1.3 The Development of Pre-hospital Emergency Medicine

The last two decades have seen a significant change to the way in which severely injured patients are managed before they reach hospital. The importance of delivering early high-quality care, commenced in the pre-hospital setting, to critically ill and injured patients has become increasingly recognised, particularly following publication of the 2007 NCEPOD report. The traditional model of paramedics attending patients outside hospital and delivering them to hospital in a timely fashion is being replaced by mobile critical care teams who attend the patient at the injury scene.

The impact on outcome of the application of this model to pre-hospital trauma care has fed into the development of PHEM as a sub-specialty of medicine. Doctors can now apply for, and receive a year of training in, PHEM as part of specialty training. This career path is supported by examamination designed by the Royal College of Surgeons – the Diploma and Fellowship in Immediate Care.

The NHS infrastructure has also changed to improve the care delivered to major trauma patients through the development of trauma networks and major trauma centres (MTCs). Trauma networks describe a hub and spoke model incorporating a geographical area containing an MTC where all or the majority of services required by major trauma patients are centralised, and a number of 'trauma units'. Smaller regional Trauma Units (TUs) receive patients who are either outside a defined transfer timeframe, or are not initially identified as major trauma. This model of care has been shown to reduce trauma-related mortality both in the UK, and in other countries with advanced healthcare systems. (13) Trauma systems are specifically designed to care for the patient from the time of injury through the pre-hospital, transport, initial management, definitive management and continuing in-hospital phases, and on to the rehabilitation stage which may be months later. (14) The care delivered should ideally be of a consistent standard at every stage in the pathway, but unfortunately, this is often not the case. The traditional pre-hospital care model saw patients taken as rapidly as possible to the nearest emergency department irrespective of the extent of injury, the needs of the patient and the clinical capability of the receiving hospital. The emphasis has now shifted to promote transport of the patient to the nearest hospital with the appropriate facilities for that patient, unless there is either significant airway compromise requiring urgent management that cannot be provided outside hospital; uncontrolled haemorrhage; or if the patient is in cardiac arrest. In these circumstances, patients are taken to the nearest TU or MTC. Subsequent transfer to an MTC after stabilisation of the patient may be required. The National Institute of Health and Care Excellence (NICE) advocates bypassing local hospitals in order to triage major trauma patients directly to an MTC if the transfer time to the major trauma centre is less than 60 minutes from the accident scene.{National InstituteforHealth:2016tq} Secondary transfers are generally considered to be detrimental, particularly in traumatic brain injury, (14,15) and should be avoided where possible. However, with the

establishment of major trauma networks and the development of a more robust infrastructure to support the smaller trauma units, the effect of secondary transfers on mortality has been attenuated. (13)

PHEM comprises the first part of any trauma system and there is a suggestion that provision of good quality care in the pre-hospital setting from high-level providers also translates into a survival benefit for major trauma patients. (2,16) One European study reported an additional 5.33 lives saved per 100 dispatches of a Helicopter Emergency Medical Service (HEMS) team consisting of a trauma surgeon or anaesthetist and a specialised nurse in this instance. (17) There are a number of factors which undoubtedly contribute to this overall survival benefit, which are predominantly related to the provision of high-level time-critical interventions on scene (emergency anaesthesia, blood transfusion, chest decompression, resuscitative thoracotomy), triage decisions and transport capability. The majority of critical teams are supported by helicopter transport, which has been also been associated with increased survival to hospital discharge when compared to ground transport. (18) There is consensus that emphasis should be placed on delivering only the interventions urgently required by each individual patient and not delaying transfer into hospital.

One frequently quoted argument against the use of specialised critical care teams in the pre-hospital setting is the potential to delay transfer of the patient to hospital and definitive care. Whilst it is probable that the delivery of advanced pre-hospital interventions on scene will delay arrival in hospital, it does not necessarily delay time to definitive care (for example emergency surgery) since the patient may move more rapidly to definitive care after hospital arrival when key interventions have been delivered earlier. There are undoubtedly patients who have time critical life-threatening injuries that require immediate treatment in the pre-hospital setting, including tension pneumothorax, airway obstruction, massive haemorrhage and traumatic cardiac arrest. It is rarely possible for these patients to wait until hospital arrival to receive the appropriate management. Intervention by highly trained teams has been shown to benefit the patient, usually with only a minor increase in scene time of up to 10 minutes, (19) or sometimes with no increased time

spent on scene. (20) Data from patients who have sustained stabbing injuries actually demonstrate a reduction in scene time for patients managed by an enhanced care team in the pre-hospital setting. Furthermore, an increase in pre-hospital time does not necessarily translate into an increase in mortality (21) if the right care is being delivered to the right patient early after injury. The outdated debate of scoop and run versus stay and play argument is usually irrelevant as there is often only a minimal difference in scene times with either approach.

1.4 Pre-hospital Emergency Anaesthesia

With the development of PHEM, the ability to deliver pre-hospital emergency anaesthesia (PHEA) to an increasing number of critically ill and injured patients who require immediate or urgent airway management before reaching hospital was developed. The increase in the number of clinicians with PHEA capability means that more patients are undergoing emergency anaesthesia on scene for a variety of clinical indications. Despite significant advances and an increasing evidence base describing PHEA and advanced airway management, the practice and delivery of this intervention remains controversial. The majority of PHEA research is derived from low-quality retrospective database reviews with heterogenous endpoints and data reporting, meaning that the benefit of the intervention is still widely debated and a demonstrable survival benefit remains elusive. Early PHEA data, much of it derived initially from the San Diego Paramedic trial, (22) do not demonstrate survival benefit and, in some cases, actually suggest that the intervention is harmful and increases mortality. (22-24) Whilst some studies have contradicted these negative findings, (25-29) the increase in mortality and morbidity associated with not correcting airway compromise does suggest an inferred benefit of PHEA. Bernard et al conducted one of the very few randomised controlled trials of pre-hospital intubation in 2010. Patients with traumatic brain injury were randomised to receive either pre-hospital intubation, performed by highly-trained paramedics who were able to carry out a drug-assisted intubation technique, or in-hospital intubation. Patients randomised to receive pre-hospital intubation were reported to have a more favourable neurological outcome at six

months compared with those who were not intubated until hospital arrival. However there was no difference in survival to hospital discharge. (26) These data support the view that there is a small but specific group of patients in whom pre-hospital intubation may be indicated, including but not limited to patients with severe traumatic brain injury. (30)

1.4.1 Is Pre-Hospital Emergency Anaesthesia Necessary?

One of the many controversies relating to the delivery of emergency anaesthesia outside hospital, is whether or not it is actually necessary. On this issue, the data remain equivocal. The requirement for provision of effective airway management in a situation of airway compromise is not controversial but the requirement for PHEA over other more basic forms of airway management remains the subject of much debate. The majority of airway management preformed outside hospital is for patients in cardiac arrest. The frequency of intubation following trauma, derived from two large United States (US) airway registries, was similar between the two studies, this indication only accounting for 6% and 8% of the interventions performed. (31,32) Outside the US, one of the largest pre-hospital emergency airway studies of the last five years comes from Sunde et al reporting data on 2327 intubations from multiple centres internationally. In this study, 55% of patients were intubated for medical reasons, of whom 62% were in cardiac arrest. The remaining 45% of patients were intubated following traumatic injury, of whom 56% were in cardiac arrest. (33)

A significant finding in the 2007 NCEPOD report was the presence of partial or complete airway obstruction in 12.6% of trauma patients on arrival in ED, despite on scene management by ambulance crews; these patients had a higher mortality. (6) Similar trauma data from the United States (US) also suggest a gap in the provision of immediate advanced airway management for major trauma patients. One study that assessed the requirement for emergency intubation in 10,000 trauma patients admitted to a Level 1 Trauma Centre. The results showed that 10% of patients required emergency intubation within 2 hours, over half of whom were urgently intubated for emergency indications including airway obstruction, severe hypoxaemia, low GCS, or cardiac arrest.(34) A similar study by Stephens et al found 18.8% of patients required

intubation within one hour of trauma centre arrival. (35) It is highly unlikely that these indications for emergency airway management only developed on arrival at the MTC.

Emergency airway management in any setting has a significant risk of complications (36,37) and an assessment of the potential benefit of the intervention against the risk of performing it in the pre-hospital setting is made for every patient on an individual basis. In the pre-hospital setting, there are usually multiple factors which contribute to the selection of those patients who have an immediate requirement for emergency airway management and those in whom PHEA should be delayed until arrival at hospital, or may not be required at all. Factors which form part of the decision-making process include the mechanism of injury, scene location, skill mix available and indication for the procedure. Currently the specific group of patients most likely to benefit from PHEA is not clearly defined. Identifying this patient group is complex, although there are some indications which are generally accepted as requiring immediate airway intervention, including complete airway obstruction, failure to oxygenate or ventilate adequately, cardiac arrest or a Glasgow Coma Scale (GCS) less than 9. (38) In some situations, and if carefully performed, excellent basic airway management can provide adequate oxygenation and ventilation, which may deliver the same results as PHEA and negate the need for advanced interventions for the majority of patients, (39) but advanced airway techniques are usually required to provide definitive airway control. However, there is considerable variation in the reported indications for pre-hospital emergency airway management.

1.4.2 Do patients benefit from PHEA?

Emergency airway management performed outside the operating theatre environment has repeatedly been shown to be associated with an increased risk of failure and poor outcome, particularly when performed by inexperienced pre-hospital personnel. These findings were widely demonstrated in the fourth National Audit Project conducted by the Royal College of Anaesthetists and the Difficult Airway Society helped to identify many of the reasons for the increased mortality associated with tracheal intubation performed outside a theatre environment. (40) These included poor identification of at-risk patients; lack of planning; inadequate provision of staff with the appropriate

skill mix to support the intervention and manage difficult or failed intubations; lack of provision of the correct equipment for difficult and failed intubations; and delayed recognition of adverse events. (41) When the report was completed in 2011, the absence, or limited use, of capnography was also quoted as a reason for the increase mortality and the mandatory use of capnography in any advanced airway intervention is now embedded in UK practice and is part of standard monitoring for both pre- and in-hospital anaesthesia. (42) The majority of the problems that occur when emergency airway management is performed in-hospital are also likely to be encountered in PHEA and might perhaps be easily mitigated with improvements in the process and system surrounding the delivery of PHEA, which this thesis sets out to determine.

1.4.3 How is Pre-Hospital Emergency Anaesthesia currently performed?

Any type of patient may be encountered in the prehospital setting – paediatric, obstetric, obese patients, and increasingly geriatric patients (4) make up a significant proportion of patients undergoing PHEA. Clinicians attending these patients must have a skillset that is extensive enough to deal with all patients and any complications that may occur. Although the benefits of early airway control, oxygenation and controlled ventilation are significant, poorly performed PHEA can have detrimental consequences. PHEA should only be performed when there is a clear indication and likely benefit. The most common indications for PHEA are impending or actual hypoxia, impending or actual ventilatory failure, threatened or actual loss of airway control or severe agitation associated with a head injury. (43) There may be some situations, in more sophisticated systems, where further indications are considered including anticipated clinical course or humanitarian reasons. In these situations the risk : benefit ratio is different and since survival or disability is unlikely to be prevented by immediate Rapid Sequence Induction of anaesthesia (RSI) the provider must be confident that the intervention can be delivered with minimal risk. (44)

1.4.3.1 Airway interventions

The optimal techniques for pre-hospital advanced airway management remain much debated. The majority of studies in this area focus on out-of-hospital cardiac arrest and only a small number describe techniques used for trauma patients. Some studies which compare the use of bag-valve mask (BVM) ventilation with advanced airway management techniques found no benefit of advanced airway techniques over BVM ventilation (23) but other studies do suggest a morbidity and mortality benefit associated with intubation for severely-injured patients (17,20,28) particularly for patients with traumatic brain injury, if performed by personnel with appropriate training and experience. (26,30,45) The studies that focus on out-of-hospital cardiac arrest also do not conclusively show a benefit of advanced techniques over basic techniques but the inability to adjust for confounders is widely acknowledged. (46,47)

1.4.3.2 Drugs

Traditionally, the technique for emergency induction of anaesthesia has included the administration of an anaesthetic induction agent, and a neuromuscular blocking agent – suxamethonium. (48) Application of gentle pressure on the cricoid cartilage (Sellick's manoeuvre) (49) and a 'foot down' position were used to minimise the identified risk of aspiration of gastric contents. (50) A successful anaesthetic technique should include all three components of safe and effective anaesthesia: anaesthesia, analgesia and muscle relaxation, with the dose adjusted to reflect any physiological compromise. In current practice, PHEA is performed using an induction agent, often ketamine, and a neuromuscular blocker. An opioid (most commonly fentanyl) is frequently used to suppress the hypertensive response to laryngoscopy, but may be reduced in dose or omitted completely if there are signs of significant physiological disturbance. Incorrect use of any of the agents involved can result in significant complications, which can be life threatening, particularly profound hypotension or post-induction cardiac arrest. (51) The use of ketamine as an induction agent has historically been associated with an increase in intracranial pressure. (52) More recent studies suggest that these concerns were unjustified and not associated with any clinical significance. (53) Ketamine is therefore now considered a safe and effective drug for use in the pre-hospital setting, (54) particularly in haemodynamically unstable patients. (55) Some disruption of cardiovascular stability is common during the induction of anaesthesia. Initially drugs

administered may lower the blood pressure, which is more commonly observed with fentanyl or propofol. The process of laryngoscopy can precipitate a marked elevation in blood pressure, (56) which is arguably more common in emergency settings, where the dose of induction agent may be modified if there are significant concerns about the severity of injury and the likely physiological response to anaesthesia. Awareness is also a recognised problem in emergency anaesthesia and a reduction in drug doses for unstable patients is likely to be a contributing factor. (57)

It is widely recognised that muscle relaxants increase the success rates of intubation (58) but the consequences of failed intubation after the onset of paralysis and rendering patients apnoeic are potentially catastrophic. One study reported a pre-hospital intubation failure rate, with suxamethonium, of 31%. The mortality for this group was 71% compared with 60% where pre-hospital intubation had been successful. (59) There is ongoing debate around the use of suxamethonium, a depolarising neuromuscular blocker, and rocuronium, an aminosteroid neuromuscular blocker with a longer non-depolarising action. A 2015 Cochrane review suggested that superior intubating conditions were achieved with the use of suxamethonium but that rocuronium should be considered as a first line agent if the intubation attempt was expected to be prolonged or difficult. (60) Rocuronium has been shown to produce more favourable intubating conditions in the pre-hospital setting. (61) Sugammadex is an agent that can be used to reverse the effects of rocuronium which has increased the popularity of this neuromuscular blocking agent but Sugammadex is difficult to prepare and its use is unlikely to be feasible in a resource-limited and time-critical pre-hospital setting.

1.4.3.3 Technique

Multiple factors are likely to influence the quality of emergency airway management including the skill level of personnel performing the intervention, (58) number of attempts at intubation,(62,63) (which may in part related to the first point), and the availability and use of anaesthetic drugs. Multiple attempts at laryngoscopy can cause bleeding or swelling in the airway and may result in significant desaturation and hypoxic episodes. (64) All efforts should thus be focused on making the first attempt at laryngoscopy successful.

Laryngoscopy is highly stimulating for patients and causes a sympathetic surge. Perkins et al demonstrated a hypertensive response to pre-hospital laryngoscopy and intubation in 79% of severely injured patients, and 9% of patients experienced a greater than 100% increase in mean arterial pressure and/or systolic blood pressure. (56) Impairment of cerebral autoregulation following traumatic brain injury leaves the brain vulnerable to surges in blood pressure and intracranial pressure, with a subsequent worsening of cerebral oedema and haematoma expansion, which can be detrimental to patient outcome. (56,65,66)

Preoxygenation

Preoxygenation via a face mask is a universally accepted method of reducing episodes of hypoxia during the drug-induced apnoeic phase of induction of anaesthesia. A non-rebreathe mask with a reservoir bag supplying 15L/min oxygen is less effective than using a bag-valve-mask with 15L/min oxygen for preoxygenating patients outside the operating theatre environment: the mean expired oxygen concentration achieved is approximately 50% using a non-rebreathe mask for preoxygenation compared with approximately 80% using bag-valve-mask ventilation. (67) Achieving arterial oxygen saturations (SaO_2) above 93% extends the time taken before hypoxia during the drug-induced apnoeic phase immediately prior to laryngoscopy. At lower values, the dissociation of oxygen from haemoglobin takes place on the steep portion of the oxyhaemoglobin dissociation curve and oxygen saturations drop rapidly. (68) Traditionally, ventilation during the drug-induced apnoeic period has been discouraged in emergency anaesthesia (48) but gentle bag-valve-mask ventilation may be indicated after muscle relaxant administration to avoid hypoxia, which has potentially devastating consequences and outweighs the potential risk of harm from gastric insufflation. Targeted preoxygenation to achieve SaO_2 greater than or equal to 93% using bag-valve mask ventilation has been shown to reduce the incidence of hypoxia associated with intubation without a significant increase in aspiration. (69)

Nasal oxygenation using low-flow nasal prongs is a recognised low-risk and easily administered procedure for providing passive apnoeic oxygenation in the pre-intubation and peri-intubation phases of emergency anaesthesia. It is achievable in the

pre-hospital setting and this intervention has previously been demonstrated to reduce desaturation rates by 6%.(70)

Cricoid Pressure

A pragmatic approach to cricoid pressure is now used in the practice of PHEA. The evidence base for this intervention is poor and based on a very limited evidence base (49) which is reviewed in Ellis 2007. (71) It can worsen the view at laryngoscopy and result in the application of greater forces in an attempt to improve the laryngoscopic view particularly when applied by less experienced assistants. (72) Most clinicians in the UK view it as a routine intervention in PHEA but have a low threshold for removing it if the view at laryngoscopy is poor.

Intubating bougies have become routine for intubation in many services delivering PHEA and have been demonstrated to be effective in unanticipated difficult intubation in the pre-hospital environment.(73)

Post intubation care

In line with in-hospital practice, there is an increasing focus on post-intubation care. If possible, post-intubation care should begin in the pre-hospital phase. Patients should be appropriately sedated using an anaesthetic agent following intubation, the dose of which is titrated to haemodynamic physiology. Further doses of neuromuscular blocking agents may also be required to enable mechanical ventilation and avoid any ventilatory compromise. The use of end-tidal carbon dioxide monitoring, has become mandatory in any intubated patient and careful attention should also be paid to the provision of appropriate ventilation strategies, incorporating lung protective ventilation if possible. Emerging evidence about the harmful effects of hyperoxia may guide future practice, particularly in patients with traumatic brain injury where a partial pressure of oxygen in arterial blood (PaO_2) greater than 65 kPa (or 487 mmHg) has been shown to be associated with worsening patient outcome. (74) Ventilation should be carefully managed to avoid hypocarbia and hypercarbia, both of which have been demonstrated to be detrimental, particularly in traumatic brain injury. (24,75,76) The San Diego paramedic trial (22) showed a significant increase in mortality for patients who experienced periods of hypocarbia secondary to hyperventilation. In this study, patients with severe traumatic brain injury (initial GCS between 3 and 8) who

could not be intubated without drugs were intubated by paramedics using midazolam and suxamethonium. Rocuronium was given following successful intubation. Of the 426 patients included in the trial, only 59 (13.8%) had complete data with regard to SaO_2 and end-tidal carbon dioxide ($EtCO_2$); case matching to controls demonstrated an association between the lowest $EtCO_2$ value and the final $EtCO_2$ value and mortality. Hypoxia during intubation (defined as $SaO_2 < 70\%$) and persistent hypoxia post intubation (defined as $SaO_2 < 90\%$) were also significantly associated with an increase in mortality. (77) Mechanical ventilation is generally considered to be superior to hand ventilation when targeting a specific range for end-tidal carbon dioxide. (78) One Scandinavian service demonstrated increased use of mechanical ventilation following the introduction of a standard operating procedure. (79)

It is generally accepted that body temperature should be maintained in the pre-hospital setting. Recent data has demonstrated a higher rate of hypothermia in patients who are anaesthetised outside hospital. (80)

Standards and safety

PHEA has become increasingly formalised and guidelines exist at local and national levels to standardise the procedure and improve patient safety, (81,82), and these have been demonstrated to change practice.(79) Where less experienced practitioners are delivering PHEA simplified and limited choices can prevent cognitive overload and may reduce human error. There is a strong focus in existing guidelines on patient safety; advanced airway management should only be delivered when appropriately skilled pre-hospital personnel are available. Otherwise meticulous attention should be paid to performing high-quality basic airway interventions. (81-83) Studies which have reviewed the implementation and effectiveness of these tools within pre-hospital services have been able to demonstrate uncomplicated introduction of processes (84) and improvement in compliance with guideline standards and patient outcomes. (79,85)

Failed intubation

A robust failed intubation plan should be well-embedded into all services delivering PHEA. The Difficult Airway Society have developed a well-established stepwise

management plan for unanticipated difficult or failed intubation and this is adopted by the majority of UK services, with only minor variations where required. (86) Any service that practices PHEA must carry airway rescue devices including basic airway adjuncts, supraglottic airways, and the capability to perform a surgical airway. Needle cricothyroidotomy is an intervention of limited value with a high failure rate (87) and is now becoming obsolete in clinical practice; most major guidelines no longer support its use. (81,86,88) Commercial surgical cricothyroidotomy kits exist but the benefit of these over a standard surgical technique is questionable. (89)

Videolaryngoscopy may be considered as part of a failed intubation plan or may at times be used for the first laryngoscopy attempt. The benefit of videolaryngoscopy for emergency airway management remains widely debated but recent evidence does not strongly support a positive benefit of this intervention. (90-92) Two major recent meta-analyses also do not suggest significant benefit from the use of videolaryngoscopy in emergency intubation . (93,94) It is not associated with an improved first pass success rate, reduced time to definitive airway control or reduced rates of hypoxia. However, significant improvement in first pass success rates for inexperienced providers were suggested, with a reduction in oesophageal intubation rates.

1.5 Who delivers PHEA?

There is ongoing debate and a lack of consensus about who should deliver pre-hospital advanced airway management and the amount of training required. Recent UK guidelines suggest that the standard of care delivered in the pre-hospital setting should be the same as that delivered in-hospital and doctors providing emergency anaesthesia should be able to do so competently, and unsupervised, in the emergency department. (81,95) Recognition of PHEM as a subspecialty in the UK has helped structure and formalise training programmes in pre-hospital care to improve the care delivered to patients. In Europe, pre-hospital emergency care is increasingly delivered by physicians (usually anaesthetists). (96) There is evidence to suggest that higher success rates and shorter on scene times exist for PHEA when delivered by physicians when compared with non-physicians. (97) This finding is supported by a meta-analysis

showing higher intubation success rates for physicians compared to non-physicians, , 0.991 and 0.955, respectively (P = 0.047). (58) As expected, success rates are generally higher for anaesthetists when compared with non-anaesthetists, (96,98) emphasising the importance of increased clinical exposure in the preservation of skills, and avoidance of skill fade. (99) In recognition of the fact that intubation without the use of drugs is generally futile, (10) the Joint Royal Colleges Ambulance Liaison Committee no longer train paramedics in tracheal intubation but recommend the use of supraglottic airway devices for advanced airway management. (12)

1.6 What are the key areas of research required in PHEA and what is the future for the intervention?

High-quality research in PHEM is possible but can be difficult to achieve. Designing and conducting a trial on severely injured trauma patients who are unable to provide informed consent is challenging. Recent interest in this intervention has generated more research in this area but the majority of studies demonstrate significant heterogeneity in the design, methodology and endpoints. (100,101) Intubation success rate, first-pass success rate, the frequency of complications, and mortality are commonly reported in the PHEA literature. Whilst the majority of studies report mortality as a primary endpoint, this is relatively crude as patients with very severe injuries usually undergo multiple interventions during their hospital stay which may vary both in, and between, trauma centres. In addition, these patients usually have a protracted course in a Critical Care facility and are vulnerable to much of the morbidity associated with these environments, making mortality an insensitive outcome measure for a single pre-hospital intervention. PHEA is an intervention which has the potential to improve outcome but can also be detrimental if performed badly or by inexperienced personnel in a poorly governed system. In systems where it is provided it should meet the same standards as emergency department anaesthetic management. In systems that cannot provide this level of care efforts should be made to achieve excellent standards of basic airway management and ventilation. (44) In 2011, an expert consensus process identified advanced airway management as one of the top five research priorities in pre-hospital critical care. Some of the most

important questions remain the most difficult to answer, for example: what are the indications for pre-hospital advanced airway management, does it confer a survival benefit, which patients should receive it, and who should deliver it? (100)

Standardisation of practice and data reporting will make the evidence-base for pre-hospital advanced airway management more robust and provide better indications of the benefits and pitfalls of this intervention. In recognition of the fact that the standardised reporting of data for pre-hospital advanced airway management remains poor, Sollid et al developed an Utstein-style template in 2009 for documenting and reporting pre-hospital airway management. (101) To date its use remains limited with relatively few studies reporting data in accordance with the template. A systematic review from 2011 used the Utstein airway variables (28 core variables and 12 fixed-system variables) to assess the quality of data reporting in PHEA studies. (102) None of the 73 studies included in the systematic review reported all the variables. The median number of core variables reported was 10 (max 21, min 2, IQR 8-12), and the median number of fixed system variables was 5 (max 11, min 0, IQR 4-8). (102) The lack of standardisation of data reporting that exists, together with marked underreporting of key variables, makes interpretation of published research very challenging. The heterogeneity that exists in the published literature on PHEA stems, in part, from the significant heterogeneity in the intervention itself. There are major inconsistencies worldwide in delivery of this intervention in terms of provider level, technique used. Whether or not drugs are used to facilitate intubation, and which drugs are used also varies hugely. Much of the US data, which forms a large part of the evidence base for PHEA, is based on intubation performed without drugs or, if drugs are used, when the technique is not consistent with rapid sequence techniques (induction agent, opioid, neuromuscular blocker) used on many parts of Europe and Australasia. One systematic review comparing mortality from pre-hospital and emergency department intubation reported that of the 21 studies and 35,838 patients included, only 10% underwent a standard rapid sequence induction. (103) The San Diego paramedic trial (22) reported significantly worse outcome for patients intubated outside hospital using midazolam and suxamethonium followed by rocuronium. However, interpretation of the results is made difficult by multiple significant episodes of hypoxia before or during intubation, hypocarbia post intubation, and changes in time at scene. (22) On the basis of the

available literature, it is unclear whether reported sub-optimal results are due to the fact that PHEA is performed or because it is being performed badly. (44)

1.7 Rationale for thesis

The persistence of airway compromise as a cause of preventable death despite advances in the practice of PHEM, suggests the underlying problem is still not being fully addressed and it is not completely clear why. The recognition and development of PHEM as a subspecialty have resulted in some improvement in the quality of care delivered but PHEA remains a controversial and often difficult intervention with a high complication rate. These facts suggest that there is still a long way to go in consistently delivering a better outcome for critically ill and injured patients with airway compromise. There are several specific areas of PHEA in which small improvements are likely to translate into a benefit in patient morbidity and mortality. It is likely that there is an imbalance between the demand for the provision of emergency or urgent airway management at an early stage post injury which is not being met by current prehospital providers. Other factors may relate to provider skill and training, and a lack of standardisation of practice. Improvements in these areas are likely to be achieved by examining the current process closely and making interventions where there are areas of identifiable weakness, and altering process to improve outcome. Within my clinical practice and my research capacity I identified a number of potentially modifiable areas in PHEA and conducted a number of studies to try and improve the process.

Specifically, the questions I sought to answer through this thesis were:

Is PHEA actually necessary?
Which patients should receive PHEA?
What does current PHEA practice look like?
Is there an unmet demand for PHEA?
Who should deliver PHEA?
How can the process be improved?
In what areas of PHEA can change most influence outcome?

1.8 Concept of the studies

The studies included in the thesis were specifically designed to attempt to address some of the above unanswered questions surrounding the practice of PHEA. In order to address these questions, I considered the three major areas of PHEA individually. These are:

1. Pre-induction
2. Induction
3. Post-induction

Improvement in the practice and delivery of PHEA might be made by improving individual aspects of these three areas, using the principle of aggregation of marginal gain. It is possible that these improvements could translate into improvements in patient safety and survival benefit.

Pre-induction

The pre-induction period is the time period between when the decision to perform anaesthesia is made until induction of anaesthesia. One of the key factors influencing this phase of PHEA which may be modifiable is patient selection. It sometimes appears very obvious which patients require urgent airway intervention: for example, those with airway obstruction, failure of oxygenation or ventilation or both, or with a significant reduction in the level of consciousness. In some patients, the indication for advanced airway intervention is less clear (e.g. humanitarian reasons; triage and transport considerations; and predicted clinical course, for example whether the patient will need immediate surgical intervention following arrival in hospital). Here, decision-making involves more human factors. As discussed, PHEA has a significant mortality rate (103,104) and careful consideration must be applied before proceeding with this intervention in patients in whom the indications are not completely clear. I played a lead role in the design and implementation of three studies that focussed on patient selection:

- A prospective observational study designed to assess whether PHEA is required in any capacity
- A retrospective database review to establish whether there is an unmet demand for PHEA

- A retrospective database review to establish whether PHEA may be detrimental to some patients, this study focussed specifically on major trauma patients with severe hypovolaemia.

Induction

The induction period is the time from when drugs are administered to anaesthetise the patient until a definitive airway has been established. Of particular relevance to this period of PHEA is the skill level of the person performing tracheal intubation. Multiple attempts at laryngoscopy and intubation are detrimental to the patient and everything should be optimised to make the first attempt at intubation successful. I undertook three studies with a view to improving patient safety during this stage of the process:

- A meta-analysis of success rates for physicians vs. non-physicians performing pre-hospital advanced airway management.
- A survey of checklists used by PHEM providers to reduce human error during PHEA and improve patient safety.
- A prospective before-after study assessing the effectiveness of apnoeic oxygenation in reducing the frequency of hypoxic episodes during the peri-intubation period.

Post-induction

The post induction phase of PHEA is the time period from when a definitive airway has been established until the arrival of the patient at hospital. Once definitive airway control has been established, careful attention should be paid to ensuring adequate oxygenation and ventilation. I performed a study focussing on adequacy of ventilation to address this point.

1.9 Study Settings

The studies in this thesis were predominantly conducted in London's Air Ambulance service which is in an urban, physician-led, pre-hospital trauma service, based in London, UK. London's Air Ambulance serves an overall population of approximately nine million (daytime population approximately 10 million) in an area of more the 600 square miles. The service operates a pre-hospital physician-paramedic team who have

received training in PHEM. The team are delivered to the scene by helicopter in daylight hours and by fast response car at night. Flight paramedics working within the London Air Ambulance service also work in Ambulance Control. These paramedics aim to dispatch the service exclusively to major trauma patients, using specific dispatch criteria target patients with severe injury. (105) A standard land ambulance is always dispatched in addition to the physician–paramedic team. The service usually attends between five and eight patients in a 24-hour period. The attending pre-hospital physician records information about each patient attended on a Microsoft ACCESS™ database shortly after missions. Information documented includes patient demographics, mechanism of injury, interventions performed, triage decision, and timings for the mission.

All physicians working with the service have more than 5-years' experience post qualification and are required to complete a minimum of 6-months anaesthesia and 6-months emergency medicine. The majority of physicians within the service are trainees or consultants in Anaesthesia or Emergency Medicine. Any physician meeting the job specifications can apply; paramedics are recruited from the London Ambulance Service. At the start of the secondment with London's Air Ambulance, all physicians and paramedics undergo four to six weeks of induction under the guidance and supervision of dedicated pre-hospital care consultants as well as weekly case review, audit and clinical governance meetings.

Data from all patients attended by the service in which I conducted my studies are recorded on patient report forms at the time of the incident. Once the patient has been transported to hospital, the data are entered into a Microsoft ACCESS™ database by the attending physician. The data that are recorded includes demographics, mission timings, and patient physiology. If a patient undergoes PHEA all relevant information is recorded including the indication for the intervention and the drugs administered. A free text section is completed describing injury mechanism, injuries sustained and other relevant information.

The pre-hospital physician-paramedic team are specifically trained to provide a number of critical interventions on scene which are potentially life-saving including

PHEA, resuscitative thoracotomy, pre-hospital blood transfusion, and Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA). Emphasis is placed on providing only those interventions which are absolutely necessary for resuscitation and stabilisation of the patient, without delaying transfer of the patient to hospital and the provision of definitive care. PHEA is performed in accordance with current UK guidelines (95) and local SOPs. These are deliberately straightforward and designed to minimise choice and reduce cognitive overload in a potentially stressful environment in an attempt to improve procedural success rates. All physicians in the service have undertaken previous training in anaesthesia in a hospital environment and have usually performed a high number of tracheal intubations before entering the service.

In 1996 the service standardised the drugs used for the provision of PHEA, selecting etomidate for the induction agent, morphine as the opiate of choice, and suxamethonium for muscle relaxation. In 2012 these drugs were changed to ketamine for induction, fentanyl as the opioid, and rocuronium as the muscle relaxant. The alteration in drug choice was in part due to recognition of the fact that a technique more aligned to that used in hospital may reduce physiological disturbance in certain patient groups, and the increasing body of evidence that ketamine was not considered detrimental for induction of patients with traumatic brain injury. (106,107) Pre-induction checklists were introduced into the service by 2006 and low fidelity simulation was employed to ensure all team members gained competence.

The indications for PHEA used by the trauma service are:

1. Actual or impending airway compromise
2. Ventilatory failure
3. Unconsciousness
4. Humanitarian need
5. Patients who are unmanageable or severely agitated after head injury
6. Anticipated clinical course

The management of failed intubation is described in the PHEA SOP and this event is subject to regular moulage within the service. The use of a supraglottic airway as a rescue device were introduced into the service in 2005, prior to this emergency

cricothyroidotomy was the final step in the management of failed intubation. Initially, the Proseal LMA™ (Intavent Direct, UK) was the supraglottic airway of choice due to its potential ability to ventilate at higher inflation pressures and because of the presence of a gastric drainage port to reduce aspiration. This was superseded by the I-Gel™ (Intersurgical, UK) in 2010 as it was considered to be easier to insert and was the device used by the local ambulance service.

Where required, ethical approval for the studies conducted with London's Air Ambulance was obtained from Barts and the London NHS Trust, which is the hospital trust in which the service is based.

Chapter 2: Is there a requirement for PHEA?

The aim of this chapter was to establish whether PHEA is actually necessary. Due to the amount of controversy that surrounds the topic, and the high-risk nature of the intervention, this is an essential question to inform practice going forward. It may be that PHEA is not required if basic airway interventions can be meticulously applied such that oxygenation and ventilation can be adequately maintained at all times. Recent research in non-traumatic cardiac arrest patients has highlighted this point. A study based in the UK assessed the use of supraglottic airway devices for non-traumatic out-of-hospital cardiac arrest failed to demonstrate superiority when compared with tracheal intubation. (108) In contrast, data from the United States suggest improved 72-hour survival when supraglottic airway devices are used when compared to tracheal intubation. (109) Data published in 2018 from a trial comparing bag-valve-mask ventilation with tracheal intubation for initial airway management was inconclusive. (39) More recently, Schwaiger et al suggested that there was no survival benefit for spontaneously breathing trauma patients intubated on-scene compared with patients intubated immediately after hospital admission. (110)

2.1 Is PHEA really necessary?

In this section I describe a study that was conducted in 2014 in London's Air Ambulance Service described in Chapter 1. My role in this study in the development of the study, analysis of the data collected and as an author of the study drafts. The study was a 1-year prospective, observational study which sought to establish the frequency and management of airway compromise in major trauma patients in the immediate post-injury period. (111) The study was designed to specifically address whether PHEA was actually a necessary intervention, that was required in addition to those airway interventions routinely provided by ambulance service personnel to manage identified airway compromise. Ambulance service personnel are able to perform basic airway interventions (airway positioning and manoeuvres, use of an oropharyngeal or nasopharyngeal airway) and some advanced airway interventions (tracheal intubation

without the use of drugs, insertion of a supraglottic airway device). The study further addressed whether the airway interventions performed by ambulance service personnel dealt adequately with the problem for which they were deployed. For the vast majority of patients, ambulance service personnel are the first responders and the pre-hospital physician-paramedic team arrived later.

2.1.1 Study design

During the one-year study period, the pre-hospital physician-paramedic team recorded the presence of any airway compromise, partial or complete, in major trauma patients, when they arrived on scene. The team were also asked to document any airway interventions which had already been performed by ambulance service personnel (most commonly a paramedic) in an attempt to treat airway compromise. Agreement between the pre-hospital physician-paramedic team members regarding the effectiveness of any applied airway interventions was used as a strategy to try and limit the risk of bias by reducing subjectivity. The initial airway assessment was carried out in an attempt to determine whether persisting airway compromise was due to the interventions used being ineffective or because appropriate interventions had not been attempted. The type, success and resulting complications of subsequent interventions were also recorded.

The study was conducted during a one-year study period (1st April 2012 until 30th March 2013) within the London Air Ambulance service described in Chapter 1. During this time an average of twelve physicians and nine paramedics rotated through the service. All personnel within the service receive a minimum of one month of supervised training during which time they will perform PHEA. On average, a physician will anaesthetise approximately 50-60 patients in the pre-hospital setting during a six-month secondment.

The study was registered as a clinical evaluation study with Barts and the London NHS Trust and ethical approval was not required as standard practice only was being assessed.

2.1.2 Results

Between 1st April 2012 until 30th March 2013, the London Ambulance Service received 1.6 million '999' emergency calls. Of these, 1963 patients (0.12%) were identified as major trauma and attended by the pre-hospital physician-paramedic team; 472 patients (24.0%) required advanced airway management and underwent tracheal intubation on scene. Consistent with other similar studies, the majority of patients were young male patients; 78% of patients attended were male, and the median age was 40 years (range 0 – 95 years). Detailed demographic data such as patient ethnicity was not available. Road traffic collisions were the most common mechanism of injury, occurring in 187 patients (39.6%). Other mechanisms of injury occurring relatively frequently included falls in 137 patients (29%), and assaults in 50 patients (10.6%). Ninety-four patients (19.9%) were declared dead before reaching hospital. Nearly 20% of patients were in traumatic cardiac arrest on scene, which is associated with a poor outcome, (112,113) and confirms the severity of injuries encountered by this group of patients. In total, 469 patients were already being attended by ambulance service personnel on arrival of the enhanced team; on only three occasions did the pre-hospital physician-paramedic team arrived on scene first.

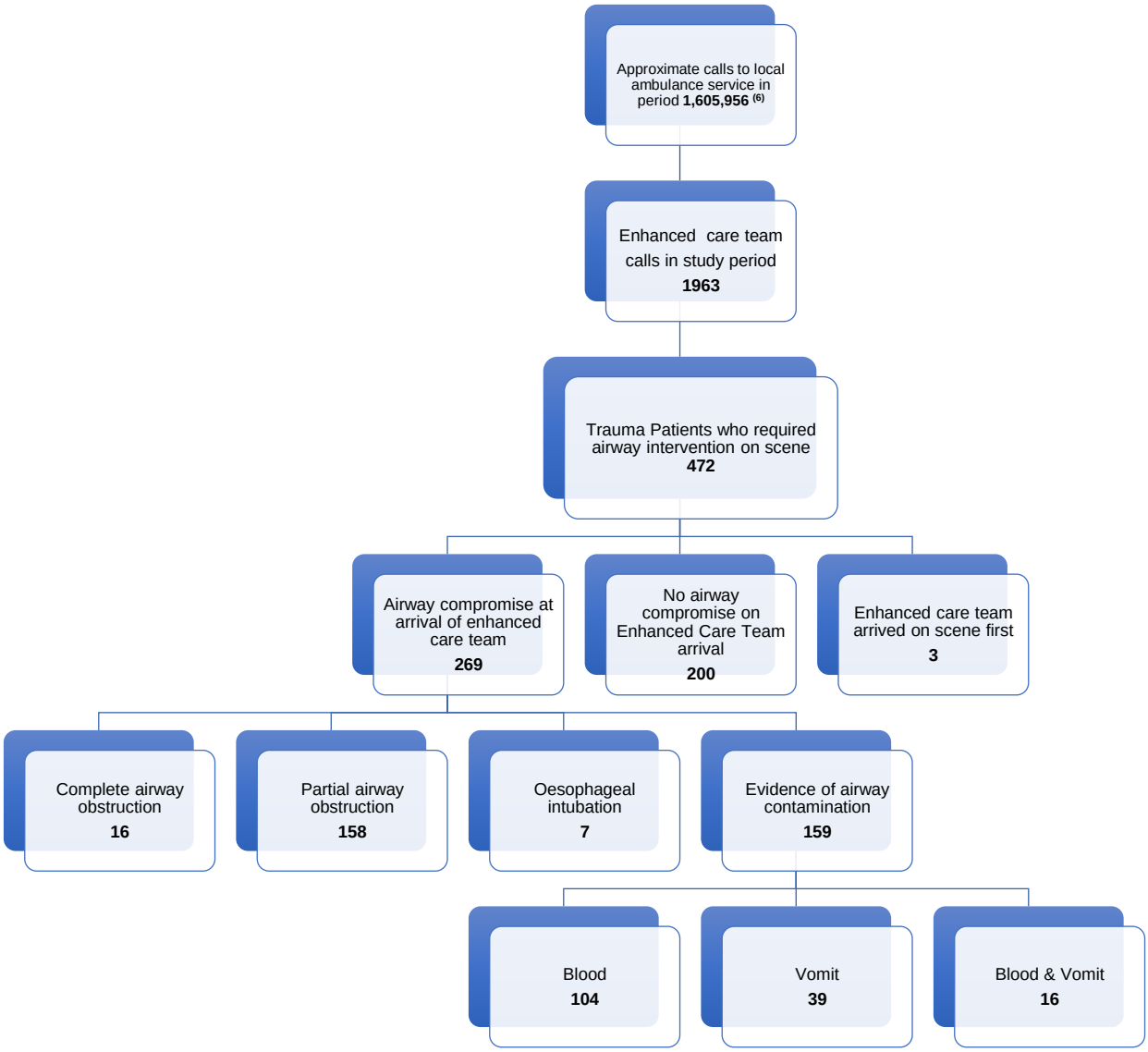
Ambulance service personnel who arrived at the patient first attempted a total of 925 airway interventions on the 469 patients they treated, ranging from the application of oxygen via a simple face mask to tracheal intubation. Airway compromise persisted in 57% of these patients (269 patients), and was present on arrival of the enhanced care team despite performance of the interventions described below in table 2.1. No airway compromise was documented on arrival of the pre-hospital physician-paramedic team in 200 patients. Of these 200 patients, 67% had received ambulance service airway interventions which were successful in treating any airway compromise.

Table 2.1: Airway interventions performed by ambulance service personnel prior to the arrival of the enhanced care team

Interventions carried out	Number of patients receiving intervention, (%)
Oxygen	417 (88.9)
Chin lift/ Jaw thrust	20 (4.2)
Oral/Nasal Airway	163 (34.8)
BVM Ventilation	134 (28.6)
Supraglottic airway device	52 (11.1)
Intubation without drugs	45 (9.6)
Suctioning of airway	94 (20.0)
Total number of interventions	**925 (100)**

One third of all patients (159 patients) had evidence of gross airway contamination on arrival of the pre-hospital physician-paramedic team causing a degree of airway obstruction, most frequently due to blood in the airway, and sometimes due to vomit in the airway or a combination of both. In 16 patients (10%), airway obstruction was complete, figure 2.1. Despite this, airway suctioning was only carried out on a small proportion of these patients prior to arrival of the pre-hospital physician-paramedic team.

Figure 2.1: Initial assessment of airway compromise by enhanced care team



In 45 patients, 49 attempts at tracheal intubation were made by ambulance service personnel without drugs as per ambulance service training and protocols. The majority of these were in established cardiac arrest. Intubation was successful in 29 patients (64%). There were 20 unsuccessful attempts at intubation including five unrecognised oesophageal intubations and two further oesophageal intubations which had been identified by the attending personnel but not rectified before the enhanced care team arrived.

A further 52 patients had a supraglottic airway inserted and the majority (92%) of supraglottic airway insertions were successful. All complications that were related to advanced airway interventions are recorded in table 2.2 below.

Table 2.2: Airway complications encountered during the 443 intubations performed by pre-hospital physician-paramedic enhanced care team

Airway complication	Number of patients n, (%)
Recognised oesophageal intubation	4, (0.9%)
Recognised mainstem bronchus intubation	3, (0.7%)
Unrecognised oesophageal intubation	0
Trauma to teeth	0
Vomiting and/or aspiration	13, (2.9%)
Hypoxia	19, (4.3%)
Bradycardia	1, (0.2%)
Hypotension	15, 3.4%

2.1.3 Discussion

The fact that 57% of patients had airway compromise on arrival of the pre-hospital physician-paramedic team, despite attempted airway interventions, suggests that there is a requirement for enhanced care which is not being met by current ambulance service care provision alone. All patients included in this study met criteria for, and required, urgent tracheal intubation and this can be considered as a surrogate marker of the need for this intervention in this patient group. Standard ambulance service airway interventions were only effective for a relatively small proportion of patients; in a number of cases, airway management provided by ambulance personnel was suboptimal.

Despite the fact that oxygen supplementation is routine in trauma patients, oxygen was not applied to 11% of patients which may have potentially resulted in significant harm. Despite the propensity to harm, this is not an uncommon finding and similar

data was reported in the 2007 NCEPOD report. (6) It is possible that the available interventions were simply not effective for this patient group due to the severity of injury and physiological derangement, but this hypothesis would only be true if all the interventions were applied appropriately and consistently to the patients with compromise. It is likely that a number of patients who did not receive appropriate airway interventions would have benefited from well-performed basic airway manoeuvres including suction. The fact that airway interventions were successful in 43% of patients supports this suggestion and argues against the fact that the interventions were ineffective because patients were too sick to benefit. There is an increasing amount of evidence, mostly in cardiac arrest patients, that tracheal intubation is not superior to well performed basic airway manoeuvres including bag-valve-mask ventilation and insertion of supraglottic airway devices. (39,108)

The low success rate of 64% for tracheal intubation performed prior to the arrival of the pre-hospital physician-paramedic team is worrying but consistent with the literature from several other paramedic services. All intubations performed by the pre-hospital physician-paramedic team were successful. Similarly, the reported complication rate for this intervention was also unacceptably high, including five unrecognised oesophageal intubations (11%), (identified and corrected by pre-hospital physician-paramedic team) and two recognised oesophageal intubations, which were corrected by the pre-hospital physician-paramedic team. One of the major factors contributing to this problem is lack of training and exposure. Major trauma is relatively rare and accounts for approximately 0.1% of the ambulance service workload. In the one-year study period, the ambulance service received over 1.6 million calls, [www.londonambulance.nhs.uk (accessed 29.06.14)] of these, only 1963 patients were identified as major trauma patients. Consequently the vast majority of paramedics intubate between one and four critically ill or injured patients per year, making it difficult to maintain this skill. (12) The success rates for intubation without the use of drugs are very low, (10), and the benefit of intubation in a setting where drugs are not required is increasingly questioned. (12) The ability of a patient to tolerate intubation without the use of drugs suggests profound physiological compromise. In contrast, the successful insertion of 48 out of 52 supraglottic airway insertions (92%) supports the

use of such devices in this setting. This finding has been reproduced in other larger studies. (109,114)

The rate of incorrect tracheal tube placement was lower for the pre-hospital physician-paramedic team, and included four oesophageal intubations, immediately recognised and corrected during the same intubation attempt, and three right mainstem bronchus intubations that were also identified and corrected before leaving scene. This finding is expected given the far greater exposure to the intervention experienced the team. In addition, tracheal intubation is performed by physicians which is associated with a higher success rate and lower complications rate. (58,115)

2.1.4 Limitations

The study had several limitations, including the fact that the time the ambulance personnel had on scene to manage the airway prior to arrival of the pre-hospital physician-paramedic team was not reported and likely to have been variable. Using the pre-hospital physician-paramedic team to assess the airway upon their arrival is a potential source of bias, as is self-reporting of complications. It is also possible that a number of trauma patients were attended and adequately managed by ambulance personnel without the pre-hospital physician-paramedic team being activated for whatever reason. There will also have been a group of major trauma patients who were not attended by the physician-paramedic pre-hospital team as there is only one operational team covering a large geographical area. The study is helpful in highlighting the fact that there are a small but identifiable group of major trauma patients in whom basic airway interventions are unsuccessful and advanced airway intervention is required in a timely fashion and prior to arrival at hospital. It is possible that some patients received advanced airway interventions outside the stated service indications but the majority of patients with advanced airway interventions would be subject to rigorous review in the service governance process. Tracheal intubation in this setting should be delivered by experienced personnel who are highly competent in advanced airway techniques. The study also suggests that basic airway management is often poorly performed, which is unacceptable. Basic airway interventions are essential in these patients whilst waiting for the delivery of more advanced

intervention and meticulous attention should be paid to performing them well as they will undoubtedly be life saving for a number of patients.

Some patients may have had airway interventions that weren't required and we have no way of identifying this group.

2.2 Is there an unmet demand for PHEA?

Having established that there is a role for PHEA, I designed and performed a study using a national trauma database to establish the demand for, and the use of, urgent airway intervention in the wider UK trauma population both in the pre-hospital phase and soon after arrival at the emergency department. It is likely that a proportion of patients who receive urgent airway management in the Emergency Department (ED) represent an unmet demand for airway intervention in the pre-hospital phase of care. In order to achieve these objectives, the study identified the proportion of major trauma patients who meet criteria for immediate intubation on scene but do not receive it, and the proportion of these can be safely managed with more basic airway management prior to hospital arrival. This is particularly likely in unconscious patients and those that have temporary airway interventions performed to treat airway obstruction and are intubated after transfer to hospital. Data were reviewed for all patients and for patients with a pre-hospital GCS < 9 , an objective and commonly used marker of requirement for intubation in trauma practice. (38,116) The mortality of patients who had airway interventions was also investigated. Relatively few studies directly address the issue of unmet demand and those that do suggest that there is an unmet demand for urgent tracheal intubation for a proportion of trauma patients in whom basic airway manoeuvres are inadequate. (34,35,111)

To address this question, I conceived and performed a study using data from the national UK Trauma Audit and Research Network (TARN), a national clinical registry of traumatic injury that receives data for major trauma patients from hospitals in England and Wales.

2.2.1 Study design

The study was a retrospective review of the TARN database, which was performed to identify all trauma patients, adults and children, who were admitted to an MTC between 1st April 2012 and 27th June 2016. All MTCs were established and commenced operation at the same time. The main objective of TARN is to facilitate the development and improvement of trauma services and contribute to a reduction in the associated burden of death and disability. All hospitals that receive trauma patients are strongly encouraged to submit high-quality data and for all hospitals in England submission is mandatory as part of trauma network quality assurance. Trauma patients' data are eligible for inclusion in the TARN database if the patients remain in hospital for more than three days, require admission to a Critical Care facility, are transferred from another hospital as a result of injuries sustained, or die from the injuries sustained. Patients more than 65 years old who have sustained an isolated neck of femur fracture and those with isolated closed limb fractures are excluded.

The study data collected included patient demographics, mechanism of injury, pre-hospital and ED descriptions of airway status on arrival, airway interventions performed, timing of airway interventions, Glasgow Coma Score (GCS), Abbreviated Injury Severity Score (AIS), Injury Severity Score (ISS), the probability of survival (PS14) and mortality. The AIS is a trauma severity scoring system that divides the body into different anatomical regions and assigns a score from 1 (minor injury) to 6 (deemed non-survivable) for each body region. The regions included in this study were head / face / thorax / abdomen / spine / pelvis / limbs. To calculate the ISS the individual scores from the 3 most injured regions are squared and added together. The PS14 is the probability of survival is calculated using a logistic regression model based on age, gender, ISS, GCS and patient co-morbidities; it is calculated as a percentage.

The airway interventions performed for each patient were included in the final analysis. Patients who were intubated were divided into separate categories:

(1) those intubated in the pre-hospital setting (PHI)

(2) those intubated in ED (EDI)

(3) those who were intubated in ED after receiving pre-hospital non-tracheal

intubation airway interventions (EDI after PHNTIAI). Pre-hospital non-tracheal intubation airway interventions were defined as airway positioning, insertion of naso- or oropharyngeal tube, or supraglottic airway device.

All data was anonymised. As additional security, projects undertaken both in-house and in collaboration with other parties are governed by a code of practice approved by a Confidentiality Advisory Group (CAG) appointed by the Health Research Authority (HRA). The CAG has given TARN permission, under Section 251 of the NHS Act 2006, to undertake research, within strictly defined criteria, on anonymised data held on its database. Access to dataset, data transfer, cleaning and information governance is performed by TARN

Statistical Methods

Demographic variables were compared between groups using Kruskal-Wallis tests for continuous data and chi-squared or Fisher's exact test for categorical data. Differences in outcome by intubation type were assessed using a logistic regression model, odds ratios and 95% confidence intervals were obtained for each group relative to ED intubation. Pairwise comparisons were made to obtain p values for each group compared to the other two groups. P values were adjusted for multiple comparisons using the Holm-Bonferroni method. Patients with a documented GCS < 9 were also categorised into intubation groups and the same statistical analysis performed to assess the validity of using GCS < 9 as an indication for urgent intubation as per current international guidelines. (38,117) Statistical analysis was performed using Stata version 14 (StataCorp Texas)

The primary outcome of the study was to establish the requirement for urgent advanced airway management in three major trauma patient cohorts as stratified by time of tracheal intubation. The proportion of patients who received advanced airway management within thirty minutes of arrival in a major trauma centre was also established. This time frame was chosen as it is a metric collected by TARN – it has been discussed and agreed by consensus as useful metric to discuss whether there is a

requirement for, and the capability to deliver, intubation early in the in-hospital resuscitation phase. Mortality (defined as hospital discharge or 30-day mortality, whichever is soonest) was investigated as a secondary outcome measure in the same cohort groups with an additional sub-group analysis for patients with a GCS ≤ 8.

2.2.2 Results

In the two-year study period, data for 70,550 trauma patients were recorded in the TARN database and included in the study. The median age of the patients was 49.0 years, (IQR 32.5–76.6 years). 43,546 patients (62%) were male and 27,004 (38%) were female. The majority of patients (67,338 patients, 95.4%) experienced blunt traumatic injury; 3212 patients were victims of penetrating trauma (4.6%).

The Injury Severity Score (ISS) was reported for all patients; 40,598 patients (57.5%) had an ISS < 15 and 29,952 patients (42.5%) > 15. The median age of the patient group with an ISS > 15 was 51.1 years (IQR 30–72.8 years), and the median ISS was 25 (IQR 17-29). Abbreviated injury scores (AIS) were also reported for all patients. The most severe injury sustained, according to AIS classification, is reported in table 2.3 below.

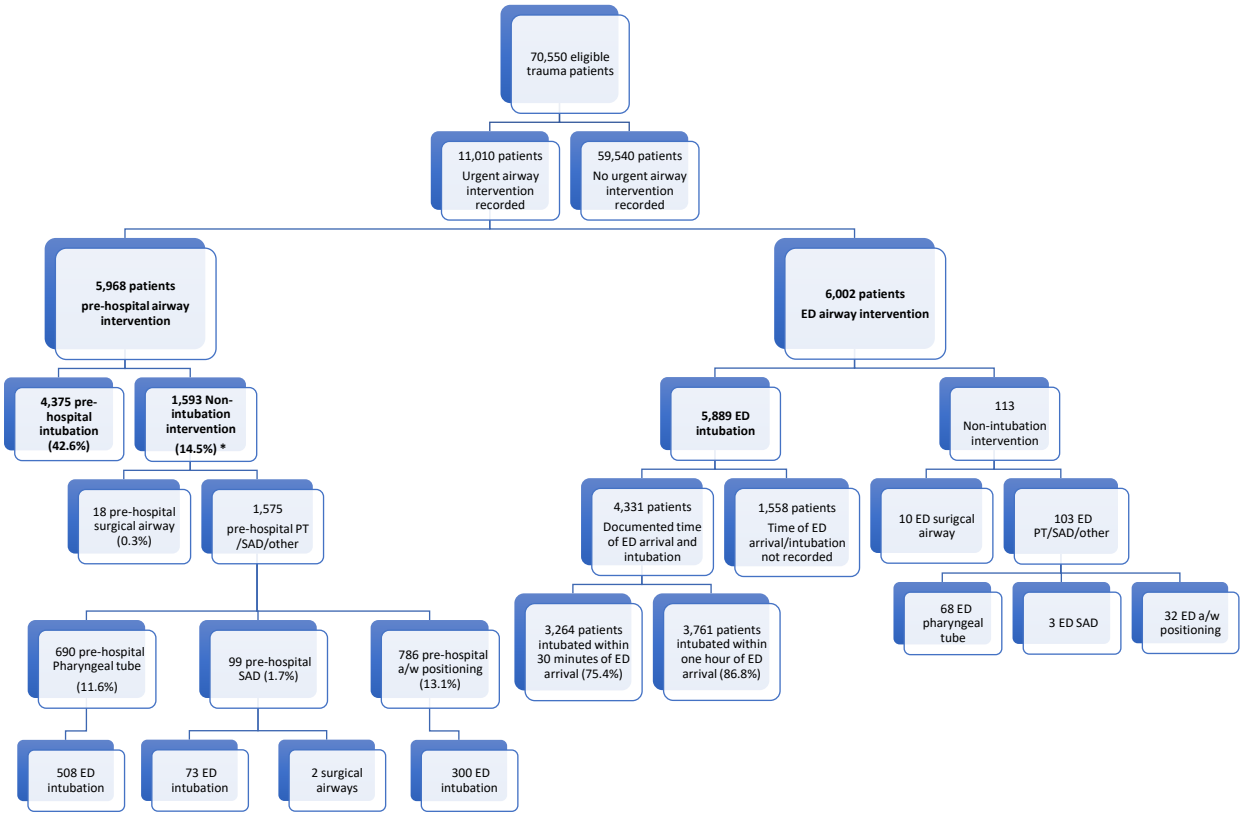
Table 2.3: Most severe injury sustained by all study patients defined by AIS classification

Most severe injury	Number of patients, n (%)
Abdomen	2062 (2.9)
Chest	11,411 (16.2)
Face	842 (1.2)
Head	17,610 (25.0)
Limbs	22,744 (32.2)
Multiple	7958 (11.3)
Other	825 (1.2)
Spine	7098 (10.0)
Total	**70,550 (100)**

Airway Interventions

Of the 70,550 patients who met TARN inclusion criteria, 11,010 (15.6%) had a recorded pre-hospital or emergency department airway intervention (figure 2.2). No early airway intervention was recorded for 59,540 patients (84.4%). An airway intervention was defined as airway positioning by pre-hospital personnel to try and improve the airway, use of a nasopharyngeal or oropharyngeal airway (pharyngeal tube, PT), insertion of a supraglottic airway device (SAD) or tracheal intubation.

Figure 2.2: Airway interventions for all patients



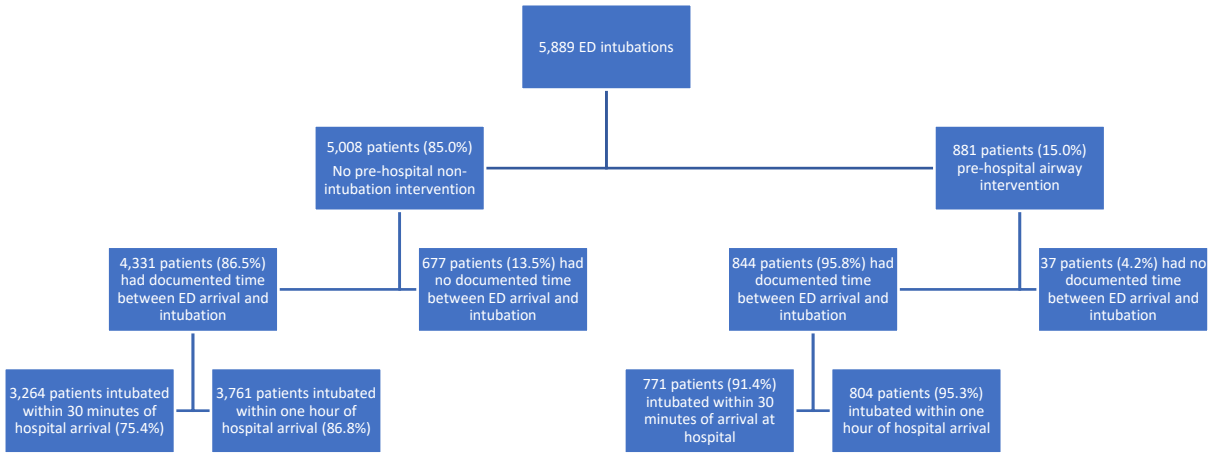
Of 11,010 urgent airway interventions, 10,264 patients (93.2%) were successfully intubated in the pre-hospital setting or in the ED. Overall, 4,375 of the 10,264 intubated patients (42.6%) underwent pre-hospital intubation and 1,593 patients (14.5%) had a pre-hospital non-intubation airway, including placement of a PT for 690 patients (11.6%) placement of a SAD for 99 patients (1.7%), and airway positioning for 783 patients (13.1%). Eighteen patients (0.3%) were reported as having an emergency surgical airway as their pre-hospital airway intervention. The demographics of the patients in the different intubation categories are recorded in table 2.4.

Table 2.4: Demographics of patients in different intubation categories

	Number of patients	Median age, years (IQR [range])	Median ISS (IQR [range])	Mean PS14 (SD)	Head AIS >/=3	Face AIS >/=3	Thorax AIS >/=3	Abdomen AIS >/=3	Spine AIS >/=3	Pelvis AIS >/=3	Male n, %	Blunt trauma n, %
PHI	4375	40 (24.8, 57.4[0-114.4])	29 (22, 38 [1-75])	66.4 (28.2)	2973, 68%	98, 2.2%	2392, 54.7%	509, 11.6%	405, 9.3%	406, 9.3%	3333, 76.2%	4169, 95.3%
EDI	5008	42.4 (24.7, 62.1 [0-100.9])	25 (17, 33 [1-75])	75.2 (26.5)	3467, 69%	54, 1.1%	1958, 39.1%	417, 8.3%	321, 6.4%	335, 6.7%	3782, 75.5%	4730, 94.4%
EDI after PHNTIAI	881	45.6 (27.1, 65.3 [0-104.5])	26 (25, 38 [1-75])	52.8 (28.6)	643, 73%	19, 2.2%	364, 41.3	69, 7.8%	59, 6.7%	68, 7.7%	626, 71.1%	849, 96.4%
P value		P<0.0001	P<0.0001		0.01	P=0.0003	P<0.0001	P<0.0001	P<0.0001	0.00002	P=0.005	P=0.03
P value EDI v. PHI		P<0.0001	P<0.0001		0.18	P<0.0001	P<0.0001	P<0.0001	P<0.0001	P<0.0001	0.454	0.132
P value EDI after PHNTIAI v.		P<0.0001	P<0.0001		0.009	0.878	P<0.0001	0.002	0.030	0.28	0.003	0.162
P value EDI v. EDI after PHNTIAI		0.0016	0.018		0.050	0.018	0.21	0.62	0.75	0.28	0.010	0.060

5,889 patients were intubated in the ED. The time between arrival and airway intervention was documented for 4,331 patients. Of the patients who were intubated in the ED and had a recorded time of arrival and time of intubation, 3,264 patients were intubated within 30 minutes of hospital arrival (75.4%) and 3,761 patients were intubated within one hour of hospital arrival (86.8%). In total, 881 patients (15.0%) who were intubated in the ED had a non-intubation airway intervention performed in the pre-hospital setting, as described above. Amongst these, the time between arrival and intervention was reported for 844 patients, 771 of whom (91.4%) were intubated within 30 minutes of arrival at hospital and 804 (95.3%) within one hour (figure 2.3).

Figure 2.3: Timing of ED airway interventions



Mortality

The overall mortality rate for patients requiring emergency intubation in any setting was 28.1%; mortality rates for the individual study groups are reported in table 2.5 below. The overall mortality rate for patients who were intubated in the ED was 25.7% (1,511 of 5,889 patients); for those patients who were intubated in the ED but who did

not receive a pre-hospital non-intubation airway intervention, the mortality rate was 21.3% (1,065 of 5,008 patients).

Table 2.5: Pairwise comparison of overall mortality for the study groups

	PH intubation	ED Intubation	ED intubation after PH non-intubation intervention
Overall mortality	1473, 33.7%	1065, 21.3%	446, 50.6%
Odds ratio (95% CI)	1.88 (1.71-2.06)	1.00	3.80 (3.27-4.40)
Comparison against EDI	P<0.0001		P<0.0001
ED+PH vs PHNTIAI			P<0.0001

GCS < 9

Overall, 6,393 of 68,206 patients with a recorded pre-hospital GCS (9.4%) had a documented GCS < 9; of these, 2,872 (44.9%) were intubated in the pre-hospital setting, and 2,505 patients (39.2%) in the ED; 1,405 patients (56.1% of those intubated in ED) were intubated within 30 minutes of hospital arrival and 1,576 patients (62.9%) within one hour. A further 1,016 patients with GCS <9 underwent non-intubation airway interventions in the pre-hospital setting, of whom 789 subsequently underwent ED intubation. The mortality rate for this patient group is reported in table 2.6 below.

Table 2.6: Pairwise comparison of mortality for patients with GCS < 9

	PHI	EDI	EDI after PHNTIAI
GCS < 9 total	2872	2505	789
GCS < 9 deaths n, (%)	1231, (42.9%)	743, (29.7%)	426, (54.0%)
Odds ratio (95% CI)	1.78 (1.59-1.99)	1.00	2.78 (2.36-3.28)
Comparison against EDI	P<0.0001		P<0.0001
ED+PH vs PH			P<0.0001

Paediatrics

Some 4,403 of 70,550 patients (6.2%) were aged 16 or less. Pre-hospital airway interventions were recorded for 402 patients (9.1%). In total, 320 paediatric patients (7.3%) underwent pre-hospital intubation. A SAD was used in six patients in the pre-hospital setting and 32 patients underwent PT insertion. Pre-hospital airway positioning was performed for 43 patients. A total of 583 children (11.8%) were intubated in the ED. The mortality rate for the paediatric population was 3.4% (151 of the 4,403 children died). Of the children that died, 76 patients (23.75%) were intubated in the pre-hospital setting and 75 children were intubated in the ED (12.9%).

2.2.3 Discussion

This study is one of the largest to date that reviews the use of emergency airway interventions for trauma patients. It suggests there is further evidence of an unmet demand in the provision of early advanced airway management for major trauma patients. Around 15% of patients with significant trauma require urgent advanced

airway management either in the pre-hospital setting or in the ED. In keeping with UK major trauma patients as a whole, those identified as having urgent airway interventions were mostly male with blunt trauma. There was also a significant proportion of elderly patients and falls of less than two metres. The frequency of paediatric airway management was low; of the 4,403 paediatric patients in the study, only 9.1% received airway interventions and 7.3% were intubated. This figure is comparable to previous database analyses, which report rates between 5% and 9% for paediatric intubation.(118,119) The AIS classification was used to report type of injury sustained, and the most severely injured body region was reported in the data. Over 30% of all included patients sustained significant limb trauma, 25% had head injuries and 16% sustained chest injuries.

Overall, 10,264 patients required intubation; nearly half of these patients received pre-hospital intubation and of these, 5889 patients (57%) were intubated in the ED. Over 70% of patients intubated in the ED required intubation within 30 minutes of hospital admission, and over 85% of patients were intubated within one hour of arrival.

There was a significant difference in outcome between the three intubation groups; those who underwent PHI, those who underwent EDI, and those who received non-intubation airway interventions in the pre-hospital setting and then subsequent EDI. Overall, all patient groups who required emergency intubation had high mortality (28.1%), which is likely to reflect the fact that patients who have indications for emergency airway intervention often have severe injuries; the mean ISS for this patient group was 30.9. Patients who were intubated in the ED but had not received other early airway interventions had the lowest mortality (21.3%). Pre-hospital intubation was associated with a significantly higher mortality (33.7%), $p<0.0001$. Patients who had ED intubation after pre-hospital airway interventions had the highest mortality (50.6%), and the odds of dying were significantly higher for this patient group when compared with patients who underwent pre-hospital intubation and compared with those patients who underwent ED intubation but did not receive pre-hospital non-intubation airway interventions ($p<0.0001$ for both groups). It is likely that many of the patients who had non-intubation airway interventions before arrival in hospital would have met the criteria for pre-hospital anaesthesia and intubation had it been

available. In total, 39.2% of patients who were unconscious on hospital arrival required intubation in ED, again suggesting that they would have met the criteria for anaesthesia and intubation prior to arriving at hospital. This finding, and the high requirement for intubation within 30 minutes of ED arrival, support the role of pre-hospital intubation. Where intubation is available, it is the sickest patients that are intubated earlier, in the pre-hospital phase. This is borne out by the difference in the ISS and probability of survival (PS14) between the three groups of patients reported in this study. Although survival is greatest after ED intubation, the significantly worse mortality for those patients who require ED intubation after non-intubation airway interventions in the pre-hospital setting, strongly suggests there is a group of patients who require emergency intubation at the earliest opportunity. It is probable that, with increasing provision of enhanced pre-hospital care in the UK, a higher proportion of critically ill patients reaching hospital alive rather than having resuscitation efforts terminated in the pre-hospital setting. A meta-analysis published in 2017 by Fevang demonstrated a higher mortality rate in patients undergoing intubation in the prehospital setting compared with those patients intubated in the Emergency Department (ED) (48% vs 29%). It was suggested that this might be because physicians in pre-hospital critical care may choose to anaesthetise more severely injured patients with less chance of survival over less injured patients but there were many confounding factors – the use of drugs for anaesthesia varied significantly, Injury Severity Score (ISS) was different between the groups and the level of provider performing PHEA also varied significantly. When subgroup analysis was performed which adjusted for ISS, GCS, or level of provider the results did not show a significant difference in mortality rates between intubation performed in the pre-hospital setting or in ED.(103)

Guidelines for emergency tracheal intubations suggest that patients with a GCS less than 9 should be intubated urgently; (38,95) 44% of patients in this study who met these recommended criteria for emergency intubation were not intubated until hospital arrival. A proportion of these patients had airway compromise identified in the pre-hospital setting and interventions performed in an attempt to improve the compromise. These findings further support the hypothesis that there are a group of patients who may have met the indications for urgent airway intervention in the pre-

hospital phase of care but did not receive intubation until arrival in the emergency department.

Comparing the data in this study to US data, significantly more UK patients received urgent intubation, 13.9% compared with 9.9%, ($p < 0.0001$). Whilst the proportion of patients requiring urgent airway intervention in the ED is lower in the US-based study this is likely to reflect the different pre-hospital infrastructure and case mix. Penetrating trauma is more common in the US and accounts for up to 60% of the national trauma burden (120), compared with a peak of 20% in the UK.(121) It is also possible that developments in UK trauma systems have improved patient management in the early phase of in-hospital treatment and trauma teams are more cohesive enabling faster delivery of the required interventions. Early intubation of compromised trauma patients is now accepted practice by the National Institute for Health and Care Excellence (NICE); recent guidelines suggest that definitive airway control should be provided within 45 minutes of the incident occurring and preferably on scene before departure to hospital.(117)

The level of available pre-hospital airway intervention provided in the UK is inconsistent, this is in part, due to variations in the skill mix and training of attending pre-hospital personnel. Unconsciousness is a standard indication for pre-hospital emergency anaesthesia when it is available. (95) It is likely that many patients in this study with a pre-hospital GCS < 9 were managed by pre-hospital personnel who did not have the necessary skillset to perform pre-hospital emergency anaesthesia and tracheal intubation. Whilst there are increasing numbers of physicians participating in pre-hospital care, particularly since the recognition of PHEM as a subspecialty, the majority of trauma patients in the UK are attended by paramedics without PHI capability. Despite this, relatively few patients included in this study were managed with a pre-hospital supraglottic airway device.

Whilst this study, and others (103), demonstrate a higher mortality rate in PHI when compared to EDI, this is likely to be due to the fact that where PHEA is available consistently on scene, sicker patients receive it in the pre-hospital setting. The patients undergoing PHI in this study had a higher ISS and lower PS14 compared with the group

intubated in ED. PS14 is the more relevant measure here as it takes into account the physiology of the patient rather than just anatomical areas that are injured. The data presented here suggest a benefit in early pre-hospital intervention – patients who required airway interventions on scene but had to wait for intubation until arrival in the ED had a significantly worse mortality than those intubated on scene. This supports the hypothesis that there is a significant unmet demand in advanced airway management the early phases of care. Over 70% of ED intubations occur within 30 minutes of arrival in the emergency department and although we cannot establish the exact proportion that require urgent intervention, a significant proportion are unconscious and previous work confirms that many are likely to have met the criteria for intubation in the pre-hospital phase and so are likely to represent unmet demand. The data suggest that, where indicated and where possible, tracheal intubation should be delivered at the earliest opportunity. Patients who require airway support in the pre-hospital setting but do not receive definitive airway management until hospital arrival are associated with a lower probability of survival, higher mortality and worse outcome. The significantly increased mortality of patients who had airway interventions but do not undergo pre-hospital intubation compared with those that are intubated in the pre-hospital phase may indicate a benefit of intubation in the early phases of care. A prospective study comparing systems with and without PHEA capability would provide a definitive answer to this question.

2.2.4 Limitations

The study is limited by missing data and the recording of similar data in more than one area of the dataset which occasionally leads to difficulty in data interpretation. Descriptions of airway interventions were not always consistent throughout the dataset. The data obtained was from Major Trauma Centres only and did not include Trauma Unit data, due to the substantially higher the data quality and completeness in the former. A further limitation is that patients who die in the pre-hospital phase are not included in the dataset. The study was unable to completely remove confounding factors from the analysis, and patient demographics, mechanism/type/severity (ISS) of injury, and physiological variables, differed substantially. Indications for intubation were not reported and it is unclear what proportion of 'urgent' intubations in the emergency department (within 30 minutes) could have safely been delayed, albeit that

the large proportion who were unconscious suggests that many were urgent. It is possible that a proportion of the anaesthetics performed in ED are for non-life-threatening injuries that subsequently go straight to theatre, or for humanitarian reasons in less severely injured patients.

Chapter 3: Is current practice safe?

Patient safety remains a priority at all times, for any given intervention. With my data having suggested a possible requirement and unmet demand for PHEA, I now set out to establish whether current practice is safe. As previously discussed in the first chapter, the evidence base contains many studies with conflicting results. As with the majority of medical practice, it is likely that interventions performed within a well-developed pre-hospital system subject to robust clinical governance and regular reviews of clinical practice produce better outcomes than those lacking this important infrastructure.

3.1 How is PHEA conducted within the trauma service?

Having conducted two studies that suggested a requirement for PHEA I developed another study to establish a benchmark for current practice, I conducted a retrospective review of the database of the pre-hospital physician-led trauma service described in Chapter 1 to review the performance and success of PHEA within the service. Twenty-five years of data were analysed to identify all patients who underwent PHEA. The primary outcome measures of the study were the intubation success rate for the trauma service. Secondary outcome measures included the frequency and management of failed intubation, and the rates of failed intubation between the two main groups of physician providers within the system, anaesthetists and non-anaesthetists. Intubation success rate was used as a quality indicator to establish how the care provided by this doctor-paramedic team compares with existing physician data. Information was gathered to assess whether the PHEA strategy was working within the service. Whilst this is a dynamic process and continually evolving, the core principles remain the same, with emphasis being placed on patient safety, teamwork, sound decision making, doing the basics well, attention to detail and robust governance.

3.1.1 Study design

A retrospective database review of the trauma service database (described in Chapter 1) was conducted to identify all patients attended by the physician-paramedic team between 1st September 1991 and 31st December 2012 who received pre-hospital advanced airway management. Advanced airway management is defined as tracheal intubation or insertion of a supraglottic airway device. Those patients who had mechanisms of injury which included drowning, hanging, traumatic asphyxia and inhalational injury were included; there were no exclusion criteria. The type of airway intervention the patients received (intubation, supraglottic airway insertion, or emergency cricothyroidotomy) was recorded. In addition, the numbers of successful intubations, and the success and type of rescue techniques performed by the physician-led pre-hospital trauma service were also recorded. Emergency cricothyroidotomy was performed either as primary airway management in certain circumstances, or as a rescue technique following failed intubation. The decision of when to perform an emergency cricothyroidotomy and when to use a supraglottic airway device for rescue of failed intubation is a clinical decision made by the attending physician.

For the attending physician performing the intubation, the primary speciality of the attending physician (anaesthesia and non-anaesthesia) and individual intubation success rates were collected. The majority of non-anaesthetists participating in this study were emergency physicians.

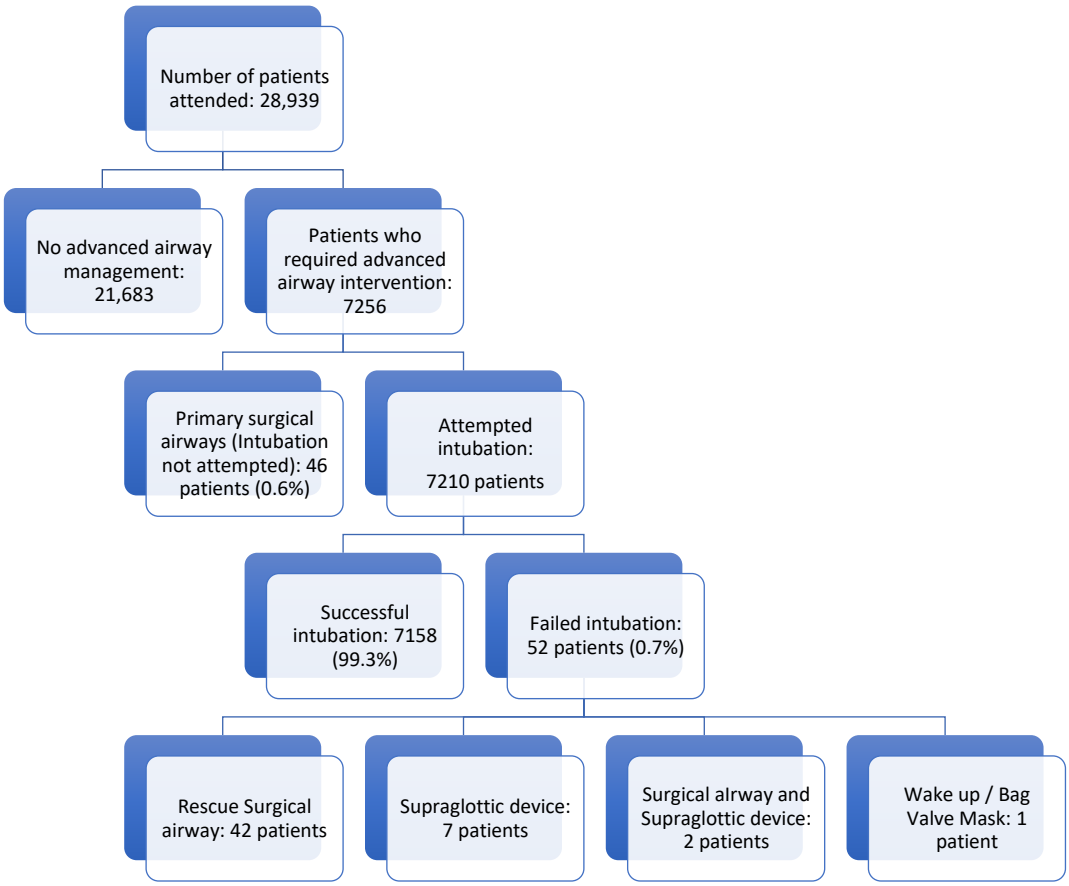
The study setting is described in detail in Chapter 1; the database used for this study was the trauma service database previously described. Data analysis was performed using simple descriptive statistics with Microsoft Excel™ 2011 and GraphPad ™. The Chi squared test was used to calculate the statistical significance of proportions and statistical significance was set at $p< 0.05$.

3.1.2 Results

During the study period, the enhanced care physician-paramedic team attended 28,939 trauma patients. Of these, 7256 (25.1%) received advanced airway management. Forty-six patients (0.6%) had an immediate surgical airway performed without any attempts made to perform laryngoscopically-guided tracheal intubation.

For the remaining 7210 patients, laryngoscopy and intubation was attempted, and was successful in 7158 (99.3% of these). Failed intubation occurred in fifty-two of 7256 patients (0.7%) . In these patients, a surgical airway was performed in 42 patients, and a supraglottic device was inserted in seven. In two patients, a supraglottic device was initially inserted but a surgical airway was performed prior to transfer to hospital. One patient underwent attempts at intubation but could not be intubated and was allowed to spontaneously breathe with support provided by bag-valve-mask ventilation during transfer to hospital, (figure 3.1). All surgical airways (primary and rescue) were successful.

Figure 3.1: Intubation and airway rescue success of physicians



The mechanisms of injury for 90 patients who underwent an emergency cricothyroidotomy are shown in table 3.1. Overall there were 18 survivors (20%) in this patient group; outcome data were unavailable for one patient. Ten of 46 patients who underwent a primary surgical airway survived (22%) compared to eight of 44 patients who received a rescue surgical airway (18%), (p = 0.797). Twenty-nine patients were in traumatic cardiac arrest at the time of having a surgical airway; all died.

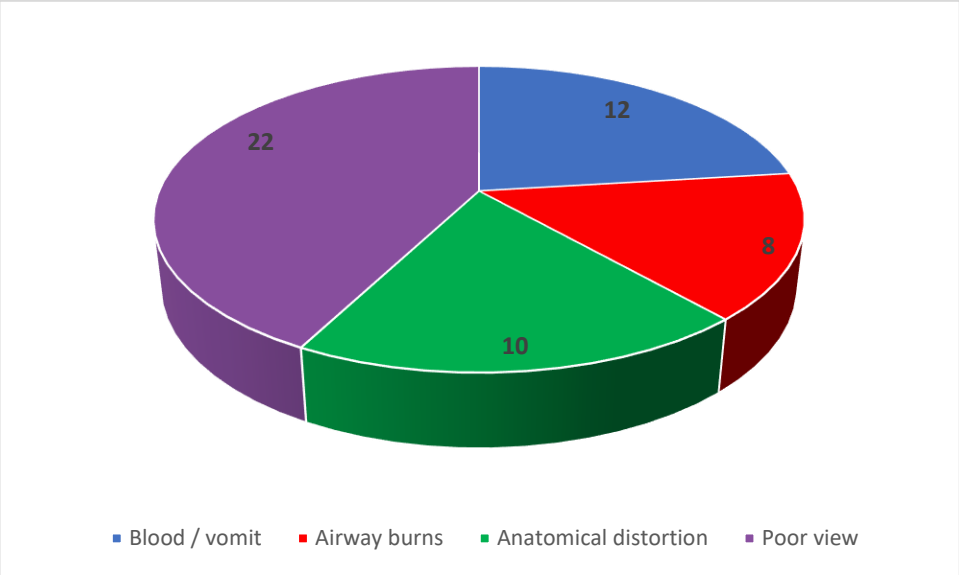
Table 3.1: Mechanism of injury for patients requiring a surgical airway

Mechanism of injury	Number of patients, n (%)	Primary procedure, n	Rescue procedure, n
Burns	21 (23.3)	9	12
Road Traffic Collision	28 (31.1)	17	11
Hanging	8 (8.9)	2	6
Blunt head / facial trauma	8 (8.9)	1	7
Fall from height	6 (6.7)	3	3
Fall under train	3 (3.3)	3	0
Multiple injuries	9 (10.0)	6	3
Penetrating	7 (7.8)	5	2
Total	**90 (100)**	**46**	**44**

The specialty of the intubating doctor was available for 7033 attempted intubations. The rate of failed intubations for non-anaesthetists was 0.9% (41 of 4394 attempted intubations). Anaesthetists attempted 2587 intubations patients and failed in 11 patients (0.4%) (p= 0.02). Of the 186 doctors who participated in the study, 41 (22%) had at least one failed intubation; 145 (78%) had no failed intubations. Nine of 41 doctors had failed intubation in more than one patient. When calculating the number of failed intubations as a proportion of the total intubations attempted by individual

doctors, the mean failure rate was 3.3% for the 41 doctors with recorded failed intubations: 6 had failure rates of > 5% and one of > 10%, compared with 0.7% for the whole cohort. The main reasons cited for failure were airway burns, poor view or grade at laryngoscopy, anatomical distortion, or airway soiling secondary to blood or vomit, figure 3.2.

Figure 3.2: Reasons for failed intubation



3.1.3 Discussion

This study was one of the largest series of physician-led PHEA and reported an overall intubation success rate (99.3%) which is similar to other smaller series where the pooled median intubation success rate is over 99%.(58,115) Surgical and supraglottic airways were, when attempted, always successful.

A significantly higher rate of failed intubation was reported for non-anaesthetists, who were twice as likely to have to perform a rescue airway intervention. This finding was expected, and can be used to facilitate training and service development. It highlights the fact that anaesthetists are more familiar with intubation techniques including difficult or failed intubation management, including techniques such as external laryngeal manipulation. Whilst most doctors have no failed intubations, early

identification of 'outliers' may be useful to target training through early focussed teaching and assessment.

Whilst uncommon, emergency cricothyroidotomy is an essential skill in the management of the difficult airway. Use of an emergency cricothyroidotomy varies between services and providers, but an incidence of up to 18% has been reported, with non-physicians tending to perform them more frequently than physicians with an incidence of 8.0% (median, range 0.5% - 18.2%) in reported case series (122-125) (126-129) (130,131) and 3.1% (range 0.1% - 7.7%) respectively (132-135). Those services which do not incorporate neuromuscular blocking agents into their PHEA protocol have a higher incidence of surgical airways as a direct consequence of more failed intubations. (58,127) A standard surgical technique is now widely acknowledged to be more successful than a needle technique (87) and the most major emergency airway guidelines no longer suggest needle cricothyroidotomy. (81,86,95)

Studies that describe case series of surgical airways performed in real patients are infrequent, the majority being mannequin-based studies. The case series described here is one of the largest to date. The data were gathered over a 25-year period, so the relatively high surgical airway rate can be explained in part by the fact that supraglottic airway devices did not achieve popularity as rescue airway devices until relatively recently. The majority of surgical airways were performed for entrapment, severe burns, or head and neck trauma. A high proportion of patients in whom surgical airways were performed the attending clinician had documented severe injuries and this is reflected in the very high mortality rate.

3.1.4 Limitations

One of the major problems with this study was data extraction. The inputting of data into the database is dependent on the attending physician and in some instances is incomplete. Despite this, I was able to perform the study that I set out to perform though having more detailed information about the PHEA process would have been beneficial to the study.

3.2 Which patients should receive PHEA?

One of the major modifiable factors influencing the outcome of PHEA is selection of the correct patients. There are circumstances in which early intubation may not be in the patient's best interests. I designed and conducted a retrospective database review to identify specific patient groups in whom PHEA may be detrimental. The study focused on awake hypotensive major trauma patients. The high GCS used to select out this patient group (GCS 13-15) demonstrates the absence of major neurological injury. The hypothesis for the study was that if the hypotension was secondary to hypovolaemia then induction of anaesthesia may precipitate cardiovascular collapse. If this occurs outside hospital following major trauma, the lack of access to the full range of resuscitation techniques and surgical interventions is likely to result in higher mortality than if anaesthesia is delayed until hospital arrival. It is possible, in this patient group that the risks of PHEA outweigh the benefits and induction of anaesthesia should be delayed until hospital arrival, particularly if anaesthesia is being provided for the more subjective and less clear indications including humanitarian considerations, to reduce the length of the time to definitive intervention, or for the predicted clinical course.

In general, the incidence of hypotension associated with PHEA in both trauma and non-trauma patients, is more than 7%.(136) Whilst cardiovascular compromise post induction of anaesthesia is likely to be multifactorial, patients who are hypotensive prior to induction of anaesthesia are at increased risk of cardiovascular demise post induction. Where reported, pre-intubation hypotension, (defined as a systolic blood pressure < 90 mmHg) is associated with a statistically significant increase in the number of episodes of post-intubation cardiac arrest. (137) Anaesthetic agents impair sympathetic innervation and cause vasodilatation to varying degrees. Ketamine is considered to be more cardiovascularly stable than most other induction agents and is usually the drug of choice in severely injured patients. In addition, decreased venous return that occurs either as a consequence of the implementation of positive pressure ventilation or ongoing bleeding which has not been controlled, contribute to hypotension and cardiovascular instability post induction.

3.2.1 Study design

The trauma service database was interrogated from September 1st 2009 to August 31st 2014 to identify trauma patients with an initial non-invasive systolic blood pressure (SBP) 90 mmHg or less and an initial GCS 13-15. Paediatric patients (aged less than 16 years), non-trauma patients (drownings / hangings / burns) and those who were not escorted to hospital by the pre-hospital physician-paramedic team were excluded. The primary outcome measure for the study was mortality (defined as death before hospital discharge).

I hand searched each individual record in the service database that was recorded during the study period to identify patients who met the study criteria above. Data collected for this patient group included initial and final blood pressure, pulse, oxygen saturations, and GCS. Mechanism of injury, PHEA (including drugs and doses administered), use of pre-hospital blood or the requirement for urgent blood transfusion on hospital arrival), and patient outcome were also recorded. All observations (recorded every 30 seconds) are downloaded in numerical format from the patient monitor (Propaq MD™, Zoll, Massachusetts, US) and printed after each mission.

The patient records of all the included patients meeting the initial criteria (initial SBP 90mmHg or less and GCS 13-15 on scene) were further scrutinised to identify patients who had evidence of severe hypovolaemia at scene, rather than the initial hypotension being secondary to other causes including cardiogenic or neurogenic shock, tension pneumothorax or cardiac tamponade. The pre-hospital information was supplemented, where possible, with clinical information from in-hospital records to identify patients with clinical evidence of bleeding or injuries which are likely to cause bleeding. The presence of severe hypovolaemia was further based on the presence of factors described below.

- Pre-hospital clinical observations (blood pressure, heart rate and oxygen saturations) recorded on arrival at the patient, and on arrival of the patient at hospital

- Pre-hospital request for urgent blood on arrival at hospital or the need for an urgent blood transfusion on hospital arrival
- Use of reduced dose of anaesthetic agents or analgesia because of suspected hypovolaemia
- Suspected and confirmed injuries
- Documented suspected hypovolaemia
- Radiology reports
- Operative findings

In order to reduce error in the study, the records identified were reviewed by a second clinician to confirm patients with severe hypovolaemia. If a difference in opinion was encountered, a third clinician was asked to confirm the findings.

When reviewing the database to identify the study group, it became apparent that some patients did not have documented values for initial blood pressure and only the presence or absence of a radial or central pulse was recorded. Those patients who only had documentation of a central pulse were included in the study. If the term 'radial pulse' was used in the database instead of a numerical value, the free text recorded by the attending clinician at the time was examined to provide further information. If the patient was reported to have a good / strong radial pulse, this was estimated to represent an SBP>90 mmHg and subsequently excluded. Where the terms, weak / absent radial pulse were used, this was taken to represent an SBP<90 mmHg. An absent radial pulse was assumed to be an SBP<80 mmHg in accordance with previously published studies. (138,139) The inclusion or exclusion of patients was performed using the clinical information provided. In order to reduce the risk of bias in this patient group, subgroup analysis was performed excluding all patients with no numerical value for blood pressure.

In order to address the primary objective of the study the patient group was divided into two subgroups, those who underwent PHEA by the physician-paramedic team and those who were not anaesthetised until after arrival in hospital (no PHEA). When performed, PHEA was delivered in accordance with the local service standard operating procedure (SOP). The PHEA technique is standardised and designed to be

deliberately simple and reproducible to reduce human error, with emphasis placed on achieving a high first pass success rate and cardiovascular stability throughout. Patients with suspected or confirmed hypovolaemia receive reduced induction doses and in some cases the opioid is omitted altogether. The PHEA SOP was revised during the study. Regular SOP review is carried out within the trauma service as part of a clinical governance system. The original SOP was written in 1996 and included the use of etomidate as an induction agent, morphine as the opiate of choice and suxamethonium for muscle relaxation. The revision document released in 2012 included ketamine for induction, rocuronium for muscle relaxation and fentanyl. The indications for PHEA are described in Chapter 1.

Statistical significance was defined as $p<0.05$. Statistical tests for categorical variables were used to analyse the data. Fishers exact test was used to calculate statistical significance of proportions. Exact logistic regression analysis was used to assess the univariate association between mortality and hypovolaemia and PHEA and to obtain univariate odds ratios (OR). For multivariable models the penalized maximum likelihood estimation (Firth) method was used to compensate for small sample bias. Age, initial heart rate and mechanism of injury were selected for multivariate models as these variables would be readily available to all clinicians on scene making the decision as to whether or not to perform PHEA. The models were fitted in all patients and in PHEA subgroups. Differences in the odds ratio by PHEA was tested by including an interaction term in the model for all patients.

3.2.2 Results

In total, 9480 patients were attended by the physician-paramedic team in the study period; 265 patients (2.8%) met the study criteria and were included. Of these, 118 patients (44%) underwent PHEA; and 147 patients (56%) were managed without PHEA. Eight patients with burns and two patients with a suspected medical event preceding traumatic injury were excluded from final analysis. Outcome data was unavailable for 19 (7%) patients; 236 patients were included in the final data analysis. The majority of patients in this study population were victims of penetrating trauma. The injury mechanism and patient demographics are described in table 3.2.

Table 3.2: Demographics of study patients

	Group 1 (No PHEA)	Group 2 (PHEA)	P value
Number of patients	135	101	
Penetrating trauma	81 (60.0%)	19 (18.8%)	p<0.001
Blunt trauma	54 (40.0%)	82 (81.2%)	
Age **Median (IQR)**	25 (20-42)	31(23.5-43)	0.005
Initial SBP **Median (IQR)**	81 (76-86)	76 (65-85)	0.01
Initial HR **Median (IQR)**	90 (80-107)	114 (94-130)	p<0.001
Initial GCS			
13	7 (5.2)	25 (24.8)	p<0.001
14	38 (28.2)	37 (36.6)	
15	90 (66.7)	39 (38.6)	
Hypovolaemia **N (%) yes**	69 (51.1)	58 (57.4)	0.34

Outcome

Twenty-one of 236 study patients died (8.9%). Using the criteria described, 127 of 236 patients had evidence of severe hypovolaemia. The remaining 109 patients were presumed to have mild to moderate hypovolaemia, or hypotension secondary to other causes such as neurogenic or cardiogenic shock, or tension pneumothorax. Eighteen of 127 severely hypovolaemic patients died (14.2%) compared with three patients (2.8%) in the group of patients presumed to have mild to moderate hypovolaemia, or hypotension secondary to other causes, (p=0.003), figure 1. The unadjusted OR for death using the exact logistic regression model was 5.80 (1.62-31.62; p=0.003). This association remained after adjustment for age, mechanism of injury, heart rate and PHEA (adjusted OR 5.93 (1.74-20.23) p=0.004, table 3.3).

Table 3.3: Multivariable logistic regression model for mortality in all patients

Variable	Effect	Odds Ratio (95% CI)	P value
Age	Per 10-year increase	1.15 (0.89-1.50)	0.29
Mechanism of Injury	Penetrating : Blunt	0.55 (0.17-1.78)	0.32
Initial heart rate	Per 1 standard deviation (SD) increase	0.79 (0.49-1.27)	0.32
Severe hypovolaemia	Yes: No	5.93 (1.74-20.23)	0.004
Intubated	Yes: No	3.07 (1.03-9.14)	0.04

PHEA was associated with a statistically significant increase in mortality for all patients. One hundred and one patients underwent PHEA and of these, 15 died (14.9%). In the group of 135 patients anaesthetised after arrival in hospital, six died (4.4%). The unadjusted OR for death using the exact logistic regression model was 3.73 (1.30-12.21; p=0.01). This association remained after adjustment for age, mechanism of injury, heart rate and hypovolaemia (adjusted OR 3.07 (1.03-9.14) p=0.04, table 2). There were no deaths due to failed intubation. Further analysis of the cause of death for each patient that died showed in all cases except one the death was attributable to hypovolaemia. One patient who did not undergo PHEA was subsequently found to have a cardiac tamponade following a stabbing injury.

Hypovolaemic trauma patients undergoing PHEA

Of the 101 patients anaesthetised on scene, 58 patients (57.4%) were considered to be severely hypovolaemic prior to induction of anaesthesia, of these 14 died (24%). Of the remaining 43 patients (42.6%) intubated on scene, one patient died (2%). The unadjusted OR for hypovolaemia was 13.12 (1.84-578.21). After adjustment for age, mechanism of injury and initial heart rate, the OR for mortality remained significant at 9.99 (95% CI 1.69-58.98; p=0.01), table 3.4.

Table 3.4: Multivariable logistic regression model for mortality in PHEA patients

Variable	Effect	Odds Ratio (95% CI)	P value
Age	Per 10-year increase	1.21 (0.87-1.68)	0.26
Mechanism of injury	Penetrating : Blunt	1.38 (0.33-5.70)	0.66
Initial heart rate	Per 1 SD increase	0.71 (0.42-1.18)	0.18
Severe hypovolaemia	Yes: No	9.99 (1.69-58.98)	0.01

There was no statistically significant difference in mortality demonstrated between hypotensive patients with and without additional evidence of severe hypovolaemia who did not undergo PHEA. In this subgroup of 135 patients who were anaesthetised after hospital arrival, 69 (51.1%) were considered to have severe hypovolaemia, 4 (5.8%) died, compared with 66 patients (48.9%) without evidence of severe hypovolaemia, of whom two (3.0%) died, p=0.681. The adjusted OR was 1.94 (0.37-10.08) p=0.43.

Subgroup analysis

Subgroup analysis was performed to reduce the risk of bias by including patients who did not have an initial SBP recorded in a numerical format but did have evidence of severe hypovolaemia. Of the 236 patients included in the study, 152 (64.4%) had a numerical value for the systolic blood pressure documented on arrival of the attending clinical team. In the remaining 84 patients, the initial blood pressure was recorded as radial, central, or unrecordable. Of the 152 patients with a numerical value for initial systolic blood pressure, 46 patients were in the PHEA group (30.3%) and 106 patients were in the non-PHEA group (69.7%). The mortality rates for these subgroups are reported in table 3.5 below.

Table 3.5: Comparison of mortality rate for study patients with a documented numerical value for initial systolic blood pressure

	Survivors	Non survivors	Total	Mortality (%)
PHEA	40	6	46	13.0
No PHEA	103	3	106	2.8
				P = 0.02

PHEA protocol

Sixty of 101 patients (59.4%) were intubated prior to the change of PHEA protocol, compared with 41 patients (40.6%) who were intubated using the revised drug protocol. Eleven of the 60 patients (18%) intubated before the change in protocol died, compared with 4 of 41 (10%) patients intubated following the change, p = 0.2693. Ninety of the 101 PHEA patients received an opioid. Of these, 49 of 58 (84%) patients who were considered to be severely hypovolaemic were given an opioid during their clinical course compared with 40 of 43 (93%) patients not considered to have severe hypovolaemia. Of the patients that died, 14 were considered to be severely hypovolaemic; 11 of these patients received an opioid. The single patient who died in the group of patients presumed not to be severely hypovolaemic also received an opioid but there was no significant difference in mortality identified that was attributable to opioid use, p = 0.3803.

3.2.3 Discussion

This study supports the hypothesis that where patients are hypovolaemic and awake on scene it might be appropriate to delay induction of anaesthesia until arrival at a major trauma centre. The results demonstrate a statistically significant three-fold increase in mortality for trauma patients who are initially hypotensive on scene and undergo PHEA, unadjusted OR 3.73 (1.30-12.21; p=0.01). This association remained after adjustment for age, mechanism of injury, heart rate and hypovolaemia (adjusted OR 3.07 (1.03-9.14) p=0.04. Patients with severe hypovolaemia who underwent PHEA had a ten-fold increase in mortality risk, p=0.004, OR 9.99 (95% CI 1.69-58.98; p=0.01), adjusted for age, mechanism of injury and initial heart rate. Significant haemorrhage was considered to be the cause of death in all but one patient who died, supporting the hypothesis that PHEA is associated with a higher mortality in hypovolaemic

patients. These findings are consistent with other published data on this topic. (140) No association could be found between outcome and the change in drug protocol.

The immediate interventions required for each patient, including emergency anaesthesia, are made on an individual patient basis by experienced pre-hospital clinicians, with adherence to SOPs developed by the service. There is significant emphasis placed on performing only urgent interventions on scene to reduce unnecessary delay in transfer of the patient to hospital.

Indications for PHEA

The indications for PHEA in trauma patients are often straightforward. Deeply unconscious patients or those with airway or ventilatory failure are obvious candidates for PHEA as soon as it is available. There are however some patients in whom the indications and timing of PHEA are less straightforward, including hypovolaemic trauma patients with high GCS. The majority of these patients will require surgery or interventional radiology to control bleeding and most will be anaesthetised in the emergency department or operating theatre. Emergency anaesthesia performed in-hospital for patients with cardiovascular compromise is often delayed until the patient is in theatre and the surgeon is ready to proceed. (141)

Haemodynamic effect of PHEA

There are potential advantages and disadvantages to PHEA in conscious hypovolaemic patients. Although PHEA inevitably increases scene time, it may improve the ease and speed of passage to the operating theatre, reducing the time spent in the emergency department. Disadvantages to PHEA are mostly related to alterations in patient physiology. Cardiovascular compromise or collapse following induction of anaesthesia is a major concern in hypovolaemic patients. Patients with significant haemodynamic instability rely on high endogenous sympathetic tone to maintain systemic vascular resistance and cardiac output. Drug choice in these patients is critical; ketamine is often considered to be the induction agent of choice in this setting. It acts as a sympathomimetic, increasing circulating catecholamines causing direct cardiac stimulation and peripheral vasoconstriction, with preservation of the baroreceptor reflex. The consequences of these effects are observed as an increase in mean arterial

pressure (MAP), pulmonary arterial pressure, heart rate, and cardiac output. (142) A 10% increase in MAP is reported in emergency surgical patients. (106) Other induction agents often cause a fall in cardiac output and MAP. Thiopentone is associated with negative inotropy, arteriolar vasodilatation and obtunded baroreceptor reflexes. (143) Propofol causes hypotension through reduced systemic vascular resistance and myocardial depression. (142) The use of propofol as an induction agent has a statistically significant association with early post-induction hypotension (in the first 10 minutes post-induction). (144) Animal data suggest significantly increased blood loss at specific time points post injury in swine anaesthetised with propofol compared with those managed via face-mask ventilation, without intubation. (145) Etomidate does not demonstrate the same degree of cardiovascular instability but adverse effects on the adrenal axis have limited its popularity. (146,147)

Opioids are administered particularly in patients where the hypertensive response to laryngoscopy is likely to be detrimental. They can result in reduction of sympathetic tone and contribute to post-induction hypotension. (56) Severe hypovolaemia secondary to haemorrhagic shock results in significant alterations in fentanyl pharmacokinetics showing reduced central clearance and volume of distribution when compared with control subjects. (148) Low protein binding, which may occur in hypovolaemic patients, particularly following crystalloid resuscitation, increases the drug free fraction and results in higher effector site concentration. This may worsen the adverse haemodynamic effects of the drug. (106,144)

There are predictable patterns of ventilation and perfusion observed in anaesthetized, ventilated patients. Perfusion increases from superior to inferior parts of the lungs with some reduction in blood flow in the most inferior parts secondary to atelectasis. Ventilation tends to be greatest in the superior lung and reduced inferiorly. Implementation of positive pressure ventilation in hypovolaemic patients results in reduced venous return (149) which may precipitate cardiac arrest in compromised patients. The application of positive end-expiratory pressure redistributes blood flow to dependent parts of the lungs, usually dorsal in supine anaesthetised patients and may worsen shunting due to limited ventilation, and increase dead space in non-dependent parts of the lung, (150) which may worsen gas exchange. Ventilation

strategies to minimize rises in intrathoracic pressure during ventilation might reduce the frequency and degree of post induction hypotension / cardiovascular collapse. Muscle relaxants and mechanical ventilation decrease the work of ventilation which may be beneficial in hypoxic patients.

Other factors influencing outcome after PHEA

One major factor affecting outcome from PHEA is the incidence of failed intubation. There were no failed intubations included in this study and the service has previously reported high intubation success rates of 99.3%.(98)

Significant hypothermia is more frequent in anaesthetised patients and may increase bleeding. Previous data from this service demonstrated significantly lower body temperatures at hospital admission in PHEA patients, (80) which has been shown to correlate with increased mortality. (151)

Few studies focus on the outcome of patients who are hypotensive and hypovolaemic prior to induction of anaesthesia. This study found that 2.8% of patients attended were significantly hypotensive prior to induction of anaesthesia. Patients considered to be hypovolaemic secondary to major haemorrhage have a 'care bundle' of interventions carried out on scene including careful handling to minimise clot disruption, use of splints, tourniquets and haemostatic agents to control external haemorrhage, administration of tranexamic acid, pre-hospital activation of massive haemorrhage protocols and administration of on-scene packed red cells. More radical resuscitation interventions, such as pre-hospital thoracotomy for cardiac tamponade and resuscitative endovascular balloon occlusion of the aorta are also considered where indicated. (152) A proportion of patients in this study were attended before this service carried packed red cells. This treatment option was introduced in 2012. (153) It may be that the potential detrimental effects of PHEA in hypovolaemic patients could be mitigated by peri-induction blood transfusion, and this is commenced where time permits. Studies to examine the effects of blood transfusion in our service are in progress.

Prior to providing blood on scene, the concept of declaring a 'Code Red' pre-alert to the hospital receiving the trauma patient, was introduced in 2009. The strategy was

designed to permit early activation of hospital major haemorrhage protocols so packed red cells and other blood products were available for patients when on arrival. It has been shown to improve delivery of blood products and reduce waste. (154) Code red is based on pre-hospital clinical assessment and declared if there is suspected active haemorrhage and a systolic blood pressure < 90 mmHg. (153) The use of pre-hospital blood is associated with an improved rate of return of spontaneous circulation following traumatic cardiac arrest from hypovolaemia but a survival benefit in this service has not been demonstrated to date. (155,156)

Use of novel therapies to reduce the incidence of cardiovascular collapse may be considered in this subgroup of trauma patients. Impedance threshold devices have been shown to augment venous return and improve systolic blood pressure and pulse pressure in animal studies of hypovolaemic shock. (157) Impedance threshold device use is described in spontaneously ventilating pigs and it may be possible to translate this to clinical practice in the pre-hospital setting by using the device in awake hypovolaemic trauma patients to improve haemodynamic stability during transfer to hospital and reduce the need for PHEA in this patient subgroup. Alternatively, if PHEA is required the device may be applied with PPV to support the blood pressure and reduce the incidence of cardiovascular collapse.

This study demonstrates an association between PHEA and mortality in hypotensive trauma patients. The effect on mortality is strengthened when haemodynamic instability is identified by the pre-hospital team as being likely due to significant hypovolaemia. Whilst it is not possible to account for all factors that influence the decision to anaesthetise a patient on scene, the study supports the view that physicians considering PHEA in conscious patients with hypotension secondary to hypovolaemia must be fully conversant with the risks of the procedure and see clear potential benefits in performing PHEA distant from surgical intervention. In these patients, it may be appropriate to delay anaesthesia until arrival at hospital or have in place strategies to reduce the detrimental physiological effects of PHEA. Delay of anaesthesia in spontaneously breathing patients until hospital arrival has not been associated with any increase in mortality. (110)

3.2.4 Limitations

There were a number of difficulties with this study which were predominantly related to the process of retrospectively identifying patients with a systolic blood pressure < 90 if there was no numerical value documented and then subsequently deciding which patients were hypovolaemic and who was hypotensive for other reasons. The study was specifically designed to be pragmatic to address the questions and decisions that pre-hospital personnel encounter in their day-to-day clinical practice. In practice, when the clinician arrives at the patient they make a timely decision about the need for anaesthesia with the limited data available to them; it may be that only one or two blood pressure readings are available. The study is a retrospective database review, restricted to pre-determined registry variables and the absence of a documented numerical value for the initial systolic blood pressure for a proportion of patients reflects the patient population attended by the service. If it is not possible to record the initial blood pressure, use of central and peripheral pulses to estimate volume status is common practice. Where no numerical value was available, patients documented to have a good/strong radial pulse were excluded as this is likely to indicate a higher blood pressure. Patients with a weak or absent radial pulse were included as this likely indicates a lower systolic blood when compared with a normal pulse. One study that examined the use of the radial pulse to estimate systolic blood pressure reported a statistically significant lowering of the mean systolic blood pressure by 28mmHg if the radial pulse was weak on palpation. (158)

Whilst the initial identification of hypotensive patients was objective, subsequent review by the authors to identify hypovolaemia was, in part, subjective, which may cause bias. In order to address this bias, subgroup analysis was performed excluding all patients with no numerical value for blood pressure. In this analysis, the mortality rate in the PHEA patients remained significantly higher; 23.3% mortality for the group of patients undergoing PHEA compared with a mortality of 5% for those patients who were intubated on hospital arrival (p=0.01).

The PHEA SOP was revised during the study. Regular SOP review is carried out within the trauma service as part of a clinical governance system. The relevant major changes were a change in induction agent from etomidate to ketamine and a change in opioid

from morphine to fentanyl. Both ketamine and etomidate are recognised for being cardiovascularly stable (106,142) and therefore the change in induction agent is unlikely to translate into any effect on mortality. Opioids are used at the discretion of the attending clinician and the SOP recommends reducing or excluding the opioid in patients with suspected hypovolaemia.

One further possible limitation is the inability to fully elucidate the role that human factors plays when deciding whether or not to anaesthetise a patient on scene. The decision to perform PHEA is undoubtedly multifactorial and factors such as physician preference, confidence, and decision-making will certainly play a significant role. Other factors such as clinical appearance or agitation indicating more severe hypovolaemia or injury severity will also have contributed. The only way to eliminate these factors would be to randomise patients prospectively with the same key physiology which would likely be considered unethical.

Scene times are not reported in this study. However, the system is subject to rigorous governance and any prolonged scene times are identified and thoroughly investigated. The authors do not believe that prolonged scene times are a contributing factor in patient demise. A recent Japanese study focussing specifically on in-hospital mortality after hypotension on scene following major trauma did not show any significant association between prehospital time and mortality. (159)

3.3 Which providers should deliver PHEA?

Intubation performed outside hospital is associated with a variety of complications including hypoxia, hypotension, tracheal tube misplacement, oesophageal intubation, vomiting and aspiration, cardiac arrhythmia, bleeding and dental damage.(111) Given the complexity of PHEA, it is critical that all factors that may influence intubation success are optimised prior to any intubation attempt. In particular, the procedure must be performed by experienced and competent clinicians who have received training in PHEA. If the personnel attending the patient do not have the skill mix to safely deliver PHEA on scene, then it should not be attempted and the airway should be managed using meticulous basic airway interventions (with or without the use of

supraglottic devices). The patient should be transferred to hospital for definitive airway management.(160) Rapid, uncomplicated and accurate placement of the tracheal tube is one quality indicator of good advanced airway management. Monitoring the success rate of intubation is a factor describing the ability of a system to deliver high-quality airway management.

The delivery of pre-hospital advanced airway management by non-physicians remains a controversial topic. A recent meta-analysis of emergency intubation performed in the pre-hospital setting reported significant differences in the success rates for different healthcare providers with different levels of training. Higher intubation success rates reported for physicians when compared with non-physicians, and for drug-assisted intubation when compared with non drug-assisted intubation; specifically a more traditional rapid sequence intubation approach using an induction agent with or without an opioid, and a neuromuscular blocking drug.(58) Some of these findings are in contradiction to those reported in another meta-analysis published in 2010. (114) Since publication of these two studies, both including data up to 2009, several large studies on pre-hospital advanced airway management have been published, markedly increasing the number of relevant reported interventions.

There is considerable variability in the provision of PHEM and PHEA worldwide. The majority of European countries staff their PHEM teams with senior physicians, many of whom only work within this field and no longer practice medicine in hospital. Outside Europe most PHEM is delivered by non-physicians. Given the wide skill mix delivering PHEM and PHEA, and the recognition that PHEA is a procedure with a high complication rate, I performed this meta-analysis to address the question of who should be performing PHEA and advanced airway management in the pre-hospital setting. It is essential that PHEM services have comprehensive and up to date information to develop infrastructure to ensure patients receive the best possible care that can be delivered prior to arrival at hospital and patient safety is prioritised.

3.3.1 Study design

A systematic search of MEDLINE and EMBASE was performed using PRISMA methodology (Preferred Reporting Items for Systematic Reviews and Meta-

Analyses).(161) The search criteria are described in table 1. All English-language original research articles related to pre-hospital tracheal intubation and PHEA published between January 1st 2006 and December 31st 2016 were identified and reviewed. Studies reporting intubation success rates as the primary outcome met the inclusion criteria and were included in the meta-analysis. The full search strategy is shown below in figure 3.3. The titles and abstracts identified by the initial search strategy were reviewed by one author (KC) to establish eligibility for inclusion. The selected studies were independently reviewed by a second author (MR) to confirm their relevance inclusion. The references of all included studies were hand-searched to identify other studies meeting inclusion criteria. Studies of paediatric tracheal intubation, comparisons of tracheal intubation with other airway devices, and those focusing on surgical airways were excluded from the meta-analysis. Also excluded were non-English studies, and those not written as original research (letters, comments, editorials and case reports). The study was registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (registration number: CRD42015027968)

Figure 3.3: Search strategy

The methodological quality of included studies was assessed using a validated system of internal and external criteria.(162) The data were extracted from all included studies and recorded in a standard Excel spreadsheet (2008 Microsoft Corporation). The following data fields were recorded and reported in the meta-analysis:

- Intubation success rate

- Number of intubation attempts
- Success rate reported by specific patient categories (cardiac arrest, trauma, non-trauma)
- Provider skill level (classified as 'expert' (experienced consultant anaesthetists), intermediate '(physicians in training in emergency medicine and anaesthesia with some anaesthetic experience)', or basic '(non-physicians or those physicians with only limited anaesthetic experience)' skill level).

To allow for comparison with earlier studies, intubation success rates are reported as median (range) unless stated otherwise. The success rates derived from individual studies were presented using a forest plot, and the overall success rate estimated using a random effects meta-analysis for proportions. Following discussion with the statistician involved in the study, I decided that a random effects model would be superior to a fixed effect meta-analysis, which assumes that there is one true effect size underlying all studies in the analysis. The included studies exhibited marked heterogeneity in terms of patients included, provider skill level and delivery of PHEA; consequently, the effect sizes underlying the different studies may be different. The random effects meta-analysis was used to overcome heterogeneity, considering that the true effect could vary from study to study. Further tests for heterogeneity were also performed, using both the I^2 and τ^2 statistics. Weighted univariate regression was used to assess the relationship between the intubation success rate and provider type, with intubation success rate as the dependent variable, and provider type as a dichotomous independent variable, using weights from the random effects meta-analysis. Comparison of PHEA and non-PHEA intubation success rates were performed using a Mann-Whitney U test and random effects meta-analysis. Results from the statistical analyses are presented as mean estimates with 95% confidence intervals (CI). All tests were two-tailed, and statistical significance was set at a p-value of <0.05. The data were analysed using R 3.1. Meta-analysis was performed using package 'meta in R'.(89)

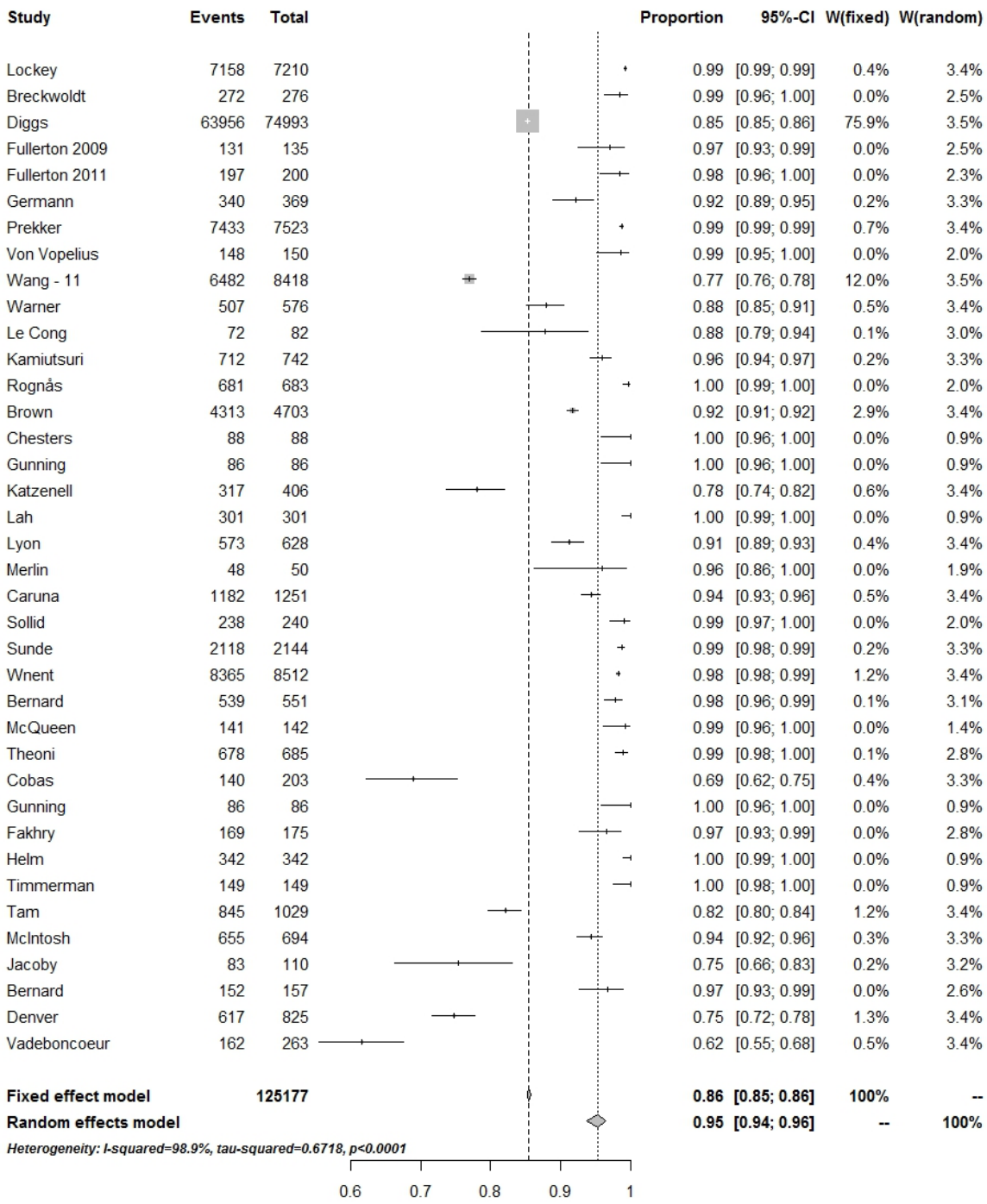
3.3.2 Results

The initial search identified 1838 articles (after application of the search limits described). From these 1838 articles, the full text versions of 128 studies were

accessed and 38 studies were included in the final analysis, which included two studies identified through searching the reference lists of other studies. Twenty-one studies were retrospective and seventeen were prospective. All studies applied observational study design.

Nineteen of the 38 studies included (50%) were conducted within non-physician-led services (paramedic-led or paramedic/nurse-led) and 19 (50%) were studies of physician-led services. In total, 125,177 attempts at tracheal intubation were reported, which included 23,738 intubation attempts by physicians and 101,439 intubation attempts by non-physicians. The crude median (range) overall success rate in the studies was 0.969 (0.615, 1.000). The estimated overall intubation success rate was 0.953 (0.938, 0.965) using random effects meta-analysis, figure 3.4.

Figure 3.4 Estimated overall intubation success rate using random effects meta-analysis



The crude median (range) reported intubation success rates for non-physicians were 0.917 (0.616, 1.000), and for physicians 0.988 (0.781,1.000), p = 0.003. These success

rates were estimated as 0.984 (0.969, 0.992) for physicians using random effects meta-analysis and 0.901 (0.871, 0.925) for non-physicians (figures 3.5 and 3.6). In weighted linear regression analysis, physician-led systems were associated with an increased success rate of 0.097 (0.035, 0.159), p=0.003.

Figure 3.5: Crude median intubation success rates for physicians

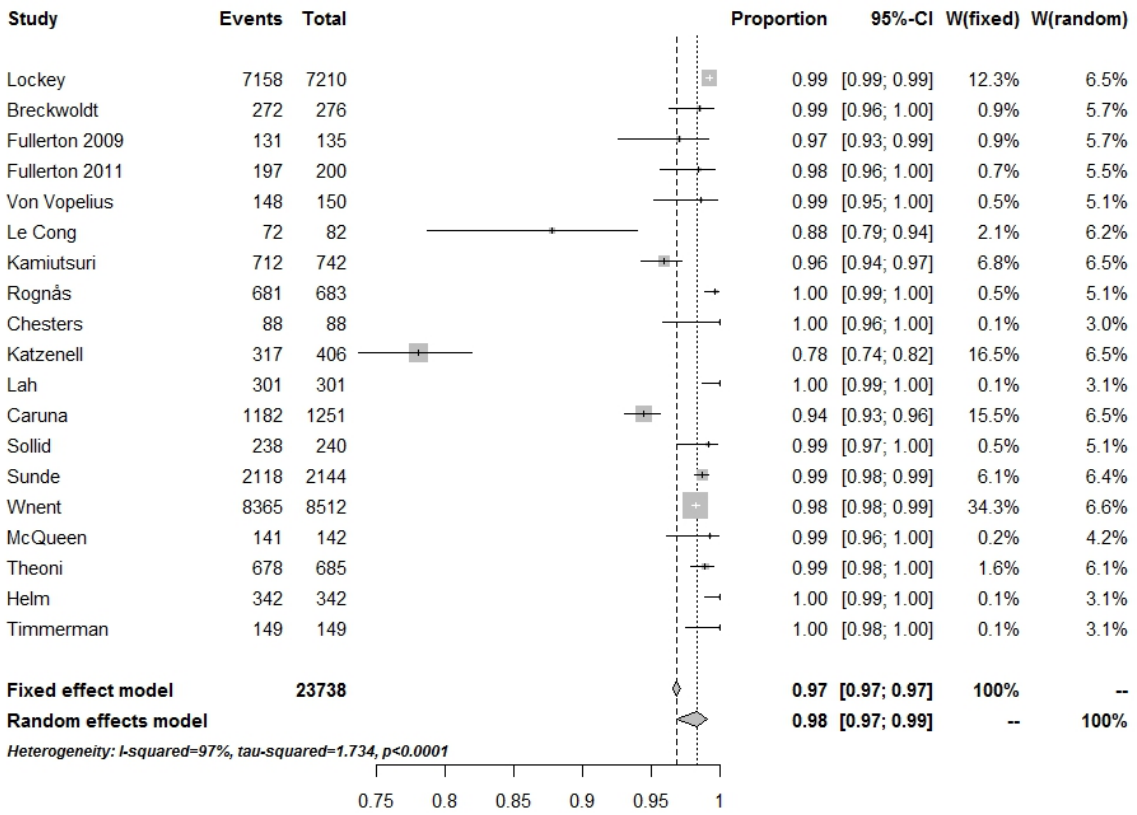
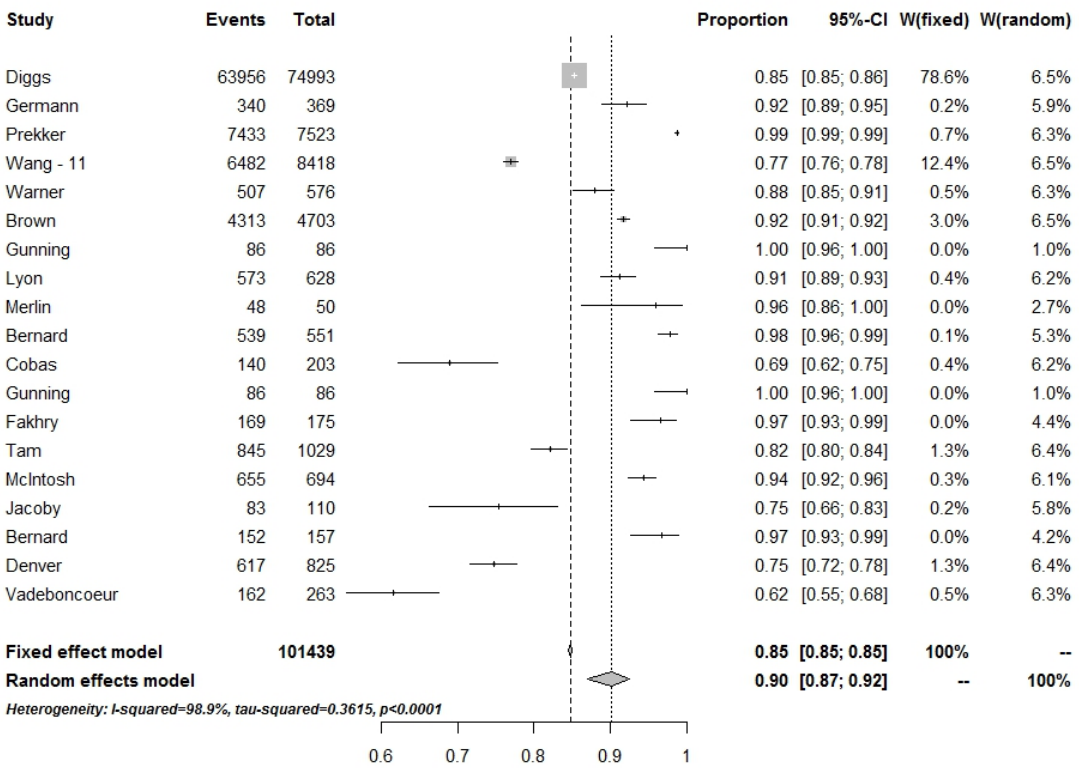


Figure 3.6 Crude median intubation success rates for non-physicians



Success rates for specific patient groups

Table 3.6 summarises the reported data in terms of the technique used for the delivery of advanced airway intervention, categorised as PHEA, non-PHEA or cardiac arrest.

Table 3.6: Summary of reported data

	PHEA	Non PHEA	Cardiac arrest
Lockey	✓	✗	✗
Breckwoldt	✓	✗	✗
Diggs	✓	✓	✓
Fullerton 2009	✗	✗	✓
Fullerton 2011	✓	✗	✗
Germann	✓	✗	✗
Prekker	✓	✓	✓
Von Vopelius	✓	✗	✗
Wang	✓	✓	✓
Warner	✓	✗	✓
Le Cong	✓	✗	✗
Kamiutsuri	✓	✗	✗
Rognås	✓	✗	✗
Brown	✓	✗	✗
Chesters	✓	✗	✗
Gunning 2013	✓	✗	✗
Katzenell	✗	✓	✗
Lah	✓	✗	✗
Lyon	✗	✗	✓
Merlin	✓	✗	✗
Caruana	✓	✗	✗
Sollid	✓	✗	✗
Sunde	✓	✗	✗
Wnent	✗	✗	✓
Bernard 2015	✓	✗	✗
McQueen	✓	✗	✗
Theoni	✓	✗	✗
Cobas	✓	✓	✗
Gunning 2009	✓	✗	✗
Fakhry	✓	✗	✗
Helm	✓	✗	✗
Timmermann	✓	✗	✗
Tam	✗	✓	✗
McIntosh	✓	✗	✗
Jacoby	✗	✗	✓
Bernard 2010	✓	✗	✗
Denver	✗	✗	✓
Vadeboncoeur	✓	✗	✗

In total, 31 studies, (15 non-physician-led and 16 physician-led), reported a PHEA technique, including use of muscle relaxants. (26,31-33,59,84,98,99,130,136,163-183)

These studies had an overall median (range) success rate of 0.980 (0.616, 1.000). Twelve studies reported non-PHEA data and/or cardiac arrest data, and demonstrated a median (range) success rate of 0.871 (0.639, 0.989), p=0.003. (31,32,59,146,164,166,184-189) Random effects meta-analysis demonstrated a statistically significant difference when comparing the intubation success rate for non-PHEA and PHEA techniques, 0.88 (95% CI 0.83 to 0.92) vs. 0.96 (0.95 to 0.98) p=0.00009. The median intubation success rate for physicians performing PHEA was 0.99 (0.937, 1.000) and 0.937 (0.616, 1.000) for non-physicians, p=0.008. Random effect meta-analysis demonstrated a success rate for physicians of 0.99 (0.98, 1.0) and 0.92 (0.90, 0.95) for non-physicians, p<0.0001.

Nine studies (24%) reported a median overall intubation success rate for cardiac arrest patients of 0.899 (0.748, 0.988). (31,32,146,164,166,184-187) Seven of these reported non-physician intubation for cardiac arrest patients, the median intubation success rate for these studies was 0.871 (0.78, 0.988). (31,32,164,166,185,187,188) The two studies for physician-led intubation had an intubation success rate of 0.983 and 0.980.(184,186)

Eight studies reported intubation success rates for trauma patients and the median overall intubation success rate was 0.895 (0.689, 0.968). (31,32,166,169,189) (26,59,179) Seven of eight studies included non-physician intubation, median success rate of 0.901 (0.826, 0.968). One study reporting data of both physician and non-physician intubation reported a success rate of 0.780. (189)

First pass intubation success rate

The number of intubation attempts was reported in fourteen studies, which recorded data for 19,178 intubation attempts in total. Of these, 14,913 intubations were successful at first attempt (77.8%). The skill level of the provider was reported for 18,630 intubation attempts. The median first pass success rate for intubations was 0.872 (0.776, 0.9795) for physicians and 0.696 (0.634, 0.973) for non-physicians.

Level of intubator skill

Studies reporting data from systems using 'expert' intubators reported a median intubation success rate of 0.994, (0.990, 1.000). Studies including personnel with an intermediate skill mix had a median success rate of 0.986, (0.878, 1.000). The reported median success rate for studies including personnel with basic skill mix was 0.917, (0.780, 1.000).

3.3.3 Discussion

The provision of PHEA and advanced airway management remains a controversial topic with studies providing evidence both for and against this intervention. Current guidelines place strong emphasis on the fact that only providers with the appropriate training and skill should undertake this intervention, given the high complication rate. (81,95)

Intubation success rates

The reporting of data for pre-hospital advanced airway management has improved significantly since the publication of previous meta-analyses in 2010. The current meta-analysis identified 38 studies published in the last ten years (2006-2016), which included 125,177 intubation attempts for meta-analysis, more than double the number included in previous analyses. The estimated overall intubation success rate of 0.969 (0.616, 1.000) in the present meta-analysis is a significant improvement when compared to 0.927 (0.882, 0.961) reported by Lossius and co-workers and 0.892 (0.877, 0.905) reported by Hubble et al. This improvement was also observed in intubation success rates for non-physicians which increased from a median of 0.849 (0.491, 0.990) (58)and 0.863 (0.826, 0.894) (114) to 0.917 (0.616, 1.000). The median overall intubation success rate for physicians in the present meta-analysis was 0.988 (0.781 to 1.000), showing more consistency with that reported by Lossius et al, 0.991 (0.973 to 1.000) (58) rather than with the findings of Hubble et al of 0.918 (0.850, 0.956). The physician data reported by the latter study represented less than 1% of the total pooled data, and included only 127 intubations. (114) This is markedly different to this meta-analysis and Lossius et al where intubation attempts by physicians account for 19.0% and 16.5% of the intubation attempts respectively. The tendency

towards improvement in intubation success rates is likely to be multifactorial. The development of this subspecialty, implementation of national (81,83,95), and local guidelines and formalisation of training programmes may have improved the practice of pre-hospital emergency medicine and may also have contributed to improved intubation success rates. Recent studies do suggest a standardisation of process in conjunction with increased intubation success. (84,160,190)

First pass intubation success rates

Analysis of the raw data demonstrated a first pass intubation was successful in 77.8% of intubation attempts. The median first pass success rate for intubations was 0.872 (0.776, 0.979) for physicians and 0.696 (0.634, 0.973) for non-physicians. A high first pass success rate is associated with better outcomes in the hospital setting and similar benefits would be expected in pre-hospital intubation. Mort et al report a significant increase in airway complications with more than two attempts at laryngoscopy. The incidence of hypoxaemia (defined as SpO2 < 90% or > 5% decrease form baseline) changed from 11.8% with less than two intubation attempts, to 70% if there were more than two attempts at laryngoscopy. (37) The increasing use of apnoeic oxygenation both in-hospital and pre-hospital reflect the recognition of this problem. Extracting robust and valid conclusions from this dataset regarding the relationship between number of intubation attempts and outcome are impeded by the fact that few studies document how many intubation attempts were made before the intubation attempt was declared a failure or alternative airway management techniques used.

Intubation success rates for specific patient groups

The results from this meta-analysis are in line with the conclusions of the previous smaller dataset (58) that where drugs are used to facilitate intubation non-physicians have a higher rate of failed intubation when compared to physicians in pre-hospital care. This may have significant safety implications since failed intubation in patients rendered apnoeic with muscle relaxants risk severe morbidity or death. (36,59,191) The intubation success rates for the specific patient groups of cardiac arrest and trauma are very similar in this meta-analysis, 0.899 and 0.890 respectively. Several studies report comparable or worse intubation success rates for patients in cardiac

arrest. (31,32,164). An exception to this is a meta-analysis by Hubble (114) who demonstrated significantly higher intubation success rates in cardiac arrest patients of 91.2% vs. 70.4% in non-arrest patients. A large recent study reported a doubling of the odds of intubation failure where no drugs were used.(33) It is previously documented that survival in patients who can be intubated without drugs is very poor.(10)

Few studies specifically addressed intubation success rates for different patient groups. The median overall intubation success rate for cardiac arrest patients was 0.899 (0.748, 0.988); 0.871 (0.78, 0.988) for non-physicians and 0.981 for physicians. The median intubation success rate for trauma patients was very similar, 0.889 (0.689, 0.968), the majority of these studies reported non-physician intubation. One study reporting data of both physician and non-physician intubation reported a success rate of 0.780, with a low first pass success rate of 45%. This study was a retrospective database review of data from the Israeli Defence Forces. Patients were attended by a pre-hospital advanced life support team which was reported to be staffed by at least one military paramedic or physician.(189) The finding of comparable success rates for both trauma and cardiac arrest patients is in contrast to the previous study by Hubble who reported lower intubation success rates in trauma patients compared with cardiac arrest patients. (114)

Data reporting

Despite the increase in the number of studies reporting pre-hospital advanced airway management, the data remains heterogeneous and difficult to interpret, with little standardisation between individual pre-hospital systems and practices. The studies are predominantly those of retrospective databases from individual pre-hospital services or Emergency Medical Service (EMS) registries. (31,32,164) A consensus-based template was developed and published in 2009 by an expert panel of pre-hospital clinicians with significant experience in advanced airway management.(101) The aim of the template was to provide a standardised method for documenting and reporting the growing data on the subject. None of the studies included in this meta-analysis reported all these variables. As the meta-analysis was designed to review the intubation success rates for different groups of pre-hospital care providers, all studies did report the highest level of provider skill on scene and the majority reported drugs

used to facilitate airway management, intubation success rates, and devices used in successful airway management. Few studies described the type of ventilation used or reported the use of end-tidal carbon dioxide ($ETCO_2$) monitoring. Recent focus on mandatory use of $ETCO_2$ monitoring for all intubated patients was supported by a large UK-based audit project (36) and it is included in guidelines for the provision of pre-hospital anaesthesia.(81,95,160,192)

Level of intubator skill

This meta-analysis also examined the skill mix of intubators described in each study. Those considered to be expert intubators, i.e. experienced consultant anaesthetists, had the highest intubation success rate (0.994, 0.990, 1.000) when compared with those of intermediate ability ('physicians in training in emergency medicine and anaesthesia with some anaesthetic experience' :0.986, 0.878, 1.000) or basic ability ('non-physicians or those physicians with only limited anaesthetic experience': 0.917, 0.780, 1.000). This finding is not unexpected and is supported by Breckwoldt et al who demonstrated a significantly higher incidence of difficult intubation amongst personnel who would be considered 'proficient' intubators, performing a median of 18 intubations annually, compared with 'expert' intubators who performed a median of 304 intubations each year.(99) Achieving the necessary skills and maintaining current experience in a pre-hospital environment can be challenging for any procedure and tracheal intubation is a particularly good example of this challenge. It is unclear from current data how many intubations should be performed in total and then annually in order to being considered competent to perform this procedure in the pre-hospital setting. One study reported that healthcare personnel needed to perform a minimum of 57 intubations before achieving a 90% success rate with this procedure. Despite this, 18% of participants still required assistance after 80 intubations.(193) I believe that practitioners who intend to perform pre-hospital advanced airway management are unlikely to achieve high levels of competence without a period of in-hospital anaesthetic training followed by an adequate number of intubations to maintain skill levels. If personnel on scene are not competent in the provision of advanced airway intervention, careful attention should be given to optimising basic airway manoeuvres and supraglottic airway devices used where appropriate.

The overall success rate of intubation performed in the pre-hospital setting has improved but this meta-analysis of the recent literature demonstrates a significant difference between physician and non-physician providers with or without the use of drugs. The finding that less experienced personnel perform less well is not unexpected but since there is considerable evidence that poorly performed intubation carries a significant morbidity and mortality, careful consideration should be given to the level of training and experience required to deliver this pre-hospital intervention safely. A robust governance system is emphasised in all pre-hospital anaesthesia guidelines and improvement and standardisation of reporting will allow better understanding of the success, process and complications of advanced airway management.

3.3.4 Limitations

The studies reporting pre-hospital emergency intubations are significantly heterogeneous in terms of provider and patient populations; many studies do not separate data into patient groups including cardiac arrest, non-cardiac arrest, trauma, or medical. They also often have the disadvantages of retrospective airway or trauma registry methodology. I recognise that successful intubation is only one quality indicator of advanced airway care and that other factors which have not been described in this meta-analysis may affect outcome.

Chapter 4: How can the practice of PHEA be improved?

The aim of this chapter was to establish whether current strategies used to improve patient safety and outcome during in hospital emergency anaesthesia can be translated into the pre-hospital environment. Much emphasis is placed on maintaining standards in the pre-hospital setting that are equivalent to those observed in hospital. The three areas studied below have all been demonstrated to improve outcome in hospital and this chapter assesses the extrapolation of these interventions to the pre-hospital environment.

4.1 Apnoeic Oxygenation

Hypoxia is one of the most common adverse events during emergency airway management, occurring in 9.2% of patients during the first attempt at intubation in an emergency setting, and in 37.8% of patients where there are repeated intubation attempts. (194) Prehospital data suggest that between 10.9% and 18.3% of patients undergoing PHEA experience episodes of hypoxaemia, defined as SaO_2 < 90%. (183,195) and these episodes are associated with an increase in morbidity and mortality. (77)

Preoxygenation is a universally accepted method of reducing episodes of hypoxia during the drug-induced apnoeic phase of induction of anaesthesia. Achieving arterial oxygen saturations (SaO_2) above 93% extends the time taken before hypoxia during the drug-induced apnoeic phase. At lower values, the dissociation of oxygen from haemoglobin takes place on the steep portion of the oxyhaemaglobin dissociation curve and SaO_2 drops rapidly. (68) Standard practice for preoxygenation typically involves use of a reservoir bag supplying high inspired oxygen. The benefit of additional apnoeic oxygenation has been widely debated, but the process has been reported to provide benefit in terms of increased peri-intubation oxygen saturation, decreased rates of hypoxia, and increased first-pass intubation success.{Silva:2017jc} Nasal oxygenation using low-flow nasal prongs is a recognised low-risk and easily administered procedure for providing passive apnoeic oxygenation in the pre-

intubation and peri-intubation phases of emergency anaesthesia. This intervention has previously been demonstrated to reduce desaturation rates by 6%.(70)

I designed and implemented this study to establish whether passive apnoeic oxygenation is superior to a conventional mask preoxygenation strategy in reducing the frequency of desaturation in a population of trauma patients undergoing PHEA.

4.1.1 Study design

This study was a prospective before-after study conducted in two physician-paramedic pre-hospital services, who treat more than 3000 patients each year. The services included were the London Air Ambulance Service described in Chapter 1 and Essex and Herts Air Ambulance Trust (EHAAT). The infrastructure of EHAAT is similar to London's Air Ambulance in terms of staffing, dispatch, the medical care provided, and the governance structure within which the services operate. The casemix differs slightly between the two services as London's Air Ambulance attends only major trauma patients whereas EHAAT attends major trauma and medically unwell patients including those in cardiac arrest.

The study included all major trauma patients attended by the two pre-hospital services who undergo PHEA. Excluded were patients:

- intubated prior to the arrival of the physician-paramedic team
- in cardiac arrest on arrival of the physician-paramedic team
- with nasal haemostatic devices *in situ* for maxillofacial haemorrhage
- who had a medical event (nontraumatic cardiac arrest or cerebrovascular event) immediately preceding their traumatic episode
- less than 16 years of age

The intervention performed in this study was apnoeic oxygenation. Patients included in the study were divided into two groups, pre and post introduction of apnoeic oxygenation:

- Standard (pre) group: Patients received supplementary oxygen via a reservoir bag applied to the patient prior to the start of PHEA.

- Intervention (post) group: Patients received additional oxygen via nasal prongs at a flow rate of 15 L/min. The nasal prongs were applied when the decision to perform PHEA was made. The standard reservoir bag was applied to the patient as per normal practice and the nasal prongs remained in situ for the duration of PHEA.

In order to ensure patient safety, bag-valve-mask ventilation was used for patients in both groups if pre-induction SpO_2 dropped to less than 90%.

The patients were subgrouped as below according to the pre-induction SpO_2 value (taken at 2 minutes prior to intubation) prior to data analysis.

No hypoxia: SpO_2 >95%

Mild / moderate hypoxia: SpO_2 85-95%

Severe hypoxia: SpO_2<85%

A training package was provided for all pre-hospital personnel prior to introducing apnoeic oxygenation into the service. This package included a review of current literature related to apnoeic oxygenation, a brief overview of the study, a questionnaire about the technique and a moulage using apnoeic oxygenation. Apnoeic oxygenation was added to the PHEA checklist, which is routinely performed before induction of anaesthesia, to ensure use of the intervention in the post intervention phase. Data collection for the post-intervention phase was started after a two-month adjustment period to ensure apnoeic oxygenation had become embedded into routine practice.

Data for the trial was downloaded after arrival in hospital from the monitors used to record the pre-hospital patients' vital signs after arrival in hospital. The monitor used by the services contributing data to the study is a Zoll X Series (Zoll, Boston, Massachusetts United States). Monitoring was connected to the patient on arrival of the doctor-paramedic pre-hospital advanced care team and disconnected when the patient arrived at hospital. Data were continuously recorded and displayed as a waveform and numerical value which was updated every 30 seconds. SpO_2 values were recorded for each patient from two minutes prior to the start of PHEA (during the preoxygenation period), until ten minutes after PHEA had been performed.

Primary endpoint

- The median SpO_2 observed between the two groups in the peri-RSI period, defined as two minutes pre-intubation to two minutes post intubation for all patients and for patient subgroups.

Secondary endpoints

- The incidence of hypoxia, defined as SpO_2 values $\leq$90% in the peri-intubation period (2 minutes before and 2 minutes after intubation for all patients and for patient subgroups.
- The incidence of severe hypoxia, defined as SpO_2 values of $\leq$85% in the peri-intubation period (2 minutes before and 2 minutes after intubation) for all patients and for patient subgroups.
- The incidence of hypoxia, defined as SpO_2 values of $\leq$90%, in the post intubation phase from intubation until ten minutes post intubation for all patients and for patient subgroups.
- The incidence of hypoxia, defined as SpO_2 values of $\leq$90%, in the recovery phase from two minutes post intubation until ten minutes post intubation for all patients and for patient subgroups.

Statistical analysis

Hypoxia rates were compared between groups using chi-squared tests. Differences between groups in SpO_2 as a continuous variable were investigated using the Mann-Whitney U test.

4.1.2 Results

In total, 725 patients were included in the study; 188 patients were included in the standard treatment group and 537 in the intervention group. There were no reported protocol violations. The overall incidence of hypoxia prior to preoxygenation and intubation (defined as initial SpO_2 reading <90%) was 16.7% (121 of 725 patients); 79 patients (10.9%) had SpO_2 less than 85%. 98 of 725 patients (13.5%) were hypoxic post intubation (defined as final SpO_2 reading <90%, observed at ten minutes post intubation); 70 of these 98 patients (9.7%) were in the group of 79 patients who were

initially hypoxic with SpO_2 less than 85% prior to intubation (i.e. the group who could not be pre-oxygenated).

Median SpO_2 in the standard group was 100% (interquartile range 96,100), and in the intervention group, 99% (interquartile range 96,100), p=0.0001. The incidence of hypoxia, defined as SpO_2 values of 90% or less, in the 2 minutes before and 2 minutes after intubation was 106/653, 16.2% in the standard group and 500/3181, 15.7% in the intervention group, p=0.74 The incidence of hypoxia, in the period from intubation until ten minutes post intubation was 177/1461 (12.1%) in the standard group and 959/8037 (11.9%) in the intervention group, p=0.84. The results from the subgroup analysis are reported in table 4.1 below. This table shows the study groups (standard and intervention) subclassified by the degree of hypoxia which is recorded as the pre-induction SpO2 value (taken at 0 minutes).

The median SpO_2 value was that of all values recorded for the all patients during the peri-intubation phase.
The categories reporting 'total 90 or less' and 'total 85 or less' refer to the number of patients who desaturated in the peri-intubation, post intubation, or recovery phase to an SpO_2 or 90% or less, or 85% or less. This figure is reported as a proportion of the number of SpO_2 values recorded for all patients in this group and sub classification.

Table 4.1: Apnoeic oxygenation subgroup analysis

Peri intubation phase 2 minutes pre to 2 minutes post intubation		**Standard**	**Intervention**	**P value**
Median SaO_2 (IQR)	All patients	100 (96,100)	99 (96,100)	p=0.0001
	No hypoxia	100 (98,100)	100 (98,100)	p=1.00
	Mild Moderate hypoxia	94 (83,97.75)	94 (88,99)	p=1.00
	Severe hypoxia	79 (66.5,86)	83 (77,95)	p=0.28
Total 90 or less / total peri intubation values (% difference)	All patients	106/653 (16.2)	560/3659 (15.3)	0.546
	No hypoxia	24/380 (6.3)	54/1492 (3.6)	0.02
	Mild Moderate hypoxia	28/72 (38.9)	131/386 (33.9)	0.947
	Severe hypoxia	41/51 (80.4)	118/177 (66.7)	0.195
Total 85 or less / total peri intubation values (% difference)	All patients	65/653 (10.0)	340/3659 (9.3)	0.864
	No hypoxia	7/380 (1.8)	20/1492 (1.3)	0.466
	Mild Moderate hypoxia	11/71 (15.3)	61/386 (15.8)	0.947
	Severe hypoxia	34/51 (66.7)	100/177 (56.5)	0.195
Post intubation phase (intubation - 10 minutes)	All patients	177/1464 (12.1)	959/8037 (11.9)	0.864
Total 90 or less / total post intubation values (% difference)	No hypoxia	43/1126 (3.8)	254/5928 (4.3)	0.476
	Mild Moderate hypoxia	39/164 (23.8)	377/1424 (26.5)	0.458
	Severe hypoxia	93/160 (58.1)	384/759 (50.6)	0.084
Recovery phase (2 minutes post intubation to 10 minutes post intubation)	All patients	139/1221 (11.4)	728/6396 (11.4)	0.998
Total 90 or less / total post intubation values (% difference)	No hypoxia	33/941 (3.5)	204/5121 (4.0)	0.488
	Mild Moderate hypoxia	31/138 (22.5)	280/1128 (24.2)	0.544
	Severe hypoxia	73/133 (54.9)	234/746 (31.4)	3.06E-07

4.1.3 Discussion

This is the first reported prospective study of the use of apnoeic oxygenation during PHEA in trauma patients. Hypoxia is a relatively common problem in patients undergoing emergency intubation; 16.7% of patients in this study were hypoxic prior to induction of anaesthesia. This is comparable to previous studies which report that up to 18% of trauma patients are hypoxic prior to airway intervention. (195-197). As episodes of hypoxia may worsen patient outcome, particularly in traumatic brain injury, (65,77,198) reducing the time spent with low oxygen saturations may translate into an improvement in morbidity and mortality. A reduction in hypoxic episodes may be achieved using simple reproducible techniques such as apnoeic oxygenation. The physiology of apnoeic oxygenation is well-described in studies from the 1950s.{Frumin} In the presence of a patent airway, there is a difference between the uptake of oxygen and the excretion of carbon dioxide at an alveolar level. (199) This discrepancy creates a negative pressure gradient that promotes the movement of oxygen into the lungs. Alveoli will continue to take up oxygen even without diaphragmatic movements or lung expansion. The presence of a continuous infusion of oxygen to the upper airways during drug-induced apnoea can supplement oxygenation levels. (200)

Despite multiple previous studies, the clinical benefit of apnoeic oxygenation remains unproven. A positive association between apnoeic oxygenation and lower rates of hypoxaemia during emergency intubation has been demonstrated (197,201,202) but these findings are not universally reproducible. A recent meta-analysis reported benefit from apnoeic oxygenation during the drug-induced apnoeic phase of intubation in terms of increased peri-intubation oxygen saturation, decreased rates of hypoxia, and increased first-pass intubation success. (203) The application and delivery of apnoeic oxygenation varies between the studies, with some using 15L/min via nasal cannulae and some studies using high flow oxygen at 50-60 L/min; endpoints also vary between studies. Results from two randomised controlled trials performed in the emergency setting could not demonstrate a benefit of apnoeic oxygenation. (204,205) Studies conducted using pre-hospital data are retrospective; two studies have demonstrated a reduction in the incidence of hypoxia but this has not reached statistical significance. (70) My study reported in this chapter provided apnoeic oxygenation at a rate of 15L/min using nasal prongs but did not show a significant

overall benefit in reducing the frequency of episodes of hypoxia during the drug-induced apnoeic phase of intubation. Apnoeic oxygenation may be beneficial where intubation is difficult and time to ventilation is prolonged. It can increase time to desaturation which reduces the incidence of desaturation and the frequency of hypoxic episodes in difficult or prolonged intubations. (206-208)

Overall, the results of this study did not demonstrate a significant reduction in the incidence of hypoxia using apnoeic oxygenation during PHEA. It is likely that where preoxygenation has been adequately performed and the intubation is uncomplicated, minimal benefit will be observed with the addition of apnoeic oxygenation. (206) The intubation success rate for the services in which the study was conducted has previously been demonstrated to be 99.1% and 99.3% (98) with a first pass success rate of 93% and 87.5% (Harris 2011) There was a statistically significant difference in the median peri-intubation oxygen saturations between the two study groups in favour of the standard group but this does not translate into any clinically relevant difference as neither result demonstrates clinically significant hypoxia.

Subgroup analysis was performed to assess the effect of apnoeic oxygenation on different categories of pre-intubation hypoxia. There was a statistically significant benefit from apnoeic oxygenation in the frequency of peri-intubation hypoxia (SpO_2 of 90% or lower) for patients who started with normal oxygen saturations (>95%). The other significant benefit was observed in the recovery phase for the group of patients who were severely hypoxic prior to induction of anaesthesia.

Apnoeic oxygenation is a simple low-cost intervention with a low complication rate. The intervention currently lacks a firm evidence base but may be helpful in a difficult intubation or where intubation takes longer than usual. The ongoing controversy surrounding use of this technique does not necessarily mean that apnoeic oxygenation is ineffective in reducing the incidence of hypoxaemia associated with emergency intubation. This study used a pragmatic approach to try and investigate the effect of apnoeic oxygenation in a cohort of severely injured patients undergoing pre-hospital intubation. Although apnoeic oxygenation is unlikely to make a difference to the majority of trauma patients who are straightforward to oxygenate and easy to

intubate, it has the potential to reduce the frequency, incidence, and duration of hypoxia in the minority of patients who are already hypoxic or require a longer time to intubate. Difficult preoxygenation is a risk factor for subsequent hypoxia, and up to 30% of patients can remain hypoxic, defined as SpO_2 < 90%, after 5 minutes of preoxygenation, (209) so apnoeic oxygenation is potentially very beneficial in the group of patients most vulnerable to hypoxia. A recent study comparing bag-mask ventilation to no ventilation during intubation of critically ill patients reported higher oxygen saturations and a lower incidence of severe hypoxemia in the bag-mask ventilation group. The use of bag-valve-mask ventilation during the drug-induced apnoeic period reduced the incidence of hypoxia, defined as SaO_2<80%, from 22.8% in the no ventilation group to 10.9% in the bag-mask ventilation group, relative risk 0.48. (210) This positive finding may be relevant to this study population because an alternative strategy to providing supplemental oxygenation in the apnoeic phase of induction might be to avoid the apnoeic phase altogether with bag-valve-mask ventilation.

Although apnoeic oxygenation did not influence peri-intubation oxygen saturations but it did reduce the frequency and duration of hypoxia in the post-intubation period. Given that apnoeic oxygenation is usually a safe and simple technique and that hypoxia can be detrimental to outcome, application of nasal cannulae during the drug-induced phase of emergency intubation may benefit a small subset of patients undergoing emergency intubation.

4.1.4 Limitations

This is a before-after study assessing whether apnoeic oxygenation is a beneficial intervention in PHEA. Whilst before-after studies are considered to be weaker methodology; at the time the study was designed there was relatively little data published on apnoeic oxygenation; the published data seemed to suggest a benefit and there was insufficient equipoise to conduct a randomised controlled study, which was the original intention and power calculations performed prior to the study predicted that 600 patients should be recruited to the study. Assuming a hypoxia rate in the standard group of 18.3%,(196) and a 6% reduction in the number of patients who desaturate when passive apnoeic oxygenation is used, (70) a study of this size

would have 80% power to detect a difference at the 5% significance level if the rate in the treatment group is less than or equal to 10% (equivalent to an odds ratio of 2.0). A sample of this size will also be powered to detect small differences in continuous endpoints such as lowest recorded saturation, with a detectable difference of 0.23 standard deviations for 80% power and 0.27 standard deviations for 90% power. The original power calculation was used as a guide for study recruitment despite the change in methodology.

Data for this study were collected using monitor downloads, introducing the possibility of drift and calibration errors. The manufacturers state the monitors potentially have up to 0.3% measurement error. It is not possible to collect specific information including patient demographics, injuries sustained or the indication for intubation. In addition, it was not possible to collect long-term patient outcome data such as survival to hospital discharge, and functional outcome at discharge. The study is designed pragmatically to enable the research to be conducted in critically ill and injured patients. The clinical treatment provided is protocol-led and all clinicians working within the services are fully conversant with these guidelines. There may be occasional circumstances where care delivered deviates from the protocol – this is at the discretion of the attending clinician. The patient population used in this study – all trauma patients undergoing RSI, may not be representative of the patient group most likely to benefit from apnoeic oxygenation. However, a study only including, for example, patients difficult to intubate or at most risk of desaturation would take a very large patient population or length of time to investigate.

4.2 Checklists in PHEA

The most important focus in PHEA is patient safety. PHEA is a complex intervention which, if performed poorly, can result in significant harm. (40,191) The risk of harm can be mitigated by certain practices including the use of pre-prepared drugs or equipment (211) and the routine implementation of checklists before complex interventions are performed. The use of a checklist before major operative procedures is now commonplace in hospital practice. From an airway perspective, recent major studies (40) and guidelines (95) recognise and support the use of checklists in

emergency airway management. It is currently unclear how often PHEA is performed in the UK, and to what extent checklists are used to support these procedures. In order to address this aspect of PHEA I participated in a study which set out to describe the current practice of PHEA in the UK, determine the use of checklists for PHEA and describe the content, format and layout of any checklists currently used in the UK.

4.2.1 Study design

The study was structured as an online survey which was circulated to all UK Helicopter Emergency Services (HEMS) and other potential providers of PHEA such as the British Association of Immediate Care (BASICS) organisations in the UK and Scottish based pre-hospital teams operating from local Emergency Departments. The survey asked questions relating to the annual number of emergency anaesthetics provided by the service, and the development and use of checklists and SOPs relating to PHEA. The construct of the checklist was analysed as part of the study. Prior to rolling out the survey at a national level, a pilot study was conducted using a group of PHEM physicians. The national survey was conducted between 01 March and 30 May 2014. Lead clinicians from the identified pre-hospital services were invited to participate in the survey via post or email. In addition to responding to the survey, a copy of any pre-induction checklists in current clinical use was also requested. To follow up, an email reminder was sent once a week for four weeks, after which a telephone call was made. If no response was received at this point, it was concluded that the service had declined to participate.

Following responses from the prehospital services, the services were grouped into those performing more the 50 emergency anaesthetics per year (high volume services) and those performing fewer than 50 per year (low volume services). The majority of checklists for PHEA comprise of ‘standard’ and ‘immediate’ sections which may be used depending on how urgently tracheal intubation needs to be performed. These sections, where present, were analysed separately. The checklists were analysed in terms of length (including a word count), structure, text and background colour, and language.

Statistical analysis was performed using Prism 6.0 (Graphpad, La Jolla, USA) software. Histogram plots were used to test for normality. Categorical data are reported as frequency (n) and percent (%), and numerical data as median with range. Fischer's exact test was used to compare categorical data and Mann-Whitney U test to compare numerical data. A two-tailed P value of <0.05 was considered significant.

Ethical approval was not required for the study.

4.2.2 Results

In total, there were 59 UK services providing physician-led PHEM; 21 HEMS services, 35 BASICS services, and three ED-based services. Two HEMS services combined operational data for clinical governance purposes and were considered as one service, so 58 individual services were considered to be eligible for inclusion in the study. Of these, 43 services agreed to participate in the survey, these included 19 HEMS services, 23 BASICS services, and three ED-based services.

Thirty (70%) of the 43 services had PHEA capability (17 HEMS, ten BASICS, three ED-based services). Specific data on the total number of PHEAs performed annually was received from 25 (83%) services. Ten services were high volume providers, performing more than 50 PHEAs annually, and 15 services were low volume providers. The ten high-volume services (all HEMS) perform approximately 84% (1361 procedures) of all PHEA procedures per year, while the 15 low-volume services (seven HEMS, six BASICS schemes, and two ED-based services) provide the remaining 16% (268 procedures/year). There was also variation in the availability of PHEA across services (Figure 2). A greater proportion of patients treated by high-volume services underwent PHEA when compared to those treated by low-volume services (11.9% versus 3.2%; OR 4.7 (95% CI: 4.1 – 5.3); $p < 0.0001$). In both groups, the most common indication for PHEA was trauma, table 4.2

Table 4.2: Provision of PHEA in the UK

	Type of PH service	
	High-Volume	**Low-Volume**
Number of services	10	20*
Median number of patients per year (range)	975 (564 – 1800)	400 (76 – 2500)*
Median number of PHEA per year (range)	109 (65 – 400)	16 (0 – 40)*
PHEA as percentage of total cases (range)	11.9 (5 – 32)	3.2 (0 – 16)*
Proportion of PHEA performed for trauma indications as percentage (range)	80.6 (51 – 100)	78.6 (63 – 100)**

*Data displayed for 15 low-volume services

**Data displayed for 14 low-volume services

Checklist utilisation

Twenty-three of 30 services providing PHEA confirmed mandatory checklist use, including all ten high volume services and 13 low volume services. A further two low-volume services confirmed an optional PHEA checklist, and five low-volume services did not use any formal checklist before delivering PHEA. All services using a checklist did so in the 'challenge-response' format.

For patients requiring immediate PHEA, ten services (seven high-volume, three low-volume) used a separate pre-induction checklist, whilst eleven services (two high-volume, nine low-volume) used their standard pre-induction checklist, and four services (one high-volume, three low-volume) waived the use of a checklist in these situations.

Checklist structure

In total, 13 of the 23 checklists (43%) were divided into distinct sections (e.g. equipment, drugs) and six (32%) consisted of a list of continuous checks. Fifteen 'standard' checklists (65%) were confined to one side of laminated paper; twelve (52%) used black lettering on a single colour background whilst seven (30%) used more than one colour for the text or background. Standard checklists contained a median of 169 (range: 52 – 286) words and 41 (range: 28 – 70) individual checks. The 'immediate' checklists contained a median of 16 (range: 15 – 17) words and 12 (range: 10 - 13) checks. The construct of the checklist and language used varied between services. Whilst some checklists consisted of simple, brief phrases on separate lines for individual checks, others use complex, full sentences covering a number of points in one check.

4.2.3 Discussion

Thirty pre-hospital services in the UK are able to deliver PHEA. Over 80% of the estimated 1600 PHEA procedures performed each year are performed on those who have suffered traumatic injury. Ten high-volume, high case-load services perform the majority of these procedures, and these services provide PHEA more consistently throughout a 24-hour period.

Checklist utilisation in the UK is increasing and has now become mandatory for the majority of services. Data from 2009 suggests that, of the services providing PHEA (212), only 65% were using a checklist prior to provision of the intervention, compared to 83% at the time the current study was conducted in 2014. All high-volume and some low-volume services use a specific PHEA checklist for PHEA. The overall performance of the checklist usage in terms of promoting familiarity for all users, regular review of language and content, and checklist revision was better for the high-volume services. There is considerable variation between the checklist length, content and format. Those used by high volume services have longer word counts and a greater number of checks to complete. The ideal length of a checklist is hard to define, it needs to cover all the relevant checks in the most concise way possible to avoid unnecessary delay in starting the intervention and checklist fatigue, but whilst maintaining its function of reducing human error and improving patient safety. It is likely that a challenge-

response structure is the most effective as complex, open-ended questions will worsen cognitive burden. It is likely that the key to promoting effective checklist use is regular training and familiarisation, the use of simple and precise language and regular review of the content.

4.2.4 Limitations

The conduct of this study using a survey format opens it up to selection bias but attempts were made to mitigate this by extensive delivery of the survey to senior clinicians preforming PHEA. The incidence of PHEA delivered in the UK is likely to be higher than that reported in this study as a consequence of missing data and non-responders. The majority of non-responders or partial responders resulting in missing data were low-volume services who are less likely to utilise checklists, which may skew the reported data.

4.3 Post intubation ventilation

Once tracheal intubation has been established the focus of care shifts to the post intubation phase, which should include ensuring the provision of appropriate oxygenation and ventilation. Monitoring of end-tidal carbon dioxide ($ETCO_2$) levels has become the gold standard for all intubated patients to provide an indication of the adequacy of ventilation.(36) $ETCO_2$ is used by many as a surrogate marker of the physiological status of the patient, indicating cardiac output and the correlation between ventilation and perfusion. However, $ETCO_2$ levels do not always provide a consistent and accurate reflection of arterial carbon dioxide levels.(213) Inadequate ventilation, either hypoventilation or hyperventilation, can be harmful in intubated trauma patients and has been demonstrated to have a deleterious effect on morbidity and mortality.(24,75,76) Whilst mortality for ventilated trauma patients is undoubtedly multifactorial, better control of ventilation with prevention of hypoxia and hypo- or hypercapnia is likely to be of significant benefit.

I performed this study to evaluate the adequacy of ventilation in pre-hospital trauma patients following intubation and during transport to hospital by comparing $ETCO_2$

levels to recommended standards obtained from local SOPs for the management of traumatic brain injury and PHEA. Ventilation was either performed manually or using a portable, pressure-controlled ventilator. The adequacy of manual vs. mechanical ventilation was assessed.

4.3.1 Study design

A prospective service evaluation study was conducted to evaluate pre-hospital ventilation delivered by the London Air Ambulance Service described in Chapter one. Data were collected for all patients attended by the physician-paramedic team who underwent PHEA between October 2015 and September 2017. Following PHEA and confirmation of the correct positioning of the tracheal tube, the patient is ventilated until arrival at hospital or until the patient is pronounced dead. Ventilation may either be performed by hand or using an Oxylog 3000 ventilator (Drager, Lubeck, Germany) at the clinician's discretion. Ventilation is titrated to the $EtCO_2$ value, which is displayed as continuous waveform capnography and as a digital value on the Propaq monitor (Zoll, Boston, Massachusetts). Data points are recorded every 30 seconds and can be subsequently downloaded from the monitor and exported into an excel spreadsheet. The monitor is connected to the patient on arrival of the doctor-paramedic pre-hospital advanced care team and disconnected when the patient arrives at hospital or is pronounced dead before reaching hospital. The Propaq monitor has an error margin of 0.3 kPa (214) so the $ETCO_2$ value was considered to be in range if it was between 3.7 kPa and 4.8 kPa.

All patients attended by the pre-hospital trauma team in whom PHEA was performed were included in the study. Patients who are intubated prior to arrival of the pre-hospital trauma team and those in whom a cardiac arrest occurred during the pre-hospital phase were excluded.

The primary objectives were to establish compliance with local standard operating procedures for ventilated patients by measuring $ETCO_2$, and to identify differences in delivery of ventilation when using manual or mechanical ventilation. Statistical analysis of the results was performed using a chi-squared test.

4.3.2 Results

In total, 280 patients were attended and had data recorded during the study period; seventeen patients were excluded as cardiac arrest occurred at some point during their management. A total number of 17,474 data points were recorded during the study from the remaining 263 patients, representing the equivalent number of $ETCO_2$ values recorded every 30 seconds. All 263 patients underwent PHEA with the pre-hospital trauma team and were transported to hospital with ongoing ventilation provided either manually or mechanically.

Overall, of the 17,474 data points recorded, the median $ETCO_2$ for all patients was 4.2kPa (range 1.0kPa to 9.5kPa). A total of 11,649 values were recorded during manual ventilation, median $ETCO_2$ 4.3kPa (range 1.0kPa to 9.5kPa). Overall, 5,825 values were recorded during mechanical ventilation. Median $ETCO_2$ 3.9kPa (range 1.0kPa to 9.1kPa). 5,958 of 11,649 values (51.2%) for manual ventilation fell within the target range compared with 3,585 of 5,825 values for mechanical ventilation, P<0.0001, table 4.3.

Table 4.3: Proportion of values within target $ETCO_2$ range, reported with and without error margins for the Propaq monitor

ETCO2 (kPa)	Total N=17474	Manual ventilation N=11649	Mechanical ventilation N = 5825	P value (manual vs. mechanical)
4-4.5	26.0% (4549)	25.3% (2951)	27.4% (1598)	P=0.003
3.7-4.8	54.6% (9543)	51.2% (5958)	61.6% (3585)	P<0.0001

4.3.3 Discussion

The service SOPs recommend a target range for $ETCO_2$ of 4.0-4.5 kPa, reflecting in part, the high incidence of head injuries attended by the service. The results of the study

demonstrated that the $ETCO_2$ target range is more likely to be achieved using mechanical ventilation but even this method only achieved the target range just over 60% of the time. The target range was achieved using a manual ventilation technique in 51.2% of patients. Whilst the results suggest relatively poor compliance with service standards, they are comparable to other similar studies. Holmes et al demonstrated abnormal $ETCO_2$ levels in 57% of pre-hospital patients; 43% of patients achieved the target range of 30 – 45 mmHg.(215) The mode of ventilation was not described. A similar study based in Australia demonstrated abnormal $ETCO_2$ in 49% of patients.(216)

Abnormal $ETCO_2$ values during ventilation have been associated with a poor outcome for polytrauma patients (76) and for patients with traumatic brain injury. (24,75,217) The San Diego Paramedic Trial in 2003 was one of the early landmark trials that suggested a link between pre-hospital rapid sequence induction and poor outcome in moderate to severe traumatic brain injury.(22) Further examination of the data revealed increased survival rates for intubated patients who arrived at hospital with an $ETCO_2$ between 30–49 mm Hg compared with those patients who were outside these parameters.(24) Other studies have demonstrated similar findings for patients ventilated outside the optimal range for $ETCO_2$.(75)

The pathophysiology relating hyper- and hypocapnia to poor outcome, particularly in traumatic brain injury, is reasonably well-described and is predominantly related to worsening of secondary brain injury through poor perfusion and further hypoxic insult. Hyperventilation increases intrathoracic pressure and lowers arterial carbon dioxide concentrations. The raised intrathoracic pressure associated with positive pressure ventilation causes a reduction in venous return, cardiac output and mean arterial pressure resulting in poor perfusion in cerebral, systemic and coronary circulations; the effects are more pronounced in hypovolaemic patients.(218-220) Intracranial pressure is adversely affected by increases in intrathoracic pressure which are transmitted through the venous system,(221) Whilst intracranial pressure may decrease with controlled hyperventilation, the increase in intrathoracic pressure and reduction in mean arterial pressure often translates into an overall reduction in cerebral perfusion pressure rather than an increase.(218) In addition, lower arterial carbon dioxide levels also cause cerebral vasoconstriction and reduced cerebral blood

flow with subsequent exacerbation of cerebral ischaemia.(222) Elevations in arterial carbon dioxide levels secondary to hypoventilation can increase intracranial pressure secondary to cerebral vasodilatation and increased cerebral blood flow. If the patient is profoundly hypoventilated then oxygenation may be compromised which is known to worsen secondary brain injury.(65,223)

Few guidelines exist for pre-hospital post intubation care. The most recent UK PHEA guidelines include post-intubation care and recommend a target $ETCO_2$ range of 4.0-4.5 kPa.(95) The pathology of cardiac events and major trauma are obviously markedly different and this target range is not reflective of the neuroprotective strategies used in the management of major trauma patients.

One expectation of mechanical ventilation is that it is easier to control $ETCO_2$, however whilst this study demonstrated an improvement in achieving the target range with mechanical ventilation, it was achieved only 60% of the time. Removal of human factors associated with the use of manual ventilation through the provision of mechanical support will undoubtedly account for the some of the observed improvement but the percentage of values within the target range is still relatively poor. In addition, the $ETCO_2$ does not necessarily accurately reflect arterial carbon dioxide concentration in the presence of significant changes in dead space or shunting secondary to significant anatomical or physiological derangement following major trauma.(213)

This study demonstrates poor compliance with tight $ETCO_2$ control for major trauma patients and the findings are consistent with other published literature. Mechanical ventilation is superior to manual ventilation for controlling $ETCO_2$ but is still does not provide optimal $ETCO_2$ control. It may be possible in the future to control $ETCO_2$ using end tidal control software which is already utilised in certain anaesthetic machines to control end-tidal inhalational anaesthetic agent concentration or end-tidal oxygen. The software monitors the gas concentrations and automatically adjust levels to maintain the required concentration over different flow rates.

4.3.4 Limitations

This study was performed using a large dataset downloaded from monitors recording patient vital signs. One limitation was the inability to specifically collect the required data points which made the dataset more difficult to interpret. It was not possible to collect specific patient demographics or outcome data. One of the more challenging aspects of the data analysis was identifying patients who were in full cardiac arrest at some time point during the data collection. Patients could have had low $ETCO_2$ for reasons other than cardiac arrest for example a misplaced tracheal tube or a low flow state. Therefore exclusion of patients in cardiac arrest had to be made by excluding all patients with an $ETCO_2$ </= 1kPa.

Chapter 5: Improving standards for PHEA

This chapter details how the research findings described in the previous chapters have been translated into clinical guidelines using consensus methodology. Once consensus had been achieved, I co-authored the two sets of guidelines which have been widely distributed into clinical practice. Novel areas such as the use of key performance indicators are now being introduced at a local level to improve the safety and efficacy of PHEA, as evidenced by a recent publication that evaluated the introduction and use of the AAGBI key performance indicators (KPIs) into the local service. (224) In addition to the production of the guidelines, I was invited to be a member of an expert panel tasked with updating a standardised data collection tool for PHEA which further enabled me to translate my research findings into clinical practice and drive improvement in PHEA.

5.1 Dissemination of the information

There is currently limited high-level evidence in the field of PHEM to help progress clinical practice and influence outcome. The majority of evidence-based medicine that informs clinical practice is based on low quality evidence, clinical experience, personal opinion, and reports published from large international registries such as the Cochrane Database. These large registries have, to date, relied heavily on RCTs to establish findings and derive recommendations. RCTs are very difficult to conduct in the pre-hospital setting, not least because of issues around the inability to gain informed consent pre intervention from severely ill or injured patients; ethical, legal and practical aspects usually limit the development of robust trials (225) which are likely to make a significant contribution to the evidence base. In addition, the nature of specific inclusion and exclusion criteria in RCTs risk creating idealised conditions in a small patient subgroup with the pathology in question, which limits generalisability of findings to the routine clinical setting. (226) As a result of such factors, there is currently limited high-level evidence in the field of PHEM to help progress clinical practice and influence outcome.

For these reasons and others - namely the promotion of consistent standardised and well-researched clinical practice - the introduction of large prehospital registries collating data from thousands of patients is considered to be very important, and attempts have been made to standardise data reporting. (101) Such large, cleaned and curated datasets may support machine learning in identifying factors which might improve outcome.

However, evidence alone is not enough: research findings are not necessarily translated into clinical practice, and the publication of guidelines does not ensure acceptance and uptake by clinicians - even when organisations are responsible for disseminating and implementing such documents. (227)

This chapter focuses on the development of guidelines using nominal group technique and the implementation of standardised data reporting to ensure safe and effective delivery of PHEA and to facilitate research in this area.

5.1.1 The Consensus Process

The process of consensus as a strategy to collate evidence, opinion, and research, often with the purpose of producing guidelines, was first used in the 1950s. It is also valuable in directing future research and service development. In the majority of cases, guidelines are developed by deriving a group decision from a set of 'expert' individuals. (228) The consensus process has five main components: three inputs (defining the task, participant identification and recruitment, and generation of information); the approach (consensus development by explicit or implicit means); and the output (dissemination of results). (229)

The most common methods used for achieving consensus in healthcare are the nominal group technique (NGT), and the Delphi technique. These formal consensus methods meet the requirements of scientific methodology. (228) They are based on the rationale that a group of people are less likely to reach an inappropriate or incorrect conclusion compared to individual assessment, and complex group decision-making is supported by the challenge and justification of individually-held views. Individual dominance can be avoided by the facilitator who has overall control of the process such that all views can be expressed and considered. As the group of people

involved in the process are usually ‘experts’ in the relevant field, the combination of expert opinion and decision-making taken together with the available published literature should produce the best available guidance.

5.1.1.1 The Nominal Group Technique

The NGT method uses structures face-to-face discussion and interaction within a group. The process usually involves between two and fourteen participants who are selected experts in the field in question; seven participants has been recommended as an optimum number. A question is formulated and presented to the group of experts who initially record their individual ideas and views independently and privately initially. At a subsequent meeting, the process is divided into separate rounds, often referred to as silent generation, round robin, clarification and voting (ranking or rating). The experts propose, rate, discuss, and re-evaluate a number of items, variables, or questions. The discussions are facilitated by someone familiar with the employing this technique, and consensus is achieved by the end of the meeting. (225) These phases of discussion are described in table 5.1 below. (230)

Table 5.1: Phases of discussion that comprise the Nominal Group Technique

Nominal Group Technique	
Silent Generation	Silent reflection on the questions raised and generation of initial response
Round Robin	Sequential proposal of ideas generated in previous round. Each participant takes their turn to express their views and introduce ideas. Process continues until no further ideas are put forward.
Clarification	Ideas generated in the previous rounds are grouped into similar categories, discussed then included, excluded or altered
Voting / Ranking	Ideas ranked in order of preference. This is a confidential process. Once completed the ranking scores are collated, statistically analysed and presented, further discussion is subsequently invited.

Variations to the NGT described above include an initial generation and discussion of ideas after exclusion of the silent generation and round robin rounds, different ranking processes (use of the Likert Scale) or a second round of ranking so participants can revise their initial scores, and increased amounts of time allocated to the process. (230)

5.1.1.2 The Delphi Technique

The Delphi technique uses a remote system whereby participants are contacted via email or postal survey so that they do not meet directly at any stage, removing the problem of geographical location. The method itself involves six stages: (231)

(1) Identifying a research problem

(2) Completing a literature search

(3) Developing a questionnaire of statements

(4) Conducting anonymous iterative mail or e-mail questionnaire rounds seeking individual views on the questions raised

(5) Providing individual and/or group feedback between rounds

(6) Summarising the findings

The process usually consists initially of email rounds (often three) in which a number of experts provide opinions on specific matters. These opinions are summarised and re-circulated to the group for ranking. Participants are given the opportunity to revise their statements in light of group feedback, and the process is repeated until a conclusion, based on the individual experts' insights in the group response, is reached. (225) The statistical basis of the Delphi method suggests that the combined numerical scores of a group of people are likely to be more accurate than individual estimates (228) Again, variations of this technique exist. One of the more widely-recognised variations of both NGT and the Delphi technique is the RAND appropriateness method (230) in which participants read a detailed literature review, then respond to a Delphi questionnaire. The results of this round are then discussed and explored in a face-to-face meeting, followed by a second-round Delphi questionnaire and re-ranking of the proposed ideas.

5.2 The development of PHEA guidelines

The infrastructure and delivery of PHEM varies significantly throughout the world. The majority of European countries provide physician-led PHEM, whilst the United States use a paramedic-led system. Variation also exists within individual countries and until recently the UK has observed many disparities in the delivery of care outside the hospital. In an attempt to disseminate information, standardise practice and improve the safety and delivery of PHEM, several guidelines have been produced internationally, a number of which focus on PHEA. (43,81,83,95,117) I was involved in the preparation and delivery of two major sets of national and international guidelines, produced by the Association of Anaesthetists of Great Britain and Ireland and by the European HEMS and Air Ambulance Committee (EHAC). Both sets of guidelines were developed using a modified nominal group technique; whilst the people involved were

different for both guidelines, the technique was the same. A panel of experts in PHEA were identified and contacted by email to invite the committee together to discuss the guideline development. The panel for the AAGBI guidelines was comprised of eight individuals, all of whom were involved in the clinical and non-clinical conduct of PHEA; the EHAC panel was comprised of twenty-eight individuals. Of the twenty-eight, twelve were directly involved in writing the guideline and the rest of the group reviewed the first and subsequent drafts, suggesting amendments where appropriate. In the initial meeting, the sections required in the guidelines were identified and allocated to one or two specific individuals to write - with a time frame for completion of one month. Once the first draft was created it was sent out to the group for comment. Two more rounds (each of one-month duration) of drafts and comments were conducted before the document was correlated in full and put forward for endorsement and publication. The AAGBI guidelines published in 2017 were a review of a previous pre-hospital anaesthesia safety guideline from 2009. These guidelines were endorsed by all of the major training providers including the Royal College of Anaesthetists, College of Emergency Medicine and Faculty of Pre-hospital Care of The Royal College of Surgeons of Edinburgh {Anaesthetists:vNuQq6Z3}. I was part of the working party within the AAGBI set up to deliver these guidelines. I was first author for two major sections within the guidelines and coordinated the preparation and completion of all sections. The EHAC guidelines were published in 2019 (43) and I was first author of the initial draft and all subsequent drafts. The drafts were reviewed by a committee of PHEA experts set up within EHAC to produce the guidelines.

Whilst the guidelines obviously reflect the different infrastructure of the services operating within the various countries, they all place emphasis on the same core messages, specifically that:

(1) The standard of care delivered should be consistent with that delivered in hospital and where advanced interventions are unavailable, meticulous care should be given to the provision of basic airway interventions.
(2) All providers of PHEA should be competent in emergency anaesthesia.
(3) Individual PHEM services should have a robust structure in place for clinical governance providing regular review of clinical practice, local guidelines and SOPs for the management of difficult airways and failed intubations, and a lead

clinician with overall responsibility for the practice of anaesthesia within the PHEM service.

5.2.1 AAGBI guidelines

Reflecting the extensive nature of these guidelines, and the input of multiple authors, I have summarised the sections discussed within the guidelines. The first section of the AAGBI guidelines was an *Executive Summary* and provided a concise description of the key messages of the document in a series of bullet points so even those people reading the document with a time pressure, or not wanting to read the entire guidelines can familiarise themselves with the key points. The whole guidelines deliberately avoids complexity and was structured to provide a framework for safe delivery of emergency anaesthesia by experienced pre-hospital doctors from anaesthetic or non-anaesthetic training backgrounds.

The subsequent sections, *Background*, and *Local Organisation* provided an overall summary on the development and current position of PHEA and acknowledge differences in local infrastructure which may influence the service that is delivered. The guidelines encourage all services to appoint a responsible lead clinician with extensive PHEM experience to deliver specific PHEA training and updates, regular appraisal, robust clinical governance and data collection, frequent case reviews and audit and an adverse event reporting system. The section on *Local Organisation* encountered some difficulty in trying to produce a document that could facilitate the provision of safe PHEA to a wide variety of practitioners with a different skillmix. As discussed, much emphasis was placed on the fact that an anaesthetic delivered in the pre-hospital setting should be delivered to the same standard as that achieved in hospital – this includes the skill level of the person performing the anaesthetic, which has often been a controversial point. In some parts of the UK, the provision of PHEM by specifically trained personnel is limited and whilst a number of these providers are without PHEA competency, they make a valuable contribution to pre-hospital airway management. It is essential that those personnel without PHEA capability ensure that basic airway manoeuvres are applied immediately and effectively for any patient with airway compromise. Wherever possible, appropriate senior support should be

provided remotely. There was much discussion within the working party about whether to acknowledge or include the more controversial and increasingly uncommon practice of pharmacologically assisted laryngeal mask insertion (PALM), a technique used by some personnel without PHEA capability whereby the patient is sedated until a laryngeal mask airway can be inserted. This is a high-risk procedure in any patient, particularly in severely ill and injured patients and in the working party ultimately decided that these particular guidelines should not endorse this practise and the technique was not described. The majority of severely ill and injured patients have intact airway reflexes and require drugs to facilitate tracheal intubation; basic and advanced airway management without PHEA does not reliably correct airway compromise. (111)

Anaesthesia for children aged eight years or under has become a sub-specialist area of in-hospital anaesthesia and young children with severe injuries ae relatively uncommon so PHEA for children was acknowledged but not discussed in detail. The key messages about the standard of care delivered remain the same for this patient group, and the guidelines emphasised that all pre-hospital organisations must have written guidelines for the management of children that accurately reflect the skillset of their practitioners. If the appropriate skillmix is not available in the pre-hospital or difficult circumstances are anticipated or encountered, the child should be rapidly transferred to the nearest hospital for the appropriate airway management, even if definitive care needs to be subsequently undertaken at a different hospital.

The section on '*Personnel and Training'* attempts to address the difficult and controversial area of the level of individual competence required to safely perform unsupervised PHEA. This point was heavily debated by the working party and all the relevant literature was reviewed. Emergency tracheal intubation is undoubtedly a learned skill which is subject to fade if not regularly used in an individual's day to day clinical practice. Studies have demonstrated poor success rates and significant complications when tracheal intubation is undertaken by individuals with an inappropriate level of skill and training. (77) The position taken in the guidelines is that providers should have the same level of training and competence that would enable them to perform unsupervised emergency anaesthesia and tracheal intubation in an ED; these skills should be obtained prior to the transition into the pre-hospital

environment. Once PHEA competency has been achieved, it must be maintained, an average of one PHEA case per month is suggested as the minimum to prevent skill fade.

Equipment and monitoring provides a list of required equipment and suggests this should be similar to equipment used in hospital; clinician familiarity and maintain appropriate standards can reduce error and improve patient safety. The requirement for equipment to be robust, portable, battery-operated and versatile in all light or weather conditions is highlighted. Most equipment used in PHEA is single use to reduce risk of infection and in recognition that services based outside the hospital environment may have limited access to sterilisation facilities. The suggested monitoring for PHEA is in accordance with other recent AAGBI guidelines on monitoring and current in-hospital practice. (42) End tidal carbon dioxide ($ETCO_2$) measurement is now mandatory for any anaesthetic delivered in or out of hospital. (40); a quantitative format is preferred to allow for $ETCO_2$ control in suspected traumatic brain injury.

The section on *Technique* acknowledges the balance between optimising the patient's clinical condition prior to transferring the patient to hospital transfer without delaying access to definitive care. Whilst PHEA increases scene time (232) it is likely to reduce the time spent in ED and therefore the time to receiving definitive treatment. It should only be performed when absolutely necessary and in the shortest time possible whilst maintaining standards and safety. This section further emphasises the fact that equivalent standards should be maintained in and out of the hospital setting, using a simple reproducible technique which is regularly practiced through moulage and simulation. There is significant focus on optimising the first attempt at intubation as subsequent attempts are associated with an increase in morbidity and mortality. (37) It discusses technique in the broad sections of preparation, induction and intubation, and post intubation care. The chapter is deliberately prescriptive to provide a detailed guide for the procedure to ensure patient safety and procedural success. The main components are described in table 5.2.

Table 5.2: Summary of PHEA technique described in 2017 AAGBI guidelines

Preparation	360° access to the patient Patient positioned at appropriate height for intubation, usually ambulance trolley Monitoring applied External conditions managed where possible (lighting, crowd control etc) Standardised 'kit dump' is prepared so that the drugs and equipment necessary for safe anaesthesia are immediately available. Verbal challenge-response checklist for equipment, drugs and doses Verbalisation of failed intubation management plan (30 second drills, supraglottic airway device, surgical airway) Pre-oxygenation and apnoeic oxygenation Team structure and brief (PHEA physician; Anaesthetic assistant; MILS; cricoid pressure and/or laryngeal manipulation)
Induction	Remove hard collar and establish MILS Cricoid pressure –possible reduction in aspiration risk (49) but may impair bag-mask ventilation and laryngoscopic view (71) so low threshold for removal. Drug administration Intubation (limited to 3 attempts) +/- external laryngeal manipulation Tracheal tube placement confirmed and tube secured in place
Post intubation care	Preparation for transfer (accessible intravenous access and adequate drug and oxygen supply) Ventilation targeted to ETCO2 of 4.0–4.5 kPa Lung protective ventilation strategies (tidal volume / PEEP) Maintenance of anaesthesia Triage decision conveyed to team and receiving hospital contacted Documentation

The *Technique* section also addresses the management of failed intubation and states that all pre-hospital organisations must have a written and well-rehearsed 'failed intubation' plan. The number of tracheal intubation attempts should be limited to three (86) and where possible, the conditions for successful intubation improved between each attempt (changing the position of the patient or intubator, changing the size of the laryngoscope blade, suctioning the airway, using external laryngeal manipulation). If a patient becomes hypoxic during attempts, they should be ventilated using a facemask or supraglottic device. Maintaining good communication at all times and verbalising the problem to the team is likely to improve team performance and patient safety. The standard approach if intubation has failed is to attempt to provide adequate ventilation of the patient then attempt to insert a supraglottic airway device. Performance of a surgical cricothyroidotomy is the final step in failed intubation algorithms. (86,88)

Pre-anaesthesia sedation is a technique that may be used when to gain control of a situation if the patient is agitated, confused or combative. (233) In this situation simple interventions such as the application of monitoring, obtaining intravenous access, or effective preoxygenation can be extremely difficult and at times the situation may become unsafe and sedation may be used to sufficiently calm the patient to allow pre-induction interventions to be performed. Sedation itself has an associated morbidity and mortality (234,235) and should only be used when absolutely necessary. The majority of sedative agents cause vasodilatation and subsequently hypotension which can be profound and precipitate cardiac arrest if the drug is not appropriately titrated and monitored. Loss of the airway secondary to deep sedation can result in hypoxia and hypercapnia. $ETCO_2$ monitoring should be used at all times during sedation to confirm the airway is open.

Transfer

I was the author of the final section of the main document focuses on the safe transfer of the patient to hospital so it is presented here in its entirety.

The patient should be transferred to hospital as quickly as possible once tracheal intubation has been established and confirmed and post intubation checks have been completed. The patient should be triaged to the most appropriate hospital, usually an

MTC, unless any criteria for diverting to another hospital are met. Secondary transfer can be detrimental to patient outcome, particularly in time-critical injury. (14) During transfer the patient should be continuously monitored and anaesthesia maintained. Careful consideration should be given to the requirement of additional equipment including a portable suction unit, intubation equipment if the tube becomes misplaced, drugs and intravenous fluids. It is the responsibility of the transferring clinician to ensure all documentation is completed. The receiving hospital should be informed on departure from scene.

As part of my contribution to the AAGBI guidelines, I also wrote a chapter on *Minimum data collection and key performance indicators* which was included as an appendix. Existing data are heterogeneous, making it difficult to draw meaningful conclusions. As pre-hospital advanced airway management has previously been identified as a research priority, (100) and consensus-derived datasets developed (101,236), this section of the guidelines was designed to complement existing data collection tools and continue to promote data collection for future research to improve practice and patient outcome. Adequate data collection is essential to underpin local audit and clinical governance processes.

The following variables have been suggested as part of the minimum dataset reported in table 5.3 below.

Table 5.3: Minimum dataset required to facilitate standardised data collection and research

	Variable to be collected
System	Highest level of EMS provider on scene Airway equipment available Anaesthetic drugs available Methods of transportation Response times
Patient	Age Gender Co-morbidities Estimated weight Presenting illness/injury Indication for airway intervention
Intervention	Vital signs pre and post induction of anaesthesia Drugs (and doses) used Number of intubation attempts Intubation success Management of failed intubation Devices used in successful airway management Adverse events (hypoxia, hypotension, dysrhythmia, aspiration, misplaced tracheal tube, oesophageal intubation (recognised / unrecognised), cardiac arrest

Measuring quality in PHEM can be challenging. Quality indicators are performance measures which are translated from industry and designed to measure the degree to

which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. The quality indicators aim to compare the care delivered against ideal criteria, and identify patients who may have received suboptimal care requiring further review and improvements in the quality of care delivered. (237) The categorisation of *Key Performance Indicators (KPIs)* within an EMS structure has been previously described using the 'Structure Process Outcome' model, (238) this model can easily be translated into defining KPIs for PHEA. The table below shows suggested KPIs for a pre-hospital service delivering PHEA, the exact content of the dataset and KPIs may be modified to specific systems and relevant governance projects. The indicators listed below because they have previously been demonstrated to be associated with good practice in the existing literature or relevant guidelines. In order to make KPI measurement an achievable but effective process it needs to be a straightforward tool, ideally derived from some data that is routinely collected in order to avoid duplicating or significantly increasing individual workload. Measuring only one aspect of the structure process outcome triad is likely to produce a narrow perspective on the quality of the care delivered and one alternative approach is to use mixed indicators that cover different aspects of the overall system. (238) The KPIs suggested in the AAGBI guidelines are designed to cover all aspects of PHEA, specifically focusing on those factors that are likely to influence patient outcome. A further alternative method would be to focus on one or two high impact clinical conditions which may occur during PHEA such as severe hypoxia, or cardiac arrest, which effectively evaluate the quality of the overall system. Focused analysis of this as part of an assessment of quality can lead to the development of care bundles which have been demonstrated to be effective in other aspects of PHEM such as pre-hospital major haemorrhage control. (152)

In 2019, Raitt and colleagues reported on the implementation of the AAGBI KPIs into a PHEM service and described adaptations made to improve the process. I reviewed this article for the Scandinavian Journal of Trauma Resuscitation and Emergency Medicine. Using the AAGBI KPIs and input from consultants working within the service, a list of ten auditable domains were identified. Data were extracted from the electronic patient records of the service and a score was assigned to the identified domains and each domain was analysed. The authors concluded that the use of KPIs focused

attention on the conduct of PHEA with the service and drove improvements in both clinical practice and record keeping. Trends were identified in poorly performing areas, leading to equipment upgrades, clinician education, further studies of system performance and improvements in completion of the EPR. (224)

Table 5.4 Key Performance Indicators for PHEA (AAGBI)

	Key Performance Indicator
System	Routine use of PHEA standard operating procedure and checklist All team members familiar with failed intubation plan Daily equipment checks performed Full monitoring, including continuous waveform capnography, available
Process	Pre-oxygenation performed for 3 minutes Intubation performed by experienced airway provider No decrease of more than 20% in systolic blood pressure No decrease in SaO2 <90%, or fall of >10% from starting value No more than two attempts required for intubation
Outcome	Position of tracheal tube maintained using waveform capnography Adequate anaesthesia maintained during transfer Cardiovascular stability maintained Ventilation titrated to ETCO2

5.2.2 European HEMS and Air Ambulance Committee guidelines

In 2015 I was asked to be a member of the EHAC Medical Working Group (EHAC MWG), a group of airway experts who were tasked with producing guidelines on PHEA and advanced airway management. I wrote the first and subsequent drafts of these guidelines and circulated them for regular review and comments within the expert group. The production of these guidelines overlapped with the development and production of the AAGBI guidelines and highlighted many similarities and differences within the infrastructure of PHEM in the UK and Europe. The process of adapting the advice to suit different pre-hospital systems was very interesting and required versatility in the approach and planning. The EHAC guidelines were developed using a nominal group technique and are shown in full below.

5.2.2.1 Best Practice Advice for Pre-hospital Emergency Anaesthesia and Advanced Airway Management

Background

Effective and timely airway management is a priority for sick and injured patients. Airway management can be classified as basic (simple airway manoeuvres, naso- and oropharyngeal airways) or advanced (placement of a supraglottic airway device, cuffed tracheal tube or surgical airway with or without the provision of emergency anaesthesia). Basic airway interventions should be performed for every patient with airway compromise; emphasis must be placed on performing the intervention well, with repeated assessment of its effectiveness. In some patients, basic interventions will be insufficient to provide adequate oxygenation and ventilation. If appropriately trained personnel are available, advanced airway interventions should be performed, prior to transfer to hospital. (34,111)

The benefit and conduct of pre-hospital emergency anaesthesia (PHEA) is widely-debated topic and has been highlighted by an expert panel as an area to be prioritised in pre-hospital research. (100) Whilst the number of advanced interventions and success rates are increasing, (33,98) the practical aspects of advanced airway management in the pre-hospital setting are not internationally consistent. Many systems performing these interventions in the challenging pre-hospital environment are deficient in one or more key components that help to ensure high quality reproducible interventions. These include well-trained providers, standardised techniques, robust failed intubation drills, key data collection, and a clinical governance structure. The level of care delivered to patients in the pre-hospital setting must be the same as that achieved in hospital. (239) Physician-staffed helicopter emergency medical services (HEMS) have the potential to deliver advanced airway management at this level, but the essential elements must be in place.

Based on published scientific reports and guidelines, (239,240) the EHAC Medical Working Group (MWG) aims to provide 'Best Practice Advice' that will define high standards of care for advanced airway management in pre-hospital systems. The guidelines will focus on safe and practical delivery of PHEA, selection of the correct patient group, and governance standards. Indications for PHEA strongly recommended by the EHAC MWG are:

- Impending or actual hypoxia
- Impending or actual acute hypercapnia
- Threatened or actual loss of airway control
- Severe agitation associated with head injury
- Reduced level of consciousness

The EHAC MWG suggests that the requirement for, and provision of PHEA should be assessed on an individual case basis. Where PHEA is indicated, it should be performed in a timely fashion and should not significantly delay transfer of the patient to hospital. These guidelines are designed for physicians; paramedics performing pre-hospital drug-assisted intubation should meet the requirements of their employers and professional governing bodies.

1) Training

Minimum standards:

Only providers with competence and experience in the delivery of in-hospital drug assisted intubation should deliver PHEA.

- Physicians entering pre-hospital practice should have a minimum of twelve months experience of in-hospital anaesthetic practice (which may include up to six-months intensive care medicine) and a minimum of twelve months experience in emergency medicine and acute medicine, before undertaking PHEA.

- Pre-hospital emergency care services should have a written standard operating procedure (SOP) for the conduct of PHEA. All relevant personnel must be fully conversant with this document.

- Pre-hospital emergency care services should provide appropriate training and competency assessment for all providers on an annual basis.

- All providers of PHEA should be competent in paediatric advanced airway management.

- The provider performing advanced airway management should be assisted by another member of the HEMS team with appropriate training for the safe delivery of PHEA, at all times.

- PHEA should be withheld if the HEMS team do not have the correct skill mix required to ensure safe and effective delivery of the procedure.
- Consultants in pre-hospital emergency medicine should be available for telephone advice at all times.
- All practitioners delivering PHEA should maintain a logbook of individual cases.

Further considerations:

- A relevant PHEA course or thorough induction training should be undertaken prior to starting clinical practice.

EHAC MWG statement: It is well recognised that poorly performed tracheal intubation is associated with an increased morbidity and mortality. (22,40) Repeated attempts at laryngoscopy increase the number of complications including severe hypoxia, regurgitation and aspiration, bradycardia and cardiac arrest. (37,241) The minimum training requirement for pre-hospital practitioners delivering drug-assisted intubation remains controversial. Individual pre-hospital emergency care services should have pre-determined criteria for the minimum training requirements and competency levels before allowing personnel to practice PHEA. There is significant variation in intubation success rates for different groups of pre-hospital care providers with different skill mix. This was confirmed in a recent meta-analysis demonstrating a median intubation success rate for physicians of 99.1% compared with 84.9% for non-physician providers. In the non-physician group, PHEA significantly increased intubation success rate. (58) If a patient can be intubated without the use of drugs mortality is likely to be very high. (10) One study suggested that a minimum of 57 intubations should be performed before providers are able to reliably perform successful tracheal intubation on a consistent basis. This study showed the intubation learning curve reached 90% success rate after a mean of 57 intubations but 18% of participants still required assistance after 80 intubations. (193) Available evidence for annual competency suggests that there is a significantly higher incidence of difficult intubation amongst 'proficient' intubators who performed a median of 18 intubations per year, compared with 'expert' intubators who performed a median of 304 intubations per year ($p < 0.05$). (242) EHAC MWG recommends that all practitioners in pre-hospital care should achieve a minimum of 80 supervised intubations, or spend the equivalent of one-year training in anaesthesia in a hospital setting before attempting pre-hospital drug assisted intubation. Maintaining currency in a pre-hospital environment can be challenging for any procedure. (243) All pre-hospital practitioners should routinely perform tracheal intubation within their regular professional capacity to ensure maintenance of essential skills.

2) Planning

Minimum standards:

- Environmental factors such as ambient light, noise and adverse weather conditions should be considered when deciding where and when to intubate the patient.

- Factors that may influence intubation success should be optimised prior to the first intubation attempt. These include good access to the patient (360-degree access where possible), and optimal positioning of the patient on an ambulance trolley placed at the correct height for the operator.

- Intubation should be performed prior to loading onto the aircraft unless adverse weather conditions prevent safe conduct. Intubation should only be performed in the aircraft provided there is no increased risk of an adverse event during the intubation procedure.

- Intubation must not be planned for, or performed in, the flight phase of aeromedical transfers.

- The triage decision and distance to destination hospital should be considered prior to intubation and discussed with the HEMS team.

Further considerations:

- Aviation regulations must be observed at all times.

EHAC MWG statement: All factors influencing the success of an intubation attempt should be optimised prior to the first attempt including access to the patient, assembly of all required equipment, full monitoring and a verbalised management plan and triage decision. Whilst movement of sick or injured patients should be limited, the EHAC MWG strongly recommends that the patient should be moved to an area with adequate space to permit 360-degree access prior to intubation. Intubation should be performed outside the aircraft unless adverse events such as bad weather, low outside temperatures, or suboptimal light are considered likely to reduce the chances of a successful intubation. The patient should be placed on an ambulance trolley at an optimum height prior to any intubation attempts. The quality of laryngeal view, intubation and first pass success rates have been demonstrated to be optimal when the trolley is placed at chest height for the intubating clinician. (244,245) Once the patient has been intubated they should be loaded onto the aircraft ensuring adequate access to the patient is maintained, with essential 'rescue' airway equipment easily available. The clinical condition of the patient should be reassessed each time the patient is moved to ensure the tracheal tube has not been misplaced or any deterioration has occurred requiring further intervention prior to take-off.

3) Equipment

Minimum standards:

The following equipment is considered essential for all intubation attempts and should be carried by personnel who are qualified to perform PHEA:

- Nasopharyngeal and oropharyngeal airways
- Two working laryngoscope handles with two different sized Macintosh blades
- Intubating bougie
- Cuffed tracheal tubes in appropriate sizes

- Spare tracheal tube (one size smaller)
- 10 or 20 ml syringe for cuff inflation (cuff checked prior to intubation)
- Tube tie or tube holder
- Bag-valve-mask with oxygen reservoir connected to oxygen
- Catheter mount
- Carbon dioxide monitoring (colorimetric and / or quantitative)
- Spare oxygen cylinder
- Suction
- Second generation supraglottic airway device (for failed intubation)
- Surgical airway equipment (e.g. scalpel / tracheal dilators / 6.0 tracheal tube / tube tie)
- Paediatric laryngoscopes with appropriately sized laryngoscope blades (size 1 and 2 Macintosh blades, and size 0 and 1 Miller blades are recommended)
- Uncuffed and cuffed tracheal tubes in appropriate size range for paediatric intubation

Further considerations:

- Videolaryngoscopy

EHAC MWG statement: All pre-hospital systems must have all the required equipment available for each intubation attempt. The service should carry a range of laryngoscope blades and tracheal tubes in different sizes, appropriate for both adult and paediatric intubation. The tube size should be calculated prior to intubation. The use of a challenge-response equipment checklist is recommended.

Videolaryngoscopy is used in an attempt to improve laryngoscopic view and increase the overall intubation success rate and first pass intubation rate. The purpose of videolaryngoscopy is to enable all medical personnel involved to observe visualisation of the glottis and participate in improving the view where possible with interventions such as external laryngeal manipulation and suction. Data on the performance of these devices in improving intubation success rates are limited in this role. Most studies suggest videolaryngoscopes confer a benefit in pre-hospital intubation, (245,246) though certain conditions, such as blood in the airway, may impair performance. (247) Use of an intubating bougie is advocated in the management of difficult airways, usually if the view at laryngoscopy is poor or after one failed attempt at normal laryngoscopy. (73,192) Routine use of a bougie for every intubation can also be considered good practice as it may optimize the first attempt at intubation.

4) Conduct of PHEA

Minimum standards required:

- PHEA should be performed using methods described in the standard operating procedure (SOP) for each individual service. Compliance with, or reasons for deviation from, the SOP should be formally documented.
- A formal checklist for PHEA should be carried out and include confirmation of monitoring, equipment, drugs, and failed intubation management.
- All required equipment should be assembled and checked prior to intubation.

- Drug doses should be calculated prior to intubation and confirmed with the anaesthetic assistant.
- Preoxygenation should be performed for at least 3 minutes before laryngoscopy.
- Each service should have, and be familiar with, a robust failed intubation plan.

Further considerations:

- Apnoeic oxygenation

EHAC MWG statement: There is increasing evidence for the benefit of both checklists and SOPs for many complex interventions. The introduction of such documents into pre-hospital practice has been shown to be feasible, (190) and result in positive behavioural change to achieve the desired standardised care. (79) It is likely to be associated with a reduced rate of failed intubation. (84,98)

PHEA drugs should include an induction agent, an opioid and a rapid-onset muscle relaxant Careful consideration should be given to the type and dose of PHEA drugs, especially in unstable patients. Induction agents can also be omitted in imminent risk of cardiac arrest. Where possible the choice of agents used within individual services should be limited to improve familiarity with the PHEA process, promote the use of reproducible techniques, and reduce human error.

Passive apnoeic oxygenation with high-flow (15 l/min) oxygen via nasal prongs (or alternative methods) is a low-risk procedure. It is currently practiced by a number of pre- and in-hospital trauma services around the world with demonstrable benefit in sustaining SaO_2 above 95% during the apnoeic phase (208) and difficult laryngoscopy. (207) Nasal prongs should be applied to the patient in the preoxygenation phase in conjunction with a standard preoxygenation technique, and remain in situ during the period of drug-induced apnoea immediately prior to intubation. One pre-hospital service demonstrated a 6% reduction in patient desaturation rates during RSI following the implementation of apnoeic oxygenation. (70) Most studies demonstrate a benefit with apnoeic oxygenation, though some do not reflect this finding. A recent randomised controlled trial using 15L/min of 100% oxygen via nasal cannulae compared to standard face mask preoxygenation failed to show any benefit (205) and the use of apnoeic oxygenation remains controversial.

The evidence for cricoid pressure is weak and relatively scarce. The authors recommend consideration of the use of cricoid pressure for PHEA under normal circumstances but practitioners should have a low threshold for removing it if the view at laryngoscopy is impaired.

External laryngeal pressure and manipulation may be of benefit when attempting to improve the view.

5) Post intubation Care and Ventilation

Minimum standards:

- Effective ventilation should be established and confirmed immediately following placement of the tracheal tube. Where available, a mechanical ventilator should be used in preference to hand ventilation, especially for longer transfers.

- The presence of an end-tidal carbon dioxide trace should be confirmed immediately after tube placement.

- The rate of ventilation should be titrated to end-tidal carbon dioxide.
- The position of tracheal tube should be confirmed and documented.
- The patient should be reassessed after each intervention or change of position, and before loading onto aircraft.
- The HEMS crew member(s) should have access to the patient during flight
- Intubation equipment and airway rescue equipment should be immediately available during flight.
- Normoxia and normocapnia should be achieved for each patient. Low to normocapnia should be considered for patients with traumatic brain injury (4.0-4.5 kPa; 30-35 mmHg).
- Ensure the patient is appropriately packaged with consideration given to clot stabilisation if bleeding, fracture immobilisation and maintenance of normothermia.
- Anaesthesia should be adequately maintained.
- The requirement for chest decompression should be considered.

Further considerations:

- Use of arterial blood gas monitoring.

EHAC MWG statement: End-tidal carbon dioxide monitoring is mandatory for all intubated patients and lack of continuous capnography is considered to be associated with an increase in morbidity and mortality. (40) Inadequate (hypo- or hyper-) ventilation can be harmful in intubated trauma patients, and is believed to contribute to an increase in mortality in this patient group, particularly in patients with traumatic brain injury. (65,77) Although outcomes for intubated ventilated trauma patients is undoubtedly multifactorial, good control of ventilation with prevention of hypoxia and hypo- or hypercapnia is likely to be of significant benefit.

Hypothermia in sick and injured patients is widely considered to be detrimental, contributing to systemic dysfunction. One study conducted in a pre-hospital setting observed higher rates of hypothermia (<35^{o}C) in patients undergoing PHEA; the mortality rate was significantly higher in this patient group. (80) The presence of hypothermia in the pre-hospital setting is usually multifactorial and related to environmental exposure for the purposes of assessment and treatment, reduced metabolic function in skeletal muscle, and administration of intravenous fluids. Clinically significant effects on plasma coagulation and platelet function are seen at temperatures below 34^{o}C and the mortality from traumatic haemorrhage is markedly increased when core temperatures fall below 32^{o}C. (248)

6) Monitoring

Minimum standards:

The following should be considered mandatory for all patients:

- Pulse oximetry
- Non-invasive blood pressure
- Heart rate
- Continuous waveform and quantitative capnography
- Continuous temperature monitoring

Further considerations:

- Lactate

EHAC MWG statement: Full monitoring should be attached to the patient prior to induction of anaesthesia and a summary of the information obtained from the monitoring recorded in the patient's documentation. (42) The temperature of the patient should be closely monitored to avoid unwanted hypothermia which may exacerbate acute traumatic coagulopathy, (249) or for targeted measurement for patients in whom therapeutic hypothermia is considered to be of benefit.

7) Special circumstances

- Night operations
- Adverse weather or environmental conditions
- Psychiatric patients
- Pregnant patients
- Children

Pre-hospital management of sick and injured patients is associated with a wide variety of challenges and factors that may influence individual patient management. It would be impossible to produce guidelines that accounted for all variables that may be encountered. Certain circumstances may require deviation from best practice guidelines. All decisions about how to proceed should be case specific and following a dynamic risk-benefit assessment and with a senior clinician providing support for the decision-making process.

8) Data collection and analysis

The practice of PHEA is increasing and adequate data collection is essential to improve practice through local audit and clinical governance processes. The following variables have been suggested as part of the minimum dataset for collection and analysis, table 5.5. (174)

Table 5.5: Data collection required for a minimum dataset (EHAAC)

	Variables
System	Highest level of EMS provider on scene Airway equipment available Anaesthetic agents available Method of transportation Response time Provision of adequate governance structure
Patient	Age Gender Co morbidity Patient category Indication for airway intervention Vital signs pre-induction of anaesthesia (Heart rate, respiratory rate, GCS, systolic BP, oxygen saturation)
Post intervention	Post intervention ventilation Vital signs post induction of anaesthesia ($ETCO_2$, heart rate, systolic BP, oxygen saturation) Survival status Number of attempts at airway intervention Complications (hypoxia, hypotension, arrhythmias / bradycardia, aspiration, misplaced tracheal tube, oesophageal intubation (recognised / unrecognised), cardiac arrest) Drugs used to facilitate procedure Overall intubation success rate Devices used in successful airway management

Further considerations:

Intubation success rate at first attempt

Management of failed intubation

All patient documentation should be completed and data collection should be tailored to the requirements and processes of individual systems.

Necessary derogations / deviations from universal guidelines / standards

Nil

Summary statement

EHAC MWG recommends a standardised approach to pre-hospital emergency anaesthesia and advanced airway management described in a clear and simple Standard Operating Procedure that is followed by competent clinicians. Only personnel with sufficient experience and expertise should deliver pre-hospital advanced airway management. Standards for the pre-hospital procedure should not be inferior to those found in-hospital regarding equipment availability, patient monitoring and post-intubation care. Continuous audit of the Key Performance Indicators is essential to maintain these standards.

5.2.3 Comparison of the AAGBI and EHAC guidelines

Whilst focussing on the same process, the AAGBI guidelines and EHAC guidelines varied in both structure and content.

5.2.3.1 Structure

In producing the AAGBI guidelines, the topic of PHEA was discussed face-to-face by the working party divided into sections and specific members of the working party, considered to be experts in the field of PHEA, were allocated a section to author. The section was structured as descriptive text, and referenced throughout. The EHAC guidelines were composed slightly differently, initially, as for the AAGBI guidelines, the MWG met and discussed how the guideline should be divided into sections. Once this had taken place, I wrote the first draft and then circulated it via email for comment. The comments were incorporated and the process repeated. When the penultimate draft had been agreed, the guideline was presented in a final face-to-face meeting and final amendments made. The EHAC guidelines was structured to give bulleted advice for each section of the guidelines followed by an MWG statement providing the evidence for the advice provided. Recommendations for further consideration were also given based on emerging evidence available at the time of writing. The EHAC guidelines are due for review and update.

5.2.3.2 Content

The key messages of the guidelines were similar:

- Pre-hospital emergency anaesthesia (PHEA) should be carried out to the same standards as in-hospital emergency anaesthesia.
- PHEA should only be carried out in organisations with comprehensive clinical governance arrangements.
- Techniques should be straightforward, reproducible and as simple as possible.
- The intervention should be carried out as soon as safely possible in this patient group.

- Where PHEA is not available, oxygenation and ventilation should be achieved with the use of basic airway manoeuvres and the use of second generation supraglottic airway devices.

The major differences centred around training and the service infrastructure.

Training

Training can be considered in two separate components – firstly the amount of training required to achieve competence prior to undertaking PHEA; secondly the number of PHEA cases that should be undertaken each year to maintain competence. Both of these areas are difficult and controversial. The guidelines attempted to give this issue some substance but it has been widely debated since publication.

The AAGBI guidelines recommend completion of the Acute Care Common Stem training programme prior to entry into PHEM. This training programme is a two-year programme which provides individuals with one year in anaesthesia and intensive care medicine and six months of training in the specialties of emergency medicine and acute medicine. The EHAC guidelines adopt a similar position with regard to in-hospital experience but also to define the problem numerically suggesting a minimum of 80 intubations should be achieved prior to being considered competent to undertake PHEA. With regard to maintenance of intubation as an essential skill, both sets of guidelines suggest that this is likely to be more easily achieved if the practitioner regularly performs emergency anaesthesia in a hospital environment and emphasise the requirement for robust and structured supervision, governance and 24-hour telephone advice from a senior colleague. In addition, there is further emphasis placed on the fact that standards achieved in PHEA should be comparable to in-hospital standards for emergency anaesthesia and PHEA should be withheld if the attending personnel do not have the correct skillmix required to ensure safe and effective delivery of the procedure.

Infrastructure

PHEA delivered in the UK is usually provided by the local HEMS service and patients are transferred to a suitable hospital in a timely fashion. Unlike some areas of Europe, transfer times are relatively short and remote locations are uncommon. The majority of European services are set up to manage much longer distances to reach patients and transfer them to the subsequent hospital. To reflect this, the EHAC guidelines gave consideration to the decision-making process regarding who should be intubated – it may be necessary to intubate sick or injured patients if transfer time is likely to be prolonged; adverse weather conditions – intubation may need to be performed in a vehicle where access is reduced in certain adverse weather conditions; night operations – currently UK night operations are limited and this was not discussed in the AAGBI guidelines but it was suggested in the EHAC guidelines that services develop specific protocols for night operations.

In contrast to Europe and the UK, the United States has a variable EMS model but paramedic-led systems dominate sometimes using physicians for telephone support. Much controversy exists around paramedic intubation with several studies showing higher rates of poor outcome, failed intubation, misplaced tracheal tubes and other significant airway complications (114) (22,58,59,250).

A joint position statement on drug-assisted pre-hospital intubation was produced by the National Association of EMS Physicians (83), the American College of Emergency Physicians, and the American College of Surgeons Committee on Trauma in 2006. Despite key system differences the guidelines are in many respects similar to the UK and Scandinavian guidelines. Standards of the equipment and monitoring used, the use of well-rehearsed failed intubation drills, and a robust clinical governance system are all common. One major difference is direction on the exact level of training that should be given to providers of drug-assisted intubation. Unlike the US guidelines UK and Scandinavian guidelines make it quite clear that providers of pre-hospital anaesthesia should have the same level of competence as in-hospital anaesthesia providers.

5.3 Nominal group technique update of the Utstein-style airway template

In addition to producing the guidelines I was invited to be a panel member for an international panel of experts in PHEA. A five-step nominal group technique was used to identify the most relevant data that should be reported for PHEA then review and update the Utstein-style airway management dataset that was initially developed in 2011. (102) This standardisation of data reporting for PHEA and advanced airway management will aim to reduce the heterogeneity in the data which has been a problem in the literature to date and facilitate better research and subsequent guideline development and evidence-based practice. A core dataset of thirty-two operational and six system variables was agreed using this technique. The updated dataset included risk factors for difficult intubation, checklist and SOP use, pre-oxygenation strategies, drugs used in airway management, airway currency training, airway management strategies, and patient safety issues which had not previously been included. (251)

Chapter 6: Summary

For decades, poor airway management has been a significant cause of morbidity for major trauma patients, and has been frequently quoted as a cause of preventable death despite the evolution of PHEM and formalisation of prehospital emergency anaesthesia (PHEA). This thesis set out to address why this might be the case, specifically focussing on a limited range of key issues.

Data presented in this thesis support the fact that PHEA is a necessary intervention for a small but identifiable subgroup of patients in whom basic airway manoeuvres are insufficient to maintain oxygenation and ventilation, and amongst whom advanced airway management cannot be delayed until hospital arrival. I further report that a significant proportion of such patients are denied this pre-hospital intervention.

The procedure of PHEA is composed of many different components, the majority of which are modifiable. Whilst intubation success rates in physician-delivered services are now usually high, many other aspects of PHEA may yet be improved. PHEA is likely to improve outcomes if the right intervention is delivered to the right patient at the right time by the right person: key will be patient selection, ensuring the provider delivering the intervention has the appropriate skillset, and the use of checklists and standard operating procedures to formalise and standardise the process and reduce human error in a stressful situation. Attention to detail throughout the process of PHEA, including careful preoxygenation, patient positioning and drug dosing, meticulous basic and advanced airway management techniques, and good postintubation care are all likely to improve the morbidity and mortality profile of this intervention.

The publications included in this thesis are specifically designed to target the potentially modifiable aspects of PHEA. Through both my ongoing research interest and my clinical practice I identified several problematic areas in the

PHEA process and designed studies accordingly to address these areas. All the studies had both scientific rationale and clinical relevance and in the majority of cases, were designed with a pragmatic approach to enable a clinician on scene to make the best decision for the patient with the information they have available at the time. Findings made in this thesis have been incorporated into two major sets of national and international guidance (43,95) and have improved PHEA practice worldwide.

Whilst the studies are designed to answer specific questions, in some cases more questions are generated which require further research in order to continue to improve practice. An obvious survival benefit remains elusive but some of the data presented here suggest there is a benefit of early intervention in specific patient groups. I believe standardisation of practice will make future data analysis much easier. Similarly, the use of a national or international database for all patients undergoing PHEA, enabling the collection and analysis of thousands of data points is likely to provide clearer indication of which patients are likely to benefit from pre-hospital emergency anaesthesia and the optimum way of performing the intervention in the pre, peri, and post intubation stages.

Chapter 7: References

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Appendix 1: London's Air Ambulance Standard Operating Procedure Pre-hospital Anaesthesia

A standard operating procedure for PHEA was in use during the time in which the studies described in this thesis were conducted. This is the most recent version of the document – minor modifications were made to the SOP in 2012 as described in section 1.9.

Pre-hospital Care Standard Operating Procedure
Pre-hospital Anaesthesia

REVIEW:	January 2017
APPROVAL/ ADOPTED:	Pre-hospital Care [PHC] Policy Board
DISTRIBUTION:	o PHC Doctors o PHC Paramedics
THIS DOCUMENT REFERS TO:	PHC Clinical Practice
RELATED DOCUMENTS:	o Safety at scene SOP

Aim:

To provide safe and effective emergency anaesthesia for PHC patients.

Objectives:

- Define indications for pre-hospital anaesthesia
- Describe the procedure for performing rapid sequence induction (RSI)
- Describe the procedure for failed intubation
- Define the training plan and final assessment for RSI

Background:

London's air Ambulance personnel carry out just over one RSI a day. This equates to a cumulative service experience of approximately 7500 pre-hospital inductions over approximately 25 years of practice. Although the RSI 'rate' has remained fairly constant the number has increased as a result of increased call volume and the move to 24 hour working. This algorithm has been developed to be simple and safe. For many years the algorithm consisted of RSI and surgical airway for failed intubation. This led to a surgical airway rate of around 1% - approximately half of which followed failed intubation and half were performed as primary procedures (where intubation was not attempted). This compares well with emergency room surgical airway rates for severely injured patients. We have added alternatives in the latest algorithm after careful examination of our pre-hospital experience and because of developments in airway management and published literature on management of the difficult airway. However we still expect the vast majority of our patients with airway compromise to either be intubated or get a surgical airway. We mainly see two types of patients who require drug assisted intubation – those who can have a controlled procedure with a few minutes of preparation and a small group who require immediate intervention with little or no time for preparation. Training should prepare the pre-hospital team for either situation.

Basic information on the drugs that we use can be found in the resource file. Ketamine is used as an induction drug, rocuronium and suxamethonium as muscle relaxants and midazolam and morphine for sedation, maintenance and analgesia. Ketamine with midazolam is used for procedural sedation and analgesia. These particular drugs are used because of their relative haemodynamic stability and their relatively wide therapeutic margin – a 10 or 20% overdose is unlikely to cause significant problems (which is relevant in a working environment where patient weight is usually estimated.

Indications for RSI

1. Actual or impending airway compromise
2. Ventilatory failure
3. Unconsciousness

4. Humanitarian need

5. Injured patients who are unmanageable or severely agitated after head injury

6. Anticipated clinical course

The decision to anaesthetise patients should be made on the basis of an 'on-scene risk-benefit assessment' in every case i.e. in each specific situation, do the potential benefits of RSI outweigh the potential risks?

Choice of drugs for induction

We have demonstrated that a 'quick look assessment' often identifies the group of patients in which most difficult laryngoscopies are likely to be encountered. We have also identified that in a significant number of our patients induction without an opioid results in significant hypertension after induction.

Option 1: Standard induction: fentanyl 3 micrograms/kg (estimated weight) followed by ketamine 2 mg/kg and rocuronium 1 mg/kg. ('3:2:1')

Option 2: 'Hypotension' or 'Frail' induction: fentanyl 1 micrograms/kg (estimated weight) followed by ketamine 1 mg/kg and rocuronium 1 mg/kg. ('1:1:1')

Option 3: Anticipated difficult intubation: ketamine 2 mg / kg + suxamethonium 1.5 mg / kg. Rocuronium 0.6 mg/kg after tracheal intubation achieved.

In patients suspected to have severe hypovolaemia the dose of induction agent and Fentanyl need to be significantly reduced. 50% of the standard dose for ketamine should be administered in the majority of these patients ('1:1:1'). Fentanyl may be omitted entirely and in some circumstances it may be appropriate to administer a muscle relaxant alone eg rocuronium only. The '3:2:1' and "1:1:1' are starting induction guides for our two commonest situations – the fit young normovolaemic patient and the hypovolaemic or patient with probably significant co-morbidities. Depending on the experience

of the anaesthetist and the state of the patient alterations may be made to these 'starting recipes' to optimise the induction.

Ketamine is best avoided in patients with significant cardiac disease or post ROSC from a cardiac cause of an arrest. Induction with 1 to 3 microg / kg Fentanyl +/- a small dose of Midazolam (depending on BP and conscious level 0.01 – 0.1 mg/ kg / 1- 10mg) and normal dose of Rocuronium is a reasonable solution in these patients. Advice should be sought in case of uncertainty.

Intubation Algorithm [Appendix 1]

- Address scene safety issues before RSI is considered, as described in the safety at scene SOP.
- Where possible establish 360 degrees of access to the patient before RSI. This may involve moving the patient to another part of the scene or onto an ambulance trolley. Even if the patient is in near or absolute cardiac arrest this may the first manoeuvre. Do not attempt intubation or RSI in confined or cramped conditions unless there is simply no alternative - it is preferable to perform this outside or on a trolley in an ambulance.
- Commence monitoring with the Propaq monitor. Remember the Ambulance Service has a monitoring device provides a reserve SpO2 and end tidal CO2 monitoring capability. Standards of monitoring satisfy the recommendations of the Association of Anaesthetists for in-hospital anaesthesia.
- Preparation for RSI: Preparations should be automatic and absolutely standard. Optimise the first attempt at intubation. Always use a size 4 laryngoscope blade in adults and in children above the age of 12 years. The flight paramedic establishes monitoring and rapidly provides a standard, laid out 'kit dump' [appendix 2] of equipment. Before commencing induction the doctor and flight paramedic run **rapidly** through the 'challenge / response' RSI checklist. [appendix 3]. There are two checklists – one for 'Urgent' RSI and one for 'Immediate' RSI.

- After administration of induction drug (+/- opiate) and muscle relaxant the patient is intubated and tube position is checked by the following: direct vision (tube seen passing through cords, 'Easi-Cap™' colourimetric CO2 detector / continuous sidestream CO_2 detection and auscultation in both axillae and over the stomach.
- Where an adequate view of the vocal cords cannot be obtained, carry out the '30 second' drills. They are named to indicate that they should be easily completed long before the blood of a normal pre-oxygenated patient starts to desaturate.

Pre RSI Sedation

- In agitated patients it may be necessary to use small amounts of sedation to facilitate pre-oxygenation. Titrate small doses (1- 2mg of midazolam) to effect. In patients who are obviously hypovolaemic and hypotensive, use even smaller doses.
- In non head-injured patients with severe limb trauma, ketamine (20 -30 mgs titrated to effect) can be used.

Pre-oxygenation

- Preoxygenate all patients in order to increase the time to commencement of desaturation. The aim of pre-oxygenation is to replace the nitrogen in the lungs with oxygen thus maximising the available reservoir of oxygen, and reduce episodes of hypoxaemia during the drug-induced apnoeic phase of RSI.
- Preoxygenation should be performed by ensuring that the patient has a tight fitting face-mask and nasal prongs, both with oxygen attached. A patent airway is essential: if necessary, use airway adjuncts (nasopharyngeal, oropharyngeal, manual airway manoeuvres).
- The nasal prongs should remain in situ for the duration of the intubation attempts to ensure ongoing passive oxygenation.
- In patients with severe facial injuries, pre-oxygenate and induce anaesthesia in the most comfortable patient position that enables good airway maintenance.

- Patients with a high BMI achieve better pre-oxygenation in a slightly (15 degrees) head-up position (with cervical spine protection maintained) or in the sitting position.

Failed intubation

- The i-gel is the default device for ventilation following a failed intubation attempt. This device minimises gastric inflation and the risks of aspiration and is therefore preferable to bag-mask ventilation (BMV).
- If no further changes can be made to improve the chances of successful intubation at a further attempt, then the options are to leave the i-gel in place for transport (if it is functioning well) or to consider a surgical airway if it is not. If anatomy / morphology of the neck suggest this will be difficult or the physician decides that the risks of surgical airway outweigh the possible benefits, the i-gel should be left in place.
- Rarely consideration should be given to allowing a patient to wake and spontaneously breathe during transfer. Cautious sedation with midazolam may be required to maintain control of the situation. Since in our patient population anaesthesia is only indicated where absolutely necessary the vast majority of our patients are not suitable for this management option.

I-gel™ device

- Although we carry the i-gel™ as an alternative airway device, we expect it to be used rarely and expect the majority of failed RSIs in our system to be rescued with a surgical airway.
- We have chosen the i-gel™ instead of a standard LMA because, even with adequate muscle relaxation, many of our patients require relatively high airway pressures. This device has been demonstrated to allow ventilation at higher airway pressures without leakage compared to the Classic LMA™.
- Manufacturer information is available in the resource file. The device is inserted until the black line reaches the teeth. It is then tested and tied

in place. A size 4 i-gel™ is suitable for all but the very tallest adult patients.

- It is used in preference to bag-mask ventilation to prevent gastric inflation and an increased risk of aspiration. It may rarely be inserted blindly into trapped patients in whom access is severely limited and augmentation of ventilation required. If this situation resolves the airway compromise, small boluses of propofol may be used to transport the patient to hospital.
- Paediatric i-gel devices are carried in the Monitor bag.

Surgical Cricothyroidotomy

- Remove the surgical airway equipment from its pouch when it is anticipated that an airway will be particularly difficult. For example:

    - Airway trauma
    - Difficult anatomy
    - Burns to face and neck precluding jaw movement
    - Possible airway burns

- The technique of surgical cricothyroidotomy we use is rapid, reliable and relatively easy. It addresses two problems that we have commonly seen in the pre-hospital environment which make some of the 'standard' techniques less appropriate. (The Difficult Airway Society now recommends a very similar technique). These are bleeding from the incision and loss of the incision into the airway before or during tube insertion. A scalpel blade is carefully inserted horizontally into the cricoid membrane using a "stab / rocking" technique. Leaving the blade in position, a tracheal hook or tracheal dilator is pushed into the incision and traction maintained. The scalpel blade is removed and (with counter traction on the tracheal hook or after opening dilators) a 6.5 mm cuffed tracheal tube is inserted (over a lubricated intubating bougie if necessary) into the trachea. The cuff is inflated, tube position confirmed in the normal way and ventilation commenced. The tube is then fixed in

position with a tie or Elastoplast. The whole procedure should take only around 30 seconds.

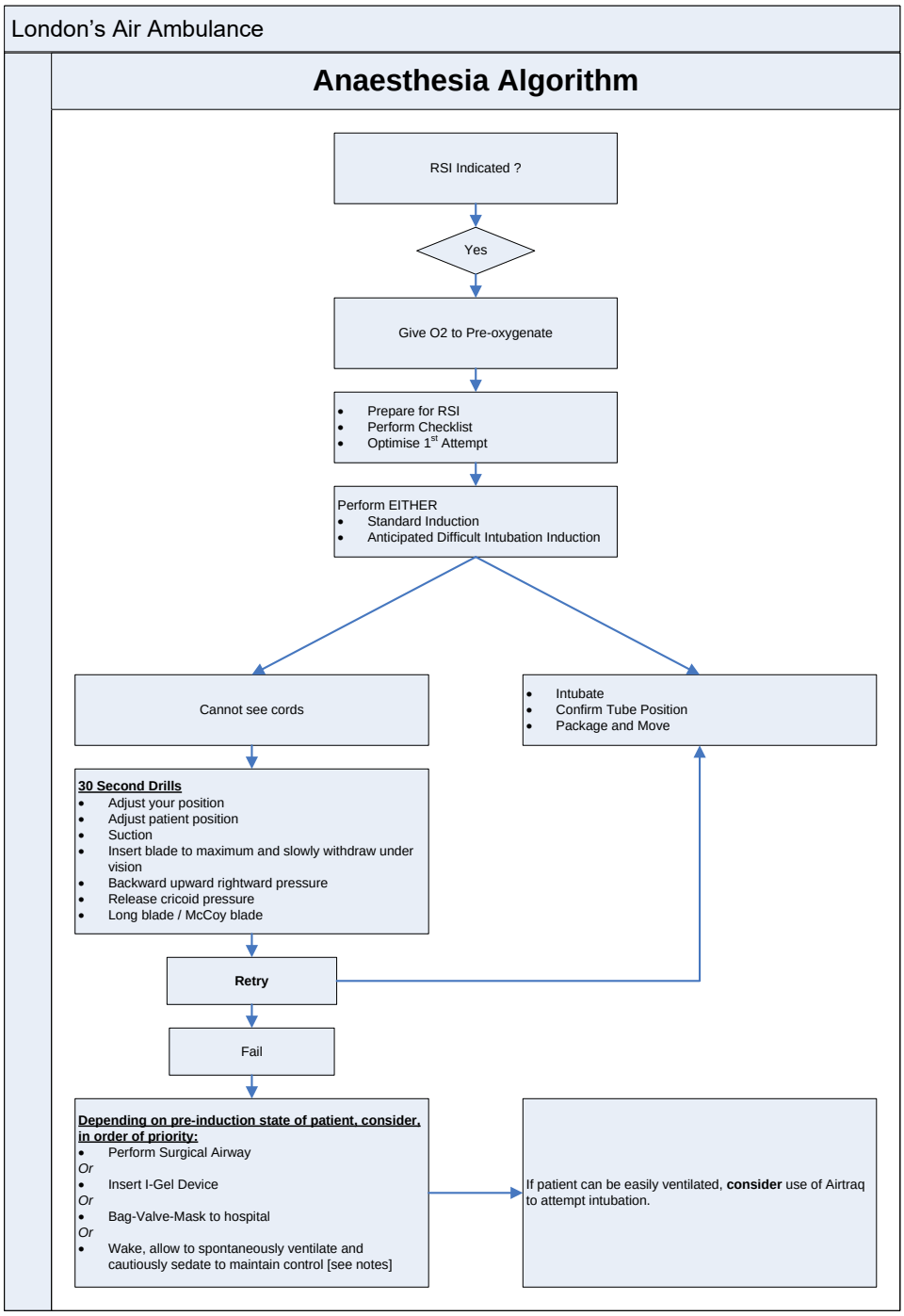
The Airtraq airway rescue device

A number of video-laryngoscopic devices are now readily available. Some are complex and others have unacceptable battery requirements. The Airtraq is disposable, easy to use and has an integrated battery. It has however been found to perform poorly in the presence of blood in the airway. This device should be used to assist intubation in patients who have had induction of anaesthesia and who can be oxygenated with bag-mask ventilation but not intubated with direct laryngoscopy.

Paediatrics

- Pre-hospital anaesthesia of small children is required only rarely. For many children the risks of pre-hospital RSI outweigh the potential benefits. Where airway compromise cannot be overcome with simple airway manoeuvres, the risk-benefit equation may change and drug-assisted intubation may become appropriate. The experience of the pre-hospital team attending the child may also influence the risks and benefits.
- The duty PHC Consultant should be consulted prior to undertaking paediatric anaesthesia.
- Equipment for paediatric intubation is kept in the 'paediatric intubation pack'. Drug dose calculators are available and, if the age of the child is known, drug doses should be calculated on the journey to scene using age + 4 x 2 for all ages, taking into consideration the body habitus and cardiovascular status
- Paediatric i-gels are carried as an airway rescue device. Needle cricothyroid equipment is carried for paediatric use but is difficult to use effectively on scene or during transfer.

The 'Intubation Algorithm'



The 'Kit-dump'

- Monitoring on – running on automatic setting at 3 minute intervals
- Spread out yellow disposable bag and lay out:
    - Laryngoscope [size 3 and 4 blade]
    - Bougie

- Tracheal tube [cuff tested]
- Circuit: Easicap, catheter mount, filter [side stream connected]
- 20 ml syringe
- Alternative smaller tube [cuff tested].
- Alternative laryngoscope [alternative blade size].
- 2 x nasopharyngeal airways
- 1 x oropharangeal airway

- Ensure availability of:
  - Bag-mask connected to O2 tubing.
  - Spare O2
  - Difficult airway kit [surgical cric./ surgical airway pouch]
  - Spare drug roll
  - Airtraq device

- Place suction to the right hand side of the patient's head. The 'Yankauer' suction catheter must be tested.

The Standard checklist

The purpose of the talk through is to:

- Allow a defined period of preoxygenation
- Check that all the necessary equipment is present and working
- Ensure the position of the patient is ideal for intubating
- Reduce the chance of failed intubation

Address every step in the procedure in the order equipment will be used. This way no piece of equipment is missed out. While talking through, ensure the patient has a tightly applied reservoir mask and that the reservoir is moving with respiration.

HEMS pre-RSI challenge-response check list

Note: This checklist is for use with stable patients. Time should not be wasted on agonal patients who require precipitant RSI (where pre-oxygenation and obtaining a set of obs may not be possible)

Nasal prongs applied for apnoeic oxygenation **Check**
Oxygen mask on tight & reservoir bag moving with ventilation……. Check
Two oxygen cylinders >half full …… Check
Spare cylinder next to patient ……..... Check
Baseline BP seen & monitor set to 2 minutes…….…… Check
Baseline saturation seen……. Check
Sidestream CO2 connected to monitor…… …. Check
Other monitoring attached …….. Check

IVI / Drugs
Cannula connected to fluid and runs easily…….. Check
Spare cannula in situ…… Check
Fentanyl dose 'x' mcg ……..……'x' mls……. Check
Ketamine dose 'x' mg…….. 'x' mls…….. Check
Roc/Sux dose 'x' mg…….. 'x' mls…….. Check

Laryngoscopes
Mac / Miller 'x' & bulb working…….. Mac / Miller 'x' Check
Alternate blade 'x' & bulb working..... Mac / Miller 'x' Check

Suction working and positioned……. Check
Back-up suction available…… Check

ET tubes
Bougie size 'x' ……size 'x' Check
Tube size 'x' ……..... ....size 'x' Check
Tube cuff tested & connector secure…… Check
Syringe for cuff…….. Check
Alternative tube size 'x' ……size 'x' Check

BVM functional and connected to flowing oxygen…… Check

Circuit:
Filter ……..... Check
Sidestream …….. . Check
Easycap …… Check

Tube tie…… Check
iGel/AirTrac available…… Check
Surgical airway kit available……. Check
Oesophageal temperature probe available……. Check
Guedel & 2 nasopharyngeals…….... Check
Thoracostomy ?..... Check

In-line immobiliser briefed…… Check
Cricoid pressure person briefed……. Check

HEMS Immediate Induction Checklist

(For patients requiring immediate drug-assisted intubation)

- Oxygen
- Nasal prongs / apnoeic oxygenation
- Drugs (induction and relaxant)
- Laryngoscope
- Suction
- Bougie
- Tube (size)
- Syringe (for cuff)
- Easycap
- BVM

Step in Talk through	Common problem	Benefits
Check baseline observations and cycle time for propaq.	Propaq slipped into manual mode and displaying old readings	
Check oxygen reservoir mask is tightly applied	No seal on mask, bag not working as reservoir, bag too cold and stiff to move in winter	Maximises pre-oxygenation
Check oxygen supply [where possible an E size cylinder]	Oxygen about to run out no reserves close at hand	Avoids hypoxia
Remove cervical collar		Jaw movement for laryngoscopy and cricoid / BURP
Check position of head and neck	Patient on scoop or floor with neck in extension, head in flexion, slight neck lat flexion	Maximises view.
Check drip is patent and easily flushed and not on side of BP cuff (or cuff down)	Drip not put in by you may never have been in or may have tissued	Avoids partial or non delivery of drugs, minimises chances of failed intubation
Check drugs and doses to be given. Check operator familiar with the doses to be given	Excess given though miscommunication [see sedation and analgesia SOP].	Avoids hypotension, ICP spikes or failed intubation through inadequate paralysis.
Check operator can perform cricoid pressure, is on left of patient & understands BURP	Most ambulance staff do not know how to perform either correctly.	Better view at laryngoscopy Minimises chances of aspiration

	Operator usually on patients right and makes view worse with BULP	
Check laryngoscope functions and working spare is present	Weak battery, damaged bulb	Equipment presence Equipment failure
Check suction is present and working	Not present at scene Weak battery with poor function Wrong suction device	Equipment presence Equipment failure
Check bougie	In summer the bougie can become very soft	Equipment presence Equipment failure
Check tube is correct size and balloon does not leak	Tube's cuff balloon has small leak	Avoids need for tube change
Check presence of catheter mount, Easicap, filter and capnography		Ensures tracheal position of tube
Check valves in self inflating bag that reservoir and oxygen supply are attached		Equipment presence Equipment failure
Check tie		Equipment presence

Appendix 2: Training package for delivery of apnoeic oxygenation

All clinicians delivering PHEA during the apnoeic oxygenation study period were asked to familiarise themselves with the information below and answer the assessment questions to safely incorporate the procedure into standard clinical practice. In addition, apnoeic oxygenation was included in the PHEA checklist used by the service. The relevant documentation was placed in the 'team read' file. Each clinician is responsible for keeping themselves up to date with the information contained within this file and a form must be signed to demonstrate the information has been read.

The training package consisted of three documents:

1) Summary of apnoeic oxygenation study
2) Description of rationale for the intervention and the procedure
3) Information and sign off for team read file

1) Summary of apnoeic oxygenation study

Background

Trauma patients are more susceptible to adverse events during RSI due to the presence of trauma-related physiological and anatomical derangements. It has been reported that 18.3% of patients undergoing pre-hospital RSI have a reduction in oxygen saturation (SaO_2) to less than 90%, or a fall of more than 10% fall if the initial value of SaO2 was less than 90% during the RSI or subsequent transfer to hospital. A decrease of this magnitude may be of great significance to oxygenation: the fall in the arterial partial pressure of oxygen is greater once the saturation of arterial blood with oxygen (SaO_2) falls below 93%. This might account for why episodes of hypoxaemia are associated with worsening morbidity and an increase in mortality.

Preoxygenation is a universally accepted method of reducing episodes of hypoxaemia during the drug-induced apnoeic phase of RSI. Current standard practice typically involves use of a non-rebreathe facemask supplying 100% oxygen. Passive apnoeic oxygenation via nasal prongs is a low-risk procedure currently practiced by a number of pre- and in-hospital trauma services around the world with demonstrable benefit. One pre-hospital service demonstrated a 6% reduction in patient desaturation rates during RSI following the implementation of apnoeic oxygenation. It can help sustain SaO_2 during apnoea or difficult laryngoscopy.

This study aims to establish whether passive apnoeic oxygenation is superior to a conventional mask preoxygenation strategy in preventing desaturation. If so, mortality or morbidity may be reduced in such patients.

Inclusion criteria

- Trauma patients attended by the London Air Ambulance doctor-paramedic team who undergo pre-hospital rapid sequence induction of anaesthesia.

Exclusion criteria

- Patients who are intubated following a medical event
- Patients who are intubated prior to London's Air Ambulance arrival
- Patients in cardiac arrest upon London's Air Ambulance arrival
- Patients with epi-stats in situ for maxillofacial haemorrhage
- Patients less than 16 years of age

Interventions

Patients undergoing pre-hospital RSI will receive additional oxygen via nasal prongs at a flow rate of 15 L/min, placed on the patient when the decision to perform RSI is made. The standard non-rebreathe facemask will also be applied to the patient as per normal practice and the nasal prongs will remain in situ for the duration of the RSI. If SaO_2 falls below 90% at any time during the preoxygenation phase in patients, gentle bag-valve-mask ventilation should be

performed in an attempt to limit the hypoxic episode, in accordance with current standard practice.

In the event of a multiple casualty scene, apnoeic oxygenation should be used on the first patient undergoing RSI. It can also be used for subsequent patients if there is adequate equipment.

Primary endpoint

- The number of patients in the study groups in whom SaO_2 falls to less than 90% in the peri-RSI period

Secondary endpoints

- Lowest SaO_2 recorded for each individual patient in the peri-RSI period
- Time to lowest SaO_2 recorded for each individual patient
- Proportion of patients experiencing mild / moderate / severe hypoxia, defined as:
    - None: SaO2 always $\geq$96%
    - Mild: a recorded SaO_2 value of 90-95%
    - Moderate: a recorded SaO_2 value 85-89%
    - Severe: a recorded SaO_2 value $\leq$ 84%
- Area under SaO_2/time curve during intubation

2) **Description of rationale for the intervention and the procedure**

Rationale

- Used to improve oxygenation during the drug-induced apnoeic phase of emergency intubation – beyond that which can be achieved with preoxygenation

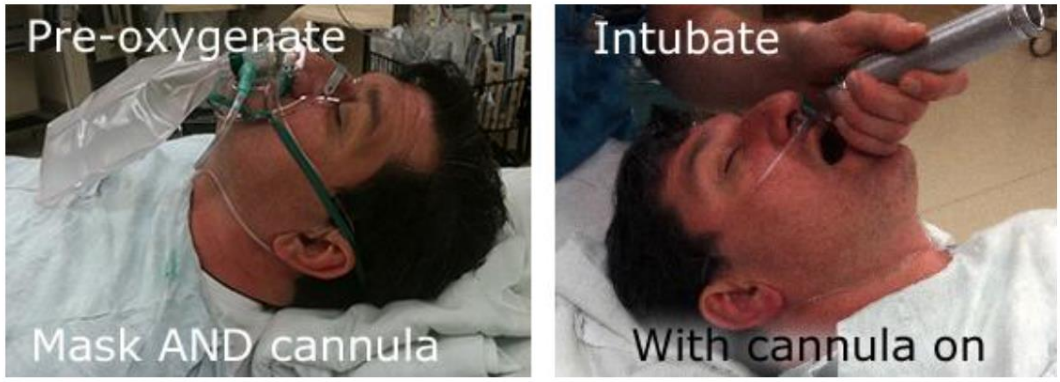
- Passive diffusion of oxygen occurs across the alveolar capillary membrane, causing decreased pressure within the alveolus and generating air movement from the nasopharynx to the alveolus.

Application of 100% oxygen via nasal prongs promotes movement of oxygen-enriched air into the alveoli

- Apnoeic oxygenation can reduce desaturation during difficult laryngoscopy. It is unlikely to lead to adverse events

Procedure

- Apply nasal cannulae with an oxygen flow rate of 15L/min to the patient and proceed with normal preoxygenation strategy
- Leave nasal cannulae in situ at flow rate of 15 L/min whilst laryngoscopy is performed – remove when correct position of the tracheal tube is confirmed



Please contact Kate Crewdson if you have any questions:

[redacted]

3) Information and sign off for team read file

1) Familiarisation with background literature in study resource file and rationale for use of apnoeic oxygenation sign off

2) Familiarisation with equipment required and practical delivery of the intervention and sign off

3) Familiarisation with modified SOP and training package

4) Question completion

<u>Apnoeic Oxygenation Questions</u>:

1) What is the physiological explanation for the proposed benefit of apnoeic oxygenation?
2) What percentage of patients have been shown to desaturate during pre-hospital RSI and which study reported this finding?
3) Where are the nasal prongs located in the HEMS kit?

Required element	**Completed to satisfactory standard**
Theory read and understood	
Questions answered	
Moulage completed	

Signed off by…….....

Date……

Appendix 3:

Survey for checklist analysis study

1. For which of the following services are you the lead clinician or medical director?
    a. A local British Association of Immediate Care Services, (BASICS), scheme
    b. A UK – based Helicopter Emergency Medical Service, (HEMS)?
2. Does your HEMS or BASIC service provide, at least some of the time, pre-hospital general anaesthesia in the form of rapid sequence induction, (RSI), using at least an induction agent and muscle relaxant?
    a. Yes
    b. No, (if you answered *yes* please continue to question 4, if you answered *no* that is the end of the survey)
3. How many patients does your service assess and treat in the pre-hospital setting on an annual basis?
    a. Exact number
    b. Unknown
4. Do you maintain a database of all pre-hospital RSI's performed in your service?
    a. Yes
    b. No
5. If known how many RSI's are currently performed annually in your service?
    a. Exact number
    b. Unknown
6. If known how many RSI's are performed annually for trauma specifically?
    a. Exact number
    b. Unknown
7. In your service when is pre-hospital RSI available?
    a. Always-24hrs a day

b. Always but daylight hours only
c. Sometimes
d. Never

Standard Operating Procedures

8. Does your service currently have and use a formal written *Standard Operating Procedure* (SOP), for pre-hospital RSI?
    a. Yes
    b. No (if you answered *yes* please go to question 9 if you answered *no* please answer 'N/A' until you get to question 15)
9. What year was an SOP for pre-hospital anaesthesia introduced in your service
    a. Exact year
    b. Unknown
    c. N/A
10. Does your SOP for pre-hospital anaesthesia contain provision for the clinician to choose from more than one induction agent and/or more than one neuromuscular blocking agent?
    a. Yes
    b. No
    c. N/A
11. How was SOP for pre-hospital RSOI itself developed?
    a. From local consensus opinion and/or a review of the evidence and/or from the extensive experience of pre-hospital RSI's in your service
    b. Copied from that of another pre-hospital service
    c. Adapted from that of another pre-hospital service
    d. Unsure
    e. N/A
12. Which of the following methods are used in your service to increase operator familiarity with pre-hospital RSI SOP's before allowing them to perform pre-hospital RSI?

a. Simulation
b. Didactic lecture-based training
c. Written information provided to clinicians
d. No methods used
e. N/A

Checklists

13. With regard to the use of a formal written pre-induction checklist in your pre-hospital service, which of the following is true?
    a. In my service a formal written pre-induction checklist exists and its use is both mandatory and routine
    b. A written pre-induction checklist exists but its use is not mandatory
    c. My service does not currently have a formal written pre-induction checklist, (if you answered *my service does not current have a formal written pre-induction checklist*, that is the end of the survey. However, if you answered yes, please go to question 14
14. What year was a formal pre-induction checklist introduced in your service
    a. Year exact
    b. Unknown
15. What is the format of your checklist?
    a. Read-do (single user)
    b. Challenge-response (two person)
16. Does your service use a separate checklist for those patients who are peri-arrest, sometimes referred to as a *crash-induction checklist* and those patients who do not require such an expeditious intubation?
    a. Yes – a different checklist is used for each of these scenarios
    b. No – the same checklist is used regardless if the patient is peri-arrest or not

    c. If a patient is peri-arrest clinicians are not required to utilise a pre-induction checklist

17. How was the checklist itself developed?
    a. From local consensus opinion and/or a review of the evidence and/or from the experience of multiple RSI's in your service
    b. Copied from that of another pre-hospital service
    c. Adapted from that of another pre-hospital service
18. Is compliance with using the pre-induction checklist among clinicians formally audited?
    a. Compliance with checklist usage is audited on a routine basis
    b. Compliance with checklist usage is audited infrequently on an ad hoc basis
    c. Compliance with checklist usage is not audited
19. How often is the content and layout of your pre-induction checklists reviewed and/or revised?
    a. Frequently
    b. Infrequently
    c. Our pre-induction checklists are not reviewed or revised
20. Is feedback sought from clinicians involved directly in delivering pre-hospital RSI with regards to checklist length, content, layout and the logistics of utilisation?
    a. Feedback is sought from clinicians who perform or are involved in the delivery of pre-hospital RSI and is done routinely and formally
    b. Feedback is sought from clinicians who perform or are involved in the delivery of pre-hospital RSI but is done informally and/or infrequently
    c. Feedback is not sought from clinicians who perform or are involved with pre-hospital RSI
21. What training methods do you use to increase operator familiarity with pre-induction checklists before using them in a clinical environment?
    a. Simulation
    b. Didactic lecture based training

c. Written information provided to clinicians
d. None

22. How often are the training methods mentioned in question 28 utilised as a way of familiarising clinicians with pre-hospital RSI checklists and SOP's?
    a. Always before a clinician starts work with the service and at regular intervals during their practice and whenever checklists and/or SOP's change?
    b. Always before a clinician starts work with the service but no on-going training
    c. Not consistently
    d. Never
23. Do you ever vary the order in which items to be checked are listed on written pre-induction checklists?
    a. Yes
    b. No