Health Services Safety Investigations Body

Investigation report

Advanced airway management in patients with a known complex disease

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Theme:
Respiratory, Acute

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A note of acknowledgement

We would like to thank Ethan’s father, Paul, who contributed to this report and shared with us his experience of caring for Ethan. We would also like to thank the healthcare staff who engaged with the investigation for their openness and willingness to support improvements in this area of care.

About Ethan

Ethan was described by his father as a boy who always had a smile for you. When he knew you well, he would love to hold your hand. Ethan was very loved and is very much missed by his family.

About this report

This is a legacy investigation completed by the Health Services Safety Investigations Body (HSSIB) under the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016.

This report is intended for healthcare organisations, policymakers, and the public to help improve patient safety in relation to the airway management of people who have complex health problems which may affect the anatomy of the airway. The report provides information about the management of difficult airways and associated risks. It refers to people who may require additional help with their breathing and specifically ‘intubation’ in patients who have an anticipated difficult airway.

Because this report is about a person with a complex disease who had an emergency related to their airway, it is technical in places. The report contains language and words which are relevant to healthcare professionals. The ‘Background’ section explains some of the medical equipment and language used.

Executive summary

Background

This investigation looks into patient safety issues associated with airway management – the techniques used by healthcare professionals to help patients to get enough oxygen into their lungs, for example during surgery or a medical emergency.

The investigation focuses on the potential safety risks to people who may have a ‘difficult airway’ – that is, the anatomy of their mouth, throat or windpipe makes it difficult for health professionals to manage their airway. This can be the case for people with certain complex health conditions or diseases. In particular, it looks at the use of advanced airway management techniques including intubation, where a tube is passed through a patient’s mouth or nose, then down into their lower airway. The tube keeps the upper part of the airway open so that air can get through to the patient’s lungs.

There is no standardised definition of a ‘difficult airway’. However, it is generally referred to as a clinical situation in which a healthcare professional who is skilled at airway management encounters difficulty with one or more standard methods of airway management.

As an example, which is referred to as ‘the reference event’, the investigation considered the airway management of Ethan, a boy aged 12 who had a diagnosis of Hunter syndrome (a genetic condition that often affects the anatomy of the airway). Ethan was admitted to an emergency department after having a seizure at home. Attempts to intubate Ethan failed and he died.

The investigation’s findings, safety recommendations and safety observations aim to help healthcare professionals quickly recognise whether someone has a potentially difficult airway and may need advanced airway management techniques to keep their airway open. Some of the findings and conclusions may also be applicable to other health conditions.

The reference event

Ethan was taken to an emergency department (ED) by ambulance after his sister found him struggling to breathe and moving in a strange way. The ED staff thought that he was fitting and that this was likely caused by a lack of oxygen to his brain.

Ethan was given medicine in the ED to control his fitting. Basic airway management techniques, such as adjusting the position of his head, neck, and jaw, were used to help keep his airway open. He was prescribed and given additional oxygen. It was thought that Ethan may need to be intubated to help keep his airway open, but the procedure was predicted to be difficult because of his Hunter syndrome and severe obstructive sleep apnoea (a sleep disorder where the airway becomes blocked).

Ethan was monitored for several hours and the risks of intubation versus managing his airway using basic airway management techniques were continually assessed. Ongoing discussions took place with Ethan’s care team at the specialist (tertiary) hospital and with a patient retrieval service (the service that would be used if Ethan needed to be transferred to a hospital with a

paediatric intensive care unit). Ethan began to show signs that his condition was deteriorating, and he was getting tired, so a decision was made to move to advanced airway management and specifically, intubation.

To ensure the best possible conditions for a potentially difficult intubation, Ethan was taken to one of the hospital's operating theatres. This had more space and easier access to more specialised airway management equipment than the ED. Intubation using a camera (videolaryngoscopy) was attempted but was unsuccessful. Ethan was given oxygen between consecutive attempts at intubation. The difficult airway guidance was followed, and an emergency opening was created at the front of his neck so a tube could be inserted into his windpipe. This was also unsuccessful. An on-call ear, nose and throat (ENT) consultant was contacted as the team was unable to intubate Ethan. Attempts at creating an airway using surgical techniques were unsuccessful and Ethan died.

The investigation

A challenging airway is a well-recognised problem in people with a known complex disease, for example a metabolic disease like Hunter syndrome. The effectiveness of enzyme replacement therapies for people with metabolic disorders means their life expectancy is improving and therefore as they live longer, they may need surgical procedures for complications of their disease. During surgical procedures where a general anaesthetic is required, normally routine procedures such as tracheal intubation may be particularly difficult. Recognised rescue strategies should intubation fail (for example the creation of an emergency front of neck airway) may also be more difficult. Both procedures may be even more difficult if they are attempted in an emergency.

Risks associated with intubation include minor injury or damage to teeth, lips, mouth, or nose. Serious problems can occur when providing adequate oxygen is difficult or impossible and can lead to emergency front of neck airway procedures, airway trauma, unplanned admission to intensive care units, and can result in brain injury or death.

There are no standards for how an anticipated difficult airway is managed. In addition, healthcare professionals working in primary, secondary, and tertiary care (for example, GP practices, hospitals and specialist units), may not all have access to information about a patient's anticipated difficult airway. These issues were explored as part of the investigation.

Findings

- There is no nationally recognised system for sharing clinical information about people with a known difficult airway between primary, secondary, and tertiary care.

- There is no standard process for documenting and sharing an individualised airway management plan for people with a complex disease to all health care professionals and services involved in their care.
- Multidisciplinary team meetings to discuss the care of people with a complex disease and who have a known difficult airway are not happening consistently between primary, secondary, and tertiary care.
- Existing guidance for healthcare professionals on how to care for people who have a complex disease and may have a difficult airway is not always co-ordinated and consistent.
- There is currently no national standard for treating people with a known potentially ‘life threatening’ difficult airway who require advanced airway management.
- The requirement for additional skills, for example a head and neck specialist or ear, nose, and throat (ENT) specialist, in emergency situations where a patient requires advanced airway management is challenging as 24-hour on-site ENT provision is not available in every hospital.
- Training and competency assessment in videolaryngoscopy is not standardised and there is variability in how and when videolaryngoscopy is used.
- Training and competency assessment for anaesthetists on airway rescue techniques such as emergency front of neck airway (eFONA) is variable.
- The design of equipment to support advanced airway management does not consistently include robust user testing at a national level to help identify and understand risks.

HSSIB makes the following safety recommendations

Safety recommendation R/2024/013:

HSSIB recommends that NHS England identifies and implements a system for sharing clinical information about people with a known difficult airway. This is to improve access to this information for healthcare professionals and reduce the risk of a person’s known difficult airway not being recognised.

Safety recommendation R/2024/014:

HSSIB recommends that the Royal College of Anaesthetists works with the Difficult Airway Society and other key stakeholders to produce a framework on the management of a potentially ‘life threatening’ difficult airway for people with a known difficult airway who require advanced airway management. This work should consider the adoption of a common language which defines and explains principles for treating people with a known potentially ‘life threatening’ difficult airway who require advanced airway management. This could optimise the chances of survival for people who experience a life-threatening airway emergency.

Safety recommendation R/2024/015:

HSSIB recommends that the Royal College of Anaesthetists makes changes to its Guidelines for the Provision of Anaesthetic Services (GPAS) requirements for all anaesthetists, to include guidance on:

- requirements for anaesthetists to have access to videolaryngoscopes in all locations where anaesthesia is delivered and airway management takes place
- requirements for all anaesthetists to be competent and skilled in the use of videolaryngoscopes
- requirements for anaesthetists to be regularly updated on airway rescue techniques, such as emergency front of neck airway
- requirements for anaesthetists and anaesthetic assistants to be regularly updated on other equipment that may be used in airway emergencies.

This will support anaesthetic staff to become familiar with and competent in the use of airway rescue equipment and techniques available locally.

Safety recommendation R/2024/016:

HSSIB recommends that the Royal College of Anaesthetists works with the Association of Anaesthetists and relevant key stakeholders to implement critical incident training for all anaesthetists and anaesthetic assistants. This should include consideration of scenario-based training and include the principles for the management of an expected or unexpected difficult airway using advanced airway techniques, including videolaryngoscopy and emergency front of neck airway.

HSSIB makes the following safety observations

Safety observation O/2024/010:

Healthcare organisations that commission elective (planned) surgical services for people with mucopolysaccharidoses (MPS) can improve safety by involving healthcare professionals from different disciplines who are experienced in airway evaluation and management, before, during and after a person's surgery.

Safety observation O/2024/011:

Healthcare organisations could improve safety of the management of difficult airways by procuring equipment that has evidence of safety by design and robust user testing and assessment.

Safety observation O/2024/012:

Healthcare providers can improve patient safety by supporting and encouraging anaesthetic staff, anaesthetic assistants and operating department practitioners to become familiar with and experienced in the use of airway rescue equipment and techniques available locally, including videolaryngoscopy.

HSSIB notes the following safety action

Safety action A/2024/001:

The British Inherited Metabolic Diseases Group has amended the content of their guidance with specific reference to specialist guidance from the Royal College of Anaesthetists and the Difficult Airway Society in relation to videolaryngoscopy and incorporating reference to both planned and unanticipated/acute airway interventions.

1. Background and context

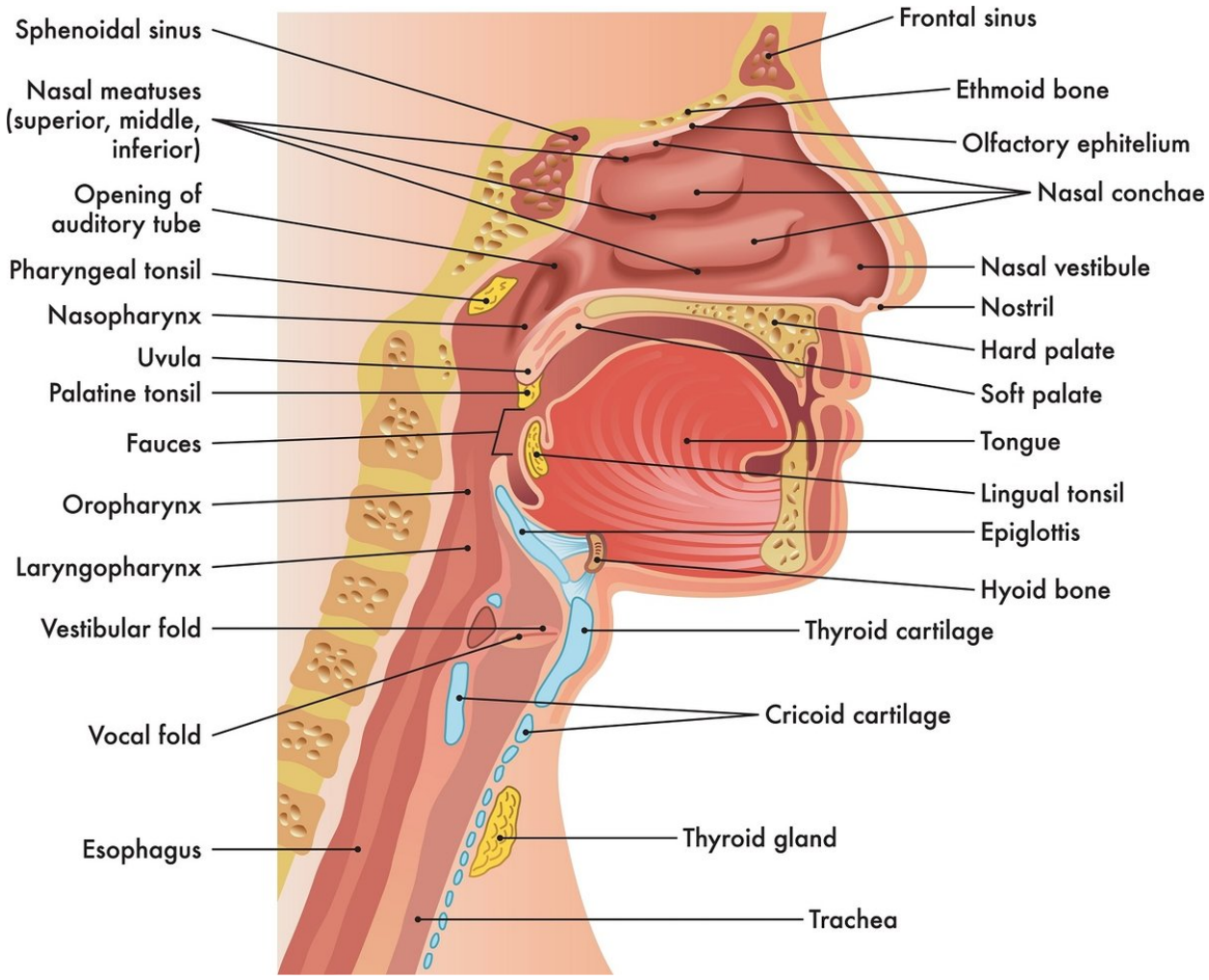
This section provides background information about the aspects of health and care considered in this investigation, including:

- the anatomy of the airway and the techniques used by medical professionals to help patients who need additional help with breathing
- what is meant by a ‘difficult airway’ and national guidance relating to difficult airway management
- information about Hunter syndrome and how it affects a person’s airway
- other definitions to help readers understand the clinical information referred to in the report.

1.1 The anatomy of the airway

1.1.1 The airway or breathing passage is the pathway through which air flows into a person’s lungs. It starts from the nose and mouth and includes the throat, windpipe, and lungs.

Figure 1 Anatomy of the airway (the nose, mouth and larynx)



1.1.2 Failure to provide an adequate airway for people who cannot maintain one can result in brain injury, with long-term implications for function and quality of life, or death (Cook et al, 2011).

1.2 Basic airway management

1.2.1 Some people in hospital, for example those with a reduced level of consciousness, may need help with keeping their airway open. This is because the tongue and soft palate can obstruct the upper airway. Basic airway management involves the use of non-invasive techniques without the need for specialised medical equipment. In these circumstances healthcare professionals will use basic airway manoeuvres which relieve upper airway obstruction (Resuscitation Council UK, 2021). Examples of basic airway manoeuvres that do not require equipment include:

- A head tilt and chin lift – this involves placing one hand on the patient's forehead and the other hand under the patient's chin and tilting the head back while lifting the chin forward to extend the neck.

- Jaw thrust – this involves lifting the patient's jaw by placing two fingers under the angle of the jaw on each side of their face and placing the thumbs on their cheeks and lifting the jaw forwards.

1.2.2 Some people with Mucopolysaccharide (MPS) diseases, including Hunter syndrome (see section 1.5) may suffer from the neck vertebrae moving beyond their normal range (cervical instability). It is therefore important that the vital juncture between the head and neck (the cervical junction) is always considered unstable until proven otherwise as forcing it may compromise the spinal cord and be life threatening. In these circumstances, jaw thrust may be an alternative way of opening the airway, followed by a chin lift using fingertips. There is a risk of cervical spine injury if head tilt is used in these patients.

1.2.3 Sometimes an additional airway device is needed in combination with the basic airway manoeuvres, such as an oropharyngeal airway or a nasopharyngeal airway:

- An oropharyngeal airway, also known as a 'Guedel airway', is a curved plastic tube with a flange (protruding rim) at one end. It sits between a patient's tongue and hard palate preventing the tongue falling backwards and occluding the airway.
- A nasopharyngeal airway is a hollow soft plastic tube with a bevel (sloping edge) at one end and a flange at the other. The airway is inserted into a patient's nasal passageway and sits in the nasopharynx (see figure 1). This type of airway device is typically better tolerated in people who are partly or fully conscious compared to oropharyngeal airways, which may cause a person to gag.

1.2.4 Additional oxygen can be given using a face mask. Sometimes a bag-mask device may be needed to support ventilation (the movement of air into and out of a patient's lungs). The self-inflating bag can be connected to a face mask. As the bag is squeezed, the contents are delivered to the patient's lungs. Additional oxygen can be attached as needed.

1.2.5 Sometimes basic airway manoeuvres even with an additional airway device are not sufficient and more advanced airway management techniques may be needed to aid oxygenation and ventilation of a patient's lungs.

1.3 Advanced airway management

Supraglottic airway devices

1.3.1 Supraglottic airway devices (SGAs) have become an essential tool in airway management and are an alternative to face mask ventilation and/or tracheal intubation (Gordon et al, 2018) (see 1.3.2 to 1.3.7). Different sorts of supraglottic airways have different characteristics. Training in their use and experience are required to ensure their safe use.

1.3.2 The use of SGAs may enable more effective ventilation and reduce the risk of air getting into a patient's stomach and increasing the risk of regurgitation and inhaling food or fluid into the lungs (pulmonary aspiration). They are a good alternative to the bag-mask ventilation and have a role in anaesthesia, resuscitation, and airway rescue. These devices were used in the reference event as detailed in section 2. Examples of SGAs include:

- Laryngeal mask airways (LMAs)
- I-gel airways.

Tracheal intubation

1.3.3 A tracheal tube is like an SGA or tracheostomy, a form of artificial airway. It is the most commonly used airway in emergencies, in higher risk patients and in those at risk of pulmonary aspiration. Tracheal intubation may be necessary when a person's airway is blocked or damaged or if they cannot breathe on their own. It should be carried out by appropriately trained staff.

1.3.4 Intubation is the process of inserting a tube called a tracheal tube into a patient's mouth or nose and then into their airway (trachea) to hold it open. Once in place, the tube is connected to a bag that gets squeezed, or a machine called a ventilator, to push air in and out of the lungs. There are several reasons why intubation may be needed, but it is mainly used to support a patient's breathing during surgery or in an emergency.

1.3.5 Staff may use a laryngoscope (or videolaryngoscope, see 1.3.8) to guide a tracheal tube into the patient's mouth or nose and through their trachea (see figure 2). The tube keeps the patient's airway open so air can get to the lungs.

Figure 2 Tracheal intubation



1.3.6 A direct laryngoscope is used by the person intubating (for example an anaesthetist), to sweep the tongue out of the way and lift up the epiglottis so that the larynx and vocal cords are visible. The anaesthetist then looks down into the patient's mouth and inserts the tracheal tube under direct vision into the trachea (see figure 3). A good view of structures helps with tracheal tube placement when using a standard direct laryngoscope.

1.3.7 Awake tracheal intubation (ATI) is defined as successful placement of a tracheal tube in a patient who is awake and breathing spontaneously. It comprises several techniques aimed at successfully securing the airway of patients in whom factors may predict difficult airway management (Vora et al, 2022).

Videolaryngoscopy

1.3.8 Videolaryngoscopes may be used to help the placement of tracheal tubes. A videolaryngoscope has a camera on the blade that projects the picture onto a videolaryngoscope screen. This means that the person intubating can 'see around the corner' and get a better view of the larynx and vocal cords, than they would do if they were just looking into the patient's mouth (Kelly & Cook, 2016). The view onto a videolaryngoscope screen is

useful for teaching intubation techniques, particularly in people with difficult airways as the whole team can see the same view, improving teamwork and communication (Kelly & Cook, 2016; National Institute for Health and Care Excellence, 2018; Hansel et al, 2022).

Emergency front of neck airway

1.3.9 Occasionally it will not be possible to ventilate a patient who is not breathing with a bag-mask, and/or to pass a tracheal tube or other device into their airway. In the circumstances where all other attempts at providing oxygen for a patient have failed it is necessary to attempt to create an airway through the neck, directly into the trachea. This is called ‘emergency front of neck airway’. This may be the case for someone with extensive facial injuries or whose airways are swollen and/or narrow, causing an obstruction in their airway.

1.3.10 The two types of emergency front of neck airway (eFONA) procedures are known as cricothyroidotomy and tracheostomy. In the vast majority emergency situations, a tracheostomy is advised against because it is time consuming, hazardous and requires considerable surgical skill and equipment. Substantial bleeding can occur (Difficult Airway Society, 2015; Pracy et al, 2016).

1.3.11 Scalpel cricothyroidotomy involves making an incision (cut) in the patient’s neck to create an airway that can be used to ventilate the patient’s lungs until intubation, or a tracheostomy is performed. Scalpel cricothyroidotomy enables ventilation of the lungs even if a patient’s airway is completely obstructed at, or above, the glottis (the opening into the windpipe).

1.3.12 The DAS (2015) guidelines suggest a standardised approach to eFONA with scalpel cricothyroidotomy as it is judged to be most likely the fastest and most reliable method of securing the airway. This is a temporary procedure providing only short-term oxygenation.

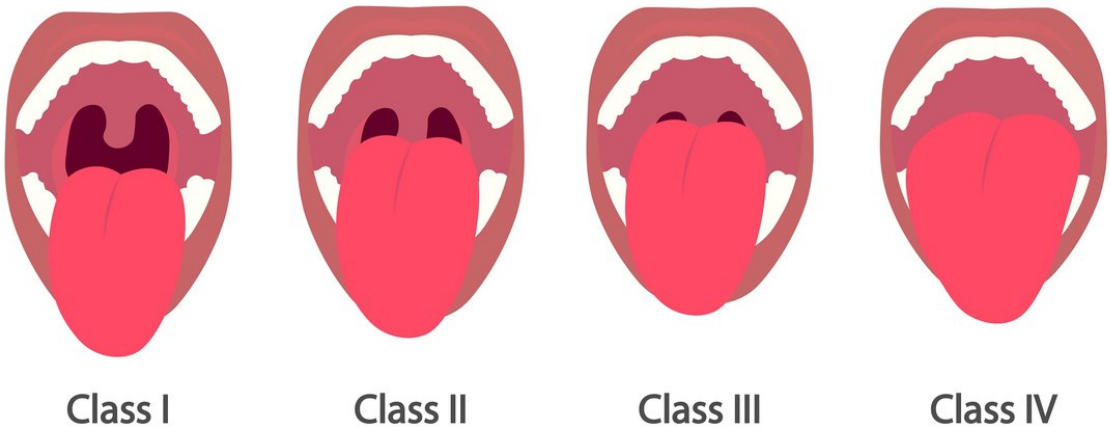
1.4 Difficult airway

1.4.1 The term ‘difficult airway’ is not ‘a specific anatomical characteristic of a patient, but the result of a combination of anatomy, clinical situation, clinician's level of expertise and available airway equipment resources’ (Roth et al, 2019). Reasons for a difficult airway associated with a patients anatomy include:

- difficulty in opening the patient’s mouth
- injury or swelling in the patient’s airway
- problems with a patient's jaw
- a growth in the patient’s mouth or neck
- the patient having had radiotherapy to their mouth or neck
- stiffness of the tissues of the pharynx and throat.

1.4.2 Anaesthetists are trained to assess patients before an anaesthetic is administered and to determine whether their airway is likely to be difficult. Mallampati et al (1985) published a ‘non-invasive score’ for the evaluation of airways, called the Mallampati grading scale. This originally consisted of three different classes and has been modified several times (Ilper et al, 2018). The test comprises a visual assessment of the distance from the base of the patient’s tongue to the roof of their mouth, and therefore the amount of space in which there is to work. The latest version of this score is based on a 1 to 4 scale.

Figure 3 The Mallampati score



Class I: The patient’s tonsils, uvula, and soft palate are completely visible. Class II: Hard and soft palate, upper tonsils, and uvula are visible. Class III: Hard and soft palate are visible, uvula is somewhat obscured. Class IV: Only hard palate is visible.

National guidance relating to a difficult airway

1.4.3 The Difficult Airway Society (DAS) is a UK-based medical specialist society formed to ‘enhance and promote’ safe airway management. The DAS trains healthcare professionals in the practice of airway management. DAS has produced national guidelines for airway management for patients who are under anaesthetic. These cover topics including:

- difficult intubation guidelines – overview
- management of unanticipated difficult tracheal intubation in adults
- failed intubation, failed oxygenation in the paralysed, anaesthetised patient
- difficult mask ventilation during routine induction of anaesthesia in a child aged 1 to 8 years
- unanticipated difficult tracheal intubation during routine induction of anaesthesia in a child aged 1 to 8 years

- cannot intubate and cannot ventilate (CICV) in a paralysed anaesthetised child aged 1 to 8 years (Association of Paediatric Anaesthetists, n.d.; Difficult Airway Society, 2015). A 'cannot intubate and cannot ventilate' (CICV) is the same scenario as 'cannot intubate cannot oxygenate' (CICO). CICO has replaced the CICV term because of the priority of oxygenation, delivering oxygen being the priority.

1.4.4 Awake tracheal intubation (ATI) guidelines have been produced in anticipation of improving the care of patients with predicted difficult airway management in the UK and beyond (Ahmad et al, 2020) and these include guidance on the management of unsuccessful ATI.

1.4.5 DAS also provides guidance on setting up a difficult airway trolley (DAT) (Difficult Airway Society, n.d.a). The guidance is intended to help staff to put together a logically and comprehensively stocked DAT that is fit for purpose for the individual organisation within which it will be used, so that the equipment is readily available in an emergency.

1.4.6 The Royal College of Anaesthetists has Guidelines for the Provision of Anaesthetic Services (GPAS). These guidelines support anaesthetists in delivering ‘high quality anaesthetic services’ (Royal College of Anaesthetists, n.d.a). The guidelines were accredited by NICE (in 2016) and are designed for anaesthetists with managerial responsibilities to set recommendations which inform how anaesthetic departments are run. The GPAS shape the standards used by the Anaesthesia Clinical Services Accreditation scheme (Royal College of Anaesthetists, n.d.b), and national regulators also recognise them.

1.4.7 The British Inherited Metabolic Disease Group (BIMDG) provides a standard on ‘Anaesthesia in patients with mucopolysaccharidoses (MPS)’ (2013).

1.5 Hunter syndrome

1.5.1 Hunter syndrome (mucopolysaccharidosis type II, also known as MPS II), is one of a group of inherited metabolic disorders collectively termed the mucopolysaccharidoses (MPSs) that can affect both children and adults. (MPS Society, n.d.; National Organization for Rare Disorders, 2019).

1.5.2 Although there is no cure for Hunter syndrome, there are treatment options that may help to improve the quality of life for people affected by it. Enzyme replacement therapy can help make the disease more manageable (MPS Society, n.d.).

1.5.3 People with Hunter syndrome may have an abnormally large head, a short neck and broad chest, and progressive growth delays resulting in a short stature. Breathing problems and a chronic runny nose are common.

1.5.4 The airways in MPS conditions are usually more complex than many other complex airways. Hunter syndrome results in the depositing of mucopolysaccharides in the tissues which result in thickened and stiff tissues. These often effect the airway structure including the tongue which makes moving these during intubation very difficult. These deposits can also result in stiffening of the tissues in the neck resulting in inflexibility of the neck. People who have Hunter syndrome can be ‘extremely difficult’ to intubate.

1.5.5 People with Hunter syndrome can develop sleep apnoea. Sleep apnoea is when a person’s breathing stops and starts while they are asleep. The most common type is called obstructive sleep apnoea (OSA) (NHS, 2022). The severity of sleep apnoea is usually calculated by medical staff during a sleep study, which monitors a person’s brain waves, blood oxygen levels, heart rate, and breathing while they are asleep (Summer and Singh, 2023).

1.5.6 Some people with sleep apnoea have their breathing supported using a special device that delivers a flow of oxygen-enriched air at a constant pressure through tubing and a mask, or hood. This is known as continuous positive airway pressure (CPAP). CPAP is a form of non-invasive (that is, used outside the body) respiratory support that is used when the person is awake and able to breathe on their own.

1.5.7 Hunter syndrome is a life limiting illness. Average life expectancy varies considerably. The life expectancy in patients with the severe form (MPS IIA) is only about 10-15 years; however, those with the milder form (MPS IIB) may live well into the seventh or eighth decades of life with supportive care and management (Defendi, 2023).

1.6 Retrieval service

1.6.1 The retrieval service is an intensive care service which transports critically ill children from local hospitals to paediatric intensive care units. The service is made up of doctors and nurses from a critical care setting who are trained in stabilising and transferring critically ill children. The retrieval service team also gives advice to staff in NHS trusts before a child is transferred to another hospital. The retrieval service can also provide intensive care to a child before the transfer, either by ambulance, helicopter, or aeroplane.

1.7 Levels of care – primary, secondary, and tertiary

1.7.1 The NHS is a complex network of healthcare services that cater to the diverse health and care needs of people accessing care. There are three main levels of care:

- primary care (for example GPs) and community services (for example, care delivered at home, in community hospitals, intermediate care facilities, clinics and schools)
- secondary care (care in hospitals either as an emergency or for planned care)

- tertiary care (highly specialised treatment).

2. The reference event

This investigation used the following patient safety incident, referred to as ‘the reference event’, to examine the issues associated with the care of people with a known difficult airway.

2.1 Ethan's story

Background

2.1.1 Ethan was diagnosed with Hunter syndrome (see 1.5) soon after his second birthday. Ethan communicated through eye movement and touch.

2.1.2 Ethan’s medical care was overseen by a GP, a community paediatrician (specialist in children’s health), community nursing staff and a multidisciplinary team of staff at a specialist tertiary centre hospital (see 1.7).

2.1.3 Ethan received weekly enzyme replacement therapy to manage his condition (see 1.5.2) and travelled to the tertiary centre for specialist appointments.

2.1.4 Hunter syndrome particularly affected Ethan’s breathing system. He had a shrunken neck, an enlarged tongue, and had narrow nasal passages. These anatomical changes resulted in Ethan snoring, having thick secretions and being unable to keep his airway open when he lay down (see 1.5.4).

2.1.5 In 2017 Ethan had an operation to remove his tonsils and adenoids to try to improve his symptoms. Following a sleep study in 2019, Ethan was diagnosed with severe obstructive sleep apnoea (OSA) (see 1.5.5). The OSA meant his breathing would stop intermittently.

2.1.6 In 2021, a further sleep study confirmed a diagnosis of ‘severe obstructive sleep apnoea’ causing the oxygen levels in his blood to fall below the expected range. Ethan was awaiting an assessment of his breathing using continuous positive airway pressure (CPAP) (see 1.5.6). This was to see whether CPAP would help his breathing at night and would reduce his sleep apnoea.

2.1.7 Ethan’s father was informed by doctors that his (Ethan’s) airway was the “biggest risk” caused by his syndrome.

2.1.8 Ethan had a heart condition linked to his Hunter syndrome. Ethan's father had been given a 'cardiovascular alert card' by the tertiary centre. This gave information on which symptoms would require Ethan to be seen urgently in an emergency department (ED). Ethan's father was told to present the alert card to a hospital if Ethan needed to be seen for any of the symptoms on the card. This alert card specifically related to symptoms linked to Ethan's heart.

2.1.9 Ethan had been admitted to the local hospital ED in February 2022 because he was struggling to breathe. It was concluded at this time that he had a cold. He was treated with saline nasal drops and discharged home with advice to come back if his condition deteriorated.

Attendance at the emergency department

2.1.10 In April 2022, Ethan's sister found him having a "fit" (seizure). An ambulance was called. Ethan was taken to the local hospital and was admitted to the ED at approximately 14:00 hours. Ethan did not have any family members with him at this point. Ethan's care was handed over from the ambulance crew to the clinical team in the ED, who assessed him at 14:07 hours. Ethan was noted as being 'drowsy with a reduced level of consciousness'.

2.1.11 Ethan was assessed as having 'noisy breathing with significant oral secretions'. Staff used non-invasive methods to help open Ethan's airway and support his breathing, which included using specific techniques to help stop Ethan's tongue obstructing his airway (see 1.2). Ethan was placed in several different positions to try to improve his ability to breathe. This included a chin lift procedure and a jaw thrust (see 1.2.1).

2.1.12 A nasopharyngeal tube (see 1.2.3) was passed through Ethan's nose to aid his breathing. Initially the tube helped Ethan to breathe; however, it had to be removed as Ethan "would not tolerate it" because it was uncomfortable.

2.1.13 Ethan was prescribed and administered medication (buccal midazolam) to stop his fitting. The decision to prescribe this was made because of the history the ambulance crew handed over and because Ethan was noted to still be making jerky, involuntary movements.

2.1.14 Staff made a care plan which included maintaining Ethan's airway. Other treatments given to Ethan in the ED included administration of fluids directly into his veins, additional medication to control his fitting, antibiotics (due to concerns that he might have pneumonia) and pain relief (paracetamol).

2.1.15 During their initial assessment, healthcare staff identified that Ethan may need more specialist paediatric intensive care and the local hospital did not have a paediatric intensive care unit (PICU). The local hospital contacted the tertiary centre with overall responsibility for

Ethan's care for more detailed information about Ethan. In addition, they alerted the retrieval service (see 1.6) for advice in case Ethan needed to be transferred to another hospital for more specialist care.

2.1.16 Staff attempted to gather information regarding Ethan's medical history from their hospital computer system. Staff identified that Ethan had attended the ED with breathing difficulties 3 months before. No other medical information regarding Ethan was found on the local hospital computer system.

2.1.17 Ethan's father arrived within 30 minutes of Ethan attending the ED. He provided staff with more information regarding Ethan's medical condition. He also gave staff Ethan's cardiac alert card.

Considerations for managing Ethan's airway

2.1.18 The initial advice from the retrieval service, at 14:38 hours, was that Ethan should be intubated. However, the retrieval service changed its advice within 7 minutes of the end of the initial call after a consultant was informed of Ethan's Hunter syndrome. A consultant from the local hospital and the on-call consultant for the retrieval service then discussed Ethan at 14:45 hours. The retrieval service consultant stated, "it will be quite a challenging intubation therefore get a videolaryngoscope and adult anaesthetic team … a very difficult intubation and should not be taken lightly".

2.1.19 The medical records show that there was ongoing communication throughout the afternoon and into the evening between the hospital, the tertiary centre, and the retrieval service. The consensus was that Ethan would have a difficult airway to manage (see 1.4). The retrieval service and the tertiary centre agreed that the local hospital should "hold off" on the intubation if possible and give Ethan time to "come around" after the medication to manage his fitting had taken effect.

2.1.20 There was a recognition that intubation may be a "longer term" consideration if Ethan could not maintain his oxygen levels within the expected range.

2.1.21 It is documented in the medical records that Ethan did not appear to be getting any worse and at times throughout the afternoon he was 'more responsive' and 'alert'. However, he still required basic airway management techniques to help maintain his airway consistently.

2.1.22 Other types of non-invasive breathing support, to administer oxygen via little plastic tubes into Ethan's nostrils, were tried to help his breathing.

2.1.23 Between 18:50 hours and 20:30 hours various healthcare professionals assessed Ethan and noted that his breathing had improved and was less noisy. Ethan's latest blood gas results indicated that he was "less acidotic" and his carbon dioxide levels had "improved slightly", (meaning his breathing was more effective). The staff noted that Ethan was awake and was "looking around" and his oxygen levels were within the expected range. There was agreement among the healthcare professionals that Ethan did not require intubation at this time. The tertiary centre and retrieval service agreed with the local hospital assessment and the retrieval service was stood down.

Intubation preparations

2.1.24 From 20:30 hours Ethan's breathing became intermittently worse. His oxygen levels were lower than the expected range and blood gas results at 20:55 hours confirmed that Ethan's condition was not as stable as it had been. Ethan's deterioration was escalated to the wider team including consultant anaesthetic and paediatric staff who assessed Ethan. A physiotherapist saw Ethan at 21:00 hours to help to remove the excessive secretions which were blocking his airway. Some improvements to his breathing were observed and his oxygen levels returned to within the expected range.

2.1.25 At 21:30 hours Ethan was transferred from the ED to the operating theatre in view of possible intubation due to his 'fluctuating condition'.

2.1.26 As Ethan was likely going to be intubated, he would require transfer to a hospital that had a PICU. The retrieval service was contacted and was asked to transfer Ethan. A computerised tomography (CT) scan was requested by the retrieval service to find out whether Ethan had sustained any brain injury because of the fitting. The retrieval service advised that Ethan's airway should be secured by intubation before having the CT scan. The tertiary centre did not have any beds, however another hospital with a PICU did have a bed for Ethan.

2.1.27 Ethan was assessed at approximately 22:00 hours in the operating theatre. The assessment was carried out by an on-call consultant anaesthetist who had been made aware of and updated on Ethan's care throughout the afternoon and had seen him earlier in the evening at 19:30 hours. Their assessment on arrival at the operating theatre was that Ethan was 'not in respiratory distress' (that is, he was getting enough oxygen and clearing enough carbon dioxide without too much effort) and his heart rate and blood pressure were noted as being in 'normal range'. A plan to use CPAP was agreed between consultant staff and the retrieval service consultant.

2.1.28 Ethan did not tolerate the CPAP from the moment it was attempted. Because of his increased work of breathing and him getting more tired, a decision was made to intubate Ethan at approximately 23:37 hours.

2.1.29 A verbal briefing was given to the operating theatre team. Staff checked the necessary operating theatre equipment which included specialised intubation equipment and a difficult airway trolley (see 1.4.5).

Intubation attempts

2.1.30 At 23:47 hours Ethan was given medication to put him to sleep and relax his muscles. Ethan was attached to monitoring devices which included capnography, which is used to measure the amount of carbon dioxide in exhaled air. He was given 100% oxygen for 5 minutes and the oxygen levels in his blood were maintained at 100%.

2.1.31 An initial attempt at intubation was made at 23:49 hours using videolaryngoscopy (see 1.3.8) with a hyperangulated blade (a medical device used during intubation). The view of Ethan's airway was assessed as a 'Grade 4 view' (see 1.4.2). Ethan's oxygen levels started to drop below the expected range and therefore Ethan was reoxygenated using a bag-mask (see 1.2.4) until his oxygen levels were back within the higher end of the expected range.

2.1.32 Ethan was given additional medication to help to relax his muscles. An attempt was made to insert an iGel 3 supraglottic airway (see 1.3.1 – 1.3.2) at 00:02 hours. However, this was unsuccessful, and it was removed.

2.1.33 Staff noted that it was 'difficult' to manage Ethan's airway. The team leader 'stopped' the procedure and discussed the airway plan with the rest of the operating theatre team. The team discussed whether to continue to attempt to intubate Ethan or whether to wake him up or to carry out an emergency front of neck airway (eFONA) (see 1.3.9 to 1.3.12).

2.1.34 At 00:06 hours the team made a third attempt to intubate Ethan with a videolaryngoscope and standard laryngoscope blade. The view of Ethan's airway was assessed again as a 'Grade 4 view'. Ethan's oxygen levels were dropping to lower than the expected range.

2.1.35 Ethan's airway was noted to become 'more rigid' and his airway was described as more difficult to oxygenate and ventilate. Ethan was given additional medication to help to relax his muscles further. Another consultant anaesthetist attempted to intubate using direct laryngoscopy (see 1.3.5 to 1.3.6) but this was unsuccessful.

2.1.36 An emergency call to the on-call ear, nose and throat (ENT) surgeon was made at 00:17 hours. The emergency call was noted by staff as 'can't intubate/ventilate' and 'difficult airway'. The retrieval service was contacted, and the team was advised to use "what had worked previously" by using a bag-mask and jaw thrusts (see 1.2).

2.1.37 Ethan's oxygen levels were noted to be significantly below the expected range. Operating theatre staff recognised that they were unable to oxygenate and unable to ventilate adequately. An eFONA was attempted at 00:24 hours without success (see 1.3.9 – 1.3.12). A large amount of blood was apparent from the incision which obscured the view of the airway. Attempts were made to stem the flow of blood from the incision. Staff immediately attempted to "compress" the area and transfusion blood was made ready.

2.1.38 Operating theatre staff attempted to use a bag-mask and jaw thrust to ventilate Ethan. Other attempts were made to ventilate Ethan using a laryngeal mask airway (see 1.3.2); both attempts were unsuccessful. Further attempts were made to ventilate Ethan. It was noted by staff that Ethan's heart rate was below the expected range and a cardiac arrest call was made at 00:25 hours. Staff immediately commenced cardiopulmonary resuscitation (CPR) and continued to try to ventilate Ethan using a bag-mask and jaw thrust.

2.1.39 The ENT consultant saw Ethan at 00:46 hours and attempted to secure an airway by carrying out a tracheostomy (see 1.3.10). It was recorded in the medical records that 'ventilation was possible' but that 'no breath sounds' could be heard; both sides of Ethan's chest were noted to be moving. The ENT consultant used an endoscope (an inspection device) to view Ethan's airway and replaced the size 5 tube with a wider size 6 tube to improve ventilation. Initially ventilation 'seemed easier' then became 'much worse'. A third tube with a "wider bore" was then used. The ENT consultant noted that the tube appeared to be against 'pink tissue' and that there appeared to be 'tracheal swelling blocking the tube'.

2.1.40 Staff were concerned that Ethan may have a pneumothorax (air accumulated between the chest wall and the lung causing the lung to collapse). Staff made an incision into Ethan's lung to release the trapped air; this did not improve Ethan's ability to be ventilated. Staff noted that Ethan also had air in the deepest layers of his skin (surgical emphysema). CPR and ventilation attempts continued, and Ethan had a blood transfusion. An adrenaline infusion was also commenced in an attempt to relax Ethan's airways.

2.1.41 Ethan's father arrived back at the hospital at 01:30 hours and it was explained that Ethan could not be intubated or ventilated and that he had suffered a cardiac arrest and could not be resuscitated.

2.1.42 In consultation with Ethan's father, operating theatre staff agreed to stop CPR approximately 80 minutes after Ethan's cardiac arrest. Ethan died at 01:43 hours.

3. Analysis and findings – the reference event

This section outlines the findings of the investigation's analysis of the reference event. The focus of the analysis was on the communication between professionals caring for Ethan and the decision making in relation to advanced airway management of someone with an anticipated difficult airway. The analysis has evidenced that the Trust followed national guidance for an unanticipated difficult airway when managing Ethan's difficult airway (no guidance exists for an anticipated difficult airway). It is important to note that all clinical decisions about Ethan's airway management were being made within the context of a continually evolving clinical picture over a period of approximately 12 hours.

The following themes emerged from the analysis of the evidence:

- communication of information between primary, secondary, and tertiary healthcare providers
- Hunter syndrome and an anticipated difficult airway
- information, advice, and guidance to staff
- decision making and optimising conditions for intubation.

These themes are also considered in the context of national guidance and policy in section 4.

3.1 Communication of information between primary, secondary, and tertiary healthcare providers

3.1.1 Ethan was well known to the community paediatric service where he lived and to the tertiary centre that had overall responsibility for his care. The local hospital was less familiar with Ethan as he had not required care there very often.

3.1.2 Letters from the tertiary centre were copied to Ethan's GP, his father and to the community paediatrics team and sometimes the local hospital. Ethan's community paediatrician was employed in a clinic that was not part of the local hospital. Therefore, medical information communicated between the tertiary centre and the community paediatrician was not always shared with the local hospital. Ethan did not have an individualised care plan from the tertiary centre.

3.1.3 Some staff at the local hospital told the investigation that it would have been helpful to have more information about Ethan in his local electronic patient record. This is because they were concerned that Ethan had a complex disease and they did not know what "normal behaviour" for Ethan was until his father arrived, which was recorded in the medical records as 'within 30 minutes of Ethan's admission'.

3.1.4 There had been no previous multidisciplinary team meeting between Ethan's GP, his local hospital and the tertiary centre relating to Ethan and his ongoing care needs. The tertiary centre told the investigation that communication about patients is traditionally via letter. It tries to ensure that all known medical professionals are copied into the letter to support communication and care co-ordination.

3.1.5 The tertiary centre also provides access to a mobile telephone application (app) for patients to use to communicate their medical information. The app can be used to share medical records with other health professionals. The app does not currently provide information about a difficult airway. The investigation spoke with Ethan's father who said that he was not aware of the app.

3.1.6 It is not possible for the investigation to say that more information in Ethan's records would have changed the outcome. This is because when the healthcare professionals individually assessed Ethan and discussed his care with each other and the wider multidisciplinary team, they described that they quickly recognised that Ethan's care may need escalating.

3.2 Hunter syndrome and an anticipated difficult airway

3.2.1 Ethan's Hunter syndrome alongside a diagnosis of severe obstructive sleep apnoea (OSA) meant he was likely to have a "difficult airway". When assessing Ethan, healthcare professionals at the local hospital recognised that any attempts at intubation would be difficult (see 2.1.18 to 2.1.20). This assessment was supported by communication between the tertiary centre and the retrieval service on the day that Ethan was admitted to the emergency department (ED).

3.2.2 Ethan's father told the investigation that Ethan's breathing had got worse in the last 2 years. He said that Ethan would take a few steps and then would have to stop and rest because he was so breathless.

3.2.3 Ethan was described by the consultant at the tertiary centre as being a "difficult airway patient" due to the position of his neck and the position of his vertebrae. The consultant told the investigation that any attempt to intubate a patient with a complex metabolic disease "should be undertaken by a clinician who has a lot of experience in dealing with difficult airways" and "with an ENT [ear, nose and throat] surgeon present". The consultant also stated that due to Ethan's "brittle airway", his sleep apnoea and his genetic disorder, Ethan was at more risk than other patients at the tertiary centre. When asked how many other patients were at the same risk as Ethan, the consultant stated that there was only one other patient who would have similar risks to Ethan due to their similarities. As mentioned in 3.1, this level of information was not known to the local hospital.

3.2.4 Ethan did not have a pre-defined plan and/or agreement giving instructions to the ambulance crew on where to send Ethan. Ambulance staff took Ethan to the nearest hospital in line with their local guidance. The investigation was told that ambulance trusts are ‘commissioned to convey patients to the nearest appropriate emergency department or, to specialist centres in the presence of specific diseases like a stroke, trauma, or a heart attack’. The local hospital did not have an on-site paediatric intensive care unit (PICU) which meant that if Ethan had been successfully intubated, he would have needed to be transferred to another hospital.

3.2.5 The tertiary centre did not have specific advice or guidance for the care of patients with an anticipated or known difficult airway who may be seen by urgent and emergency care services in the community or local hospital. Ethan did not have a pre-defined airway management plan written by the tertiary centre in discussion with the local hospital.

3.2.6 Staff interviewed said it would be helpful to have a mechanism to alert them to patients who have a known difficult airway and to indicate their specific needs.

3.3 Information, advice, and guidance to staff

3.3.1 During interviews and review of medical records, the investigation identified that information sharing between the local hospital and the tertiary centre and retrieval service was initially undertaken by non-consultant medical staff under the guidance of their consultant colleagues. This meant the retrieval service’s initial advice to intubate was changed after a consultant was informed of Ethan’s Hunter syndrome. The conversations thereafter between the retrieval service, the tertiary centre and the local hospital were between senior doctors. The communication and management was potentially made more complex because the retrieval team was not from the tertiary centre and there was no direct three way communication between the tertiary centre, the local hospital and the retrieval team.

3.3.2 The on-call consultant from the tertiary centre told the investigation that their advice was, “if at all possible, to avoid it [intubation]”. An interview with a consultant from the local hospital recalls the tertiary centre advising to intubate. The investigation team met with staff from the tertiary centre who said that “it is well known that with this condition [Hunter syndrome] that they [the patient] could have a very difficult airway”. Another staff member said that Hunter syndrome patients could be “very difficult” to intubate “even for someone [a healthcare professional] who is experienced”. In addition, the tertiary centre told the investigation, “you need lots of information [from a trust] to brief a consultant” and that “there are lots of moving parts” to ensure that appropriate advice is provided.

3.3.3 During the reference event there was agreement from all healthcare professionals throughout the afternoon and evening that intubation should not be attempted unless necessary.

3.3.4 At the time of the reference event, a policy was in place at the ED of the local hospital which related to giving an anaesthetic to a child in the paediatric ED. The policy stated:

'If a difficult airway is anticipated, prior to intubation the on-call ENT team (based at another NHS trust) should be contacted and asked to attend.'

The investigation was told that this policy was only valid for the Trust's ED, and as such, did not cover the operating theatre where Ethan's intubation was attempted. The policy stated:

'… the ED is a remote, often unfamiliar site and therefore a more difficult environment in which to give an anaesthetic than an operating theatre. As a consequence, it is well recognised that the incidence of anaesthetic complications is higher in the ED and extra caution is required to minimise the risk to what is an already vulnerable patient group.'

The ENT on-call team was not contacted during the time Ethan was in the ED.

3.3.5 The local hospital had an explicit policy for 'the management of a difficult or failed intubation and for impossible bag-valve-mask ventilation'. It had formally adopted the Difficult Airway Society (DAS) guidelines (2015) as departmental policy. The investigation heard at interviews with healthcare professionals responsible for Ethan's airway management that DAS guidance was followed.

3.3.6 The investigation heard at interview and could see in the medical records that an intubation plan was made and was discussed with the operating theatre team. It is recorded that all staff caring for Ethan were aware that intubation may be difficult and were aware of a 'difficult airway' and had access to the difficult airway trolley (see 1.4.5). The investigation was able to observe the location of the difficult airway trolley.

3.3.7 Team members were allocated respective responsibilities for administering medication, assisting with the airway and other general duties. A healthcare professional was allocated the role of 'scribe' to note the procedure chronologically. Staff told the investigation at interview that the scribe role provided a level of independent scrutiny during time-critical emergency situations. The scribe ensured that the team did not become task focused and miss any signs that Ethan's condition might be deteriorating.

3.3.8 From the investigation's analysis of the medical records, in addition to the information given in interviews, the healthcare professionals did appear to follow the DAS guidance for an unanticipated difficult airway. The DAS guidance for adults was followed as Ethan was 12 years

of age (the DAS guidance for children is for those aged 1 to 8 years). The consultant anaesthetist called for the assistance of the ENT team when they reached the situation of ‘cannot intubate, cannot oxygenate’ (CICO). There is no guidance for a predicted or anticipated difficult airway.

3.3.9 As described at 2.1.37, unsuccessful attempts were made to create an emergency front of neck airway (eFONA) using surgical cricothyroidotomy (see 1.3.10) while awaiting the arrival of the ENT surgeon. The consultant anaesthetist who attempted the eFONA told the investigation they had received training on this in line with Resuscitation Council guidance. In addition, other medical staff present, including trainee doctors and consultants, confirmed they had received training in performing eFONA in both classroom and scenario-based training sessions.

3.3.10 Staff told the investigation that seeing Ethan deteriorate so rapidly after initial attempts at intubation and for him to die was ‘very difficult’ and ‘no amount of training prepares you for this’.

3.4 Decision making and optimising conditions for intubation

3.4.1 The investigation considered whether Ethan’s age (12 years old) influenced the decisions made about the right time to intubate him. The investigation was told that other factors had been considered in relation to intubation. For example, if Ethan needed to be transferred to another hospital, he would need his airway secured in the form of intubation. Also, if he required a scan of his head, he would need to be intubated. The investigation was told and observed in the medical records that the decision to intubate was based on Ethan’s clinical need.

3.4.2 The decision to intubate Ethan was planned in consultation with the wider multidisciplinary team, which included paediatric anaesthetists, paediatricians, ED staff and staff with previous experience of intubating patients with complex needs. There was evidence of on-call staff and rostered staff working together to support decision making and involving the retrieval service and tertiary centre in those decisions.

3.4.3 An operating theatre was confirmed as the most appropriate place to intubate Ethan. The team was prepared in advance of intubation and had access to the difficult airway trolley. In line with the national standards for invasive procedures (NatSSIPs) (Centre for Perioperative Care, 2023), there was a ‘STOP’ moment to ensure everyone knew their role and there was “a shared mental model” of what would happen. Videolaryngoscopy was used for the initial attempts at intubation in line with advice from the retrieval service.

3.4.4 The investigation was told that the consultant anaesthetist who attempted the initial intubation had experience in managing difficult airways in paediatric patients and had worked in a tertiary centre with people like Ethan. They told the investigation they were competent in videolaryngoscopy. Another anaesthetist who attempted intubation was experienced in paediatric anaesthesia and worked as a paediatric anaesthetist. They felt more confident with

using direct laryngoscopy. As part of the plan to optimise the chance of a successful intubation, the decision about who would undertake it was based on staff members' experience of intubation of patients with a difficult airway.

3.4.5 Awake tracheal intubation (see 1.4.4) using fibreoptic intubation was not attempted. The decision to put Ethan to sleep rather than attempt an awake intubation was made to avoid further distress for Ethan. Awake tracheal intubation is described in literature as the gold standard for management of the anticipated difficult airway, because of its high success rates and low risk profile (Vora et al, 2022). The investigation spoke with subject matter advisors (SMA) who gave opposing views on whether intubation should have been done with Ethan awake or asleep. This is because Ethan did not tolerate a nasopharyngeal airway or CPAP. Given these findings, and Ethan being a child, the investigation was told by an SMA he would likely not tolerate awake fibreoptic intubation. An alternative view was that whilst the advice and guidance was to "avoid intubation if at all possible", fibreoptic intubation may have been considered.

3.4.6 Multiple repeat attempts at intubation were made and this is an identified risk. The difficulty in achieving an advanced airway such as intubation resulted in a 'cannot intubate, cannot oxygenate' situation (CICO). It is well recognised that a change of approach is required rather than repeated use of a technique that has already failed (Cook et al, 2011). The medical records and interviews suggest that while repeated attempts were made, alternative techniques were used in line with national guidance. As described in section 1.5.4, people with Mucopolysaccharidosis are known to have very difficult airways. It is possible that whatever intervention was attempted, the same outcome of death might have occurred.

3.4.7 The investigation reviewed the care of Ethan from the time he arrived at the hospital at 14:00 hours until his death and analysed the decisions and who made them and considered decision making in the context of fatigue. Several healthcare professionals were involved in Ethan's care. The investigation identified examples of shared decision making in managing Ethan's symptoms and making sure the environment was optimised to achieve a successful intubation when needed. However, the investigation could not identify whether the risk of fatigue of some staff had been considered in decision making. Research has found that fatigue can have a detrimental effect on people's performance and increase the likelihood of human error (Wagstaff and Sigstad Lie, 2011).

3.4.8 The consultant anaesthetist who performed the initial attempt at intubation was working a 'non-resident on-call' shift, meaning they were available for advice and guidance and would go to the hospital if needed. They said they were "… keeping an eye from home … generally taking it easy". They were made aware of Ethan on his arrival at the ED and attended on site in the evening.

3.4.9 Another consultant anaesthetist had been in the hospital throughout the day and was involved in the third intubation attempt. They described at interview that towards the end of the failed attempts at intubation and a failed eFONA “we were mentally and physically exhausted … it is hard to describe how harrowing this is”. It is well documented in the research that human performance is liable to deteriorate in high-pressure situations and when a safety critical task such as tracheal intubation is found to be difficult or impossible, with each attempt the staff get more anxious, 'frazzled', stressed and are likely to struggle to communicate and make decisions (Kelly et al, 2023).

3.4.10 Research has shown that relatively moderate levels of fatigue (for example 17 hours of sustained wakefulness) impairs performance to an extent equivalent to or greater than is currently acceptable for alcohol intoxication (Dawson and Reid, 1997). The on-call ENT consultant told the investigation they had been sleeping before being called in. However, the anaesthetic consultant who attempted the first intubation had been on call and awake since at least 08:00 hours. The consultant who attempted the second intubation had been working in the hospital throughout the day.

3.4.11 The investigation was unable to state with any certainty that fatigue had an adverse impact on Ethan’s intubation.

3.4.12 The hospital did provide support to staff involved in the care of Ethan.

Summary of findings from reference event

Ethan did not have an individualised airway management plan that formed part of a wider care plan addressing not just his complex airway issues but listing all his care needs, including behaviour management and communication. The system wasn’t robust enough for information about Ethan’s known difficult airway to be shared between primary, secondary, and tertiary care.

Analysis of Ethan’s care suggests that while the sharing of information about his anticipated difficult airway was limited, the healthcare professionals assessing Ethan identified that he was at risk of having a difficult airway. There is currently no guidance for managing an anticipated difficult airway and therefore when Ethan required advanced airway management, the local hospital followed existing national guidance for management of an unanticipated difficult airway. The local ED policy did refer to calling an ENT surgeon if intubation was required in the ED; however, this was not policy in the rest of the hospital. The local hospital did not have access to an onsite PICU and there was not an on-site ENT specialist at the time of the incident.

4. Analysis and findings – the wider investigation

This section provides an overview of the analysis and findings from HSIB's national investigation, which focused on the national policies and guidance that govern the care of people with a known difficult airway. It considered the communication, preparation and planning for cases where a patient needs advanced airway management by healthcare professionals. The methodology for the national investigation is described in the appendix.

The findings are presented within the following themes:

- communication of information between primary, secondary, and tertiary healthcare providers
- airway management guidance in England
- training and competence in the use of advanced airway management techniques
- workplace culture and the introduction of new technology.

4.1 Communication of information between primary, secondary, and tertiary healthcare providers

4.1.1 The investigation found that there is no consistent method for sharing important clinical information about a person with a known difficult airway. Some hospitals write a letter which describes their airway assessment, and this is shared with the individual's GP and sometimes with the person themselves (or their carer). Wilkes et al (2013) reported that not all anaesthetists consistently write letters and only half of GPs receiving a difficult airway communication forwarded this on. The investigation was told that any letter to an individual and their GP must include a specific difficult airway code, so the information about a difficult airway is recorded on their individual medical records. This relies on individuals knowing and using the specific code and the GP uploading the relevant detail to the emergency summary care record. In addition, some hospitals are trying to add a 'pop up alert' to the patient electronic record system however this is reliant on IT infrastructure and resources to make these changes, and this is not consistent in all hospitals.

4.1.2 Research suggests that if people are only told verbally about potential risks with their airway, they will forget the information, in part because they do not realise the significance or because they were told after surgery when still drowsy (Francon and Bruder, 2008). This makes it difficult for healthcare staff to follow up and prepare for a subsequent intubation, especially when a person is then treated in another hospital and by another anaesthetist (Tessler et al, 2006).

4.1.3 Barron et al (2003) published recommendations on the care of people with an unpredicted difficult airway. These recommendations suggested that ‘every person with a difficult airway should receive a document from the anaesthesia team addressed to subsequent colleagues. This document should describe thoroughly the ‘difficulties’ encountered’. In contrast, a survey relating to Barron et al’s paper indicates that the implementation of this document is insufficient to communicate the level of risk of people with a difficult airway (Haigh et al, 2006).

4.1.4 The Society for Mucopolysaccharide Diseases (MPS) told the investigation that there have been several attempts to support the sharing of information around complex airways, such as alert cards or care plans. However, they described that the challenge faced by many families, is that in an emergency they are not always listened to.

4.1.5 The Difficult Airway Society (DAS) launched the ‘DAS Airway Alert Card and Difficult Airway Database project’ in November 2018, following a 24-month pilot (Sajayan et al, 2020). This project is described as a streamlined national airway alert reporting system, which aims to:

- create a database with detailed information about a person’s difficult airway
- issue an ‘Airway Alert Card’ to people who have had a difficult airway incident
- provide data for research to help understand and develop safer airway management techniques.

4.1.6 It is expected that after identifying a difficult airway, ‘anaesthetists disseminate this information to patients and their GPs’ (Difficult Airway Society, n.d.b). Ideally, critical information about a patient’s difficult airway should be recorded in such a way that it is reliably available at any time and should follow the patient wherever they go for their next operation or procedure, or for use if the patient is critically ill.

4.1.7 The DAS database is anonymous but has detailed information about the person’s airway incident. This would result in the issuing of an ‘Airway Alert Card’ (see figure 4), much like a medical bracelet, to people who have had a difficult airway. An individual can carry this and present it to the anaesthetist before their next operation. The database is intended to be accessible to authorised doctors upon entering a code printed on the Airway Alert Card or using a person’s NHS number.

Figure 4 Airway Alert Card



4.1.8 Guidance is provided by DAS to healthcare professionals on what to do to if they want to add a person to the database who they have identified as having a difficult airway. This includes seeking consent from the person identified as having a difficult airway for information governance purposes. A letter can then be printed and sent to their GP.

4.1.9 It is intended that when a person produces this card for a future anaesthetic in any hospital in the UK the healthcare professionals can immediately look at the key information printed on the card.

4.1.10 The investigation was told of limitations to the DAS database. These include:

- no resource funding
- not all hospitals are signed up
- some hospitals have concerns about the structure and IT security of the DAS database despite the precautions listed
- it is not for use with people under 18
- the patient has to consent to have their information uploaded to the website meaning it has to be done once the patient is fully awake and competent to give their consent.

4.1.11 Research evidence from the first analysis of the DAS National Difficult Airway Database found that unanticipated difficult airway management continues to occur despite airway assessment, and the rate of critical incidents in this group of patients is high (Sajayan et al, 2022).

4.1.12 The investigation was told that people with inherited metabolic disorders (collectively termed the mucopolysaccharidoses (MPSs) are included within a commissioned NHS funded lysosomal storage diseases (LSD) service. The LSD service does not collect monitoring data for people with a known difficult airway. The investigation was told by a subject matter advisor

that the LSD service is establishing a specific cardiac surgery service for people with MPS. As a part of the preparatory work, it is considering the multidisciplinary input that may be required for specific airway evaluation and management required before, during and after surgery.

4.1.13 The investigation was told by the MPS society that the challenge for people with complex conditions with multiple co-morbidities is that they could be required to carry an alert card for each co-morbidity. They told the investigation that 'the airways in MPS conditions are usually more complex than general rare disease airway management and requires a more in depth understanding […] and there is a need to ensure that each person with MPS, identified with a complex airway, has an individualised management plan, that is shared with local district hospitals, to ensure that the right professionals and services are available and trained, to deal with both routine and emergency admissions'.

4.1.14 The investigation was also told by a tertiary centre and other hospitals that increasingly, healthcare professionals from the multidisciplinary team are having virtual 'Teams meetings' and that these meetings include the local paediatrician and GP. The purpose of these is to discuss the care of patients with complex healthcare needs, including those who have a difficult airway.

4.1.15 Previous Healthcare Safety Investigation Branch (HSIB) investigations have identified risks associated with sharing important clinical information (Healthcare Safety Investigation Branch, 2023a). There is variability in how healthcare professionals are alerted to patient risks. Various methods are used, including:

- the NHS app which is available to everyone and includes fields for allergy and adverse reactions as well as one for health conditions
- the summary care record
- alerts on electronic patient record systems
- red flags or triangles on paper-based patient records.

4.1.16 The Association of Paediatric Anaesthetists of Great Britain and Ireland (APAGBI) published Best Practice Guidelines on Paediatric Preassessment (2022). This guidance is designed to describe the establishment and delivery of a paediatric preassessment service in any hospital where children aged 0-18 years of age undergo surgery or other procedures under anaesthetic, and the functions it should deliver. It describes the benefits for every child from straightforward to complex, undergoing straightforward or complex surgery. Specifically, it states:

‘In District General Hospitals and Teaching Hospitals, a governance process should be established to ensure a multi-disciplinary approach to the care of children usually under the care of a specialist centre. This can be by direct links with the regional specialist centre or by working with regional operational delivery networks. This should provide assurance on the most appropriate place for any procedures or investigations to be performed’. (APAGBI, 2022)

The investigation was told by an SMA that the establishment of preassessment services in a standardised way is underway and this is another safety mechanism for detecting and planning for children with known difficult airways.

4.1.17 The investigation identified that there are systems in place to communicate that a person may have a difficult airway, but that these are not consistently used across England and therefore may not work in communicating that a person has a difficult airway.

4.1.18 The investigation was told by many paediatric and adult airway leads that they would welcome a centrally resourced system of reporting and providing a database of clinical information for patients with known or anticipated difficult airways. It was recognised by subject matter advisors that this would require effective and standardised NHS IT infrastructures and appropriate safeguards for data protection but also enable easy and immediate access to the information. The risks associated with managing a difficult airway are significant and, where possible, all healthcare professionals should be aware that a person has an anticipated difficult airway.

HSSIB makes the following safety recommendation

Safety recommendation R/2024/013:

HSSIB recommends that NHS England identifies and implements a system for sharing clinical information about people with a known difficult airway. This is to improve access to this information for healthcare professionals and reduce the risk of a person’s known difficult airway not being recognised.

4.2 Airway management guidance in England

A difficult airway

4.2.1 A difficult airway scenario is a rare and potentially life-threatening event for a patient and a stressful experience for the anaesthetist involved (Difficult Airway Society, n.d.). The Royal College of Anaesthetists’ 4th National Audit Project looking at ‘Major complications of airway management in the United Kingdom’ (Cook et al, 2011) highlighted ‘significant deficiency in

airway assessment' as a factor in many of the cases of major airway complications it reviewed. It was reported that out of 133 reports from anaesthesia incidents, difficulty in airway management was anticipated in 66 cases but subsequent management of the airway was not always matched to the initial assessment.

4.2.2 Airway abnormalities in people with MPS are varied and complex and assessment of the airway should be holistic and include multiple parameters (Stepien et al, 2022). An assessment to predict potential airway difficulty is essential and forms part of any anaesthetic review. Conventional airway assessment practice relies on trying to predict a difficult airway. According to research, the term 'difficult airway' is poorly defined with variation in definitions used in different scientific literature (Apfelbaum et al, 2013). In addition, while some research suggests that there are reliable assessment tests available to predict a difficult airway, the investigation was told by subject matter advisors that accurate prediction of difficult laryngoscopy is generally regarded as being flawed. This is supported by research (Baker, 2015; Frerk et al, 2015; Norskov et al, 2014).

4.2.3 Research suggests that when potential difficulties with airway management are identified, a strategy is required. A strategy is a co-ordinated, logical sequence of plans (Cook et al, 2011).

National guidance on managing a difficult airway

4.2.4 National guidance by DAS (2015) aims to provide a 'structured response to a potentially life-threatening clinical problem'. The guidelines include flowcharts that illustrate each stage of the airway plan (see 1.4.3) and culminates in a plan for managing a 'cannot intubate cannot oxygenate' (CICO) situation that indicates when emergency front of neck airway (eFONA) should be carried out. The investigation was told by many healthcare professionals that the guidance is well known, is easy to follow and all staff spoken to advised that their organisation follows the DAS guidance. Importantly, the DAS flowcharts are for the management of an unanticipated difficult airway, there is no current national guidance for an anticipated difficult airway.

4.2.5 The DAS flowcharts have a 'call for help' prompt in bold red letters, but the supporting text in most cases does not state who should be called for help or what their skill set should be.

4.2.6 The guidance document 'Cannot intubate and cannot ventilate (CICV) in a paralysed anaesthetised child aged 1 to 8 years' (Association for Paediatric Anaesthetists, n.d.) does say to call for assistance from an ENT specialist and gives guidance on what to do if an ENT specialist is available or not available.

4.2.7 National guidance refers to surgical cricothyroidotomy (see 1.3.9 to 1.3.12) for adults requiring eFONA and emphasises that regular training is needed to reinforce and retain skills. A simple plan to rescue the airway using familiar equipment and rehearsed techniques is likely to increase the chance of a successful outcome (Frerk et al, 2015; Pracy et al, 2016).

4.2.8 The guidance for children aged 1 to 8 years refers to performing a cannula cricothyroidotomy (see 1.3.10) only if an ENT specialist is not available and then to progress to surgical cricothyroidotomy if this fails (Difficult Airway Society, 2015).

4.2.9 National guidance by the British Inherited Metabolic Disease Group (2013) provides a warning regarding general anaesthesia in patients with mucopolysaccharidoses (MPS) which includes Hunter syndrome. Specifically, it states:

‘WARNING: General anaesthesia in many patients with mucopolysaccharidoses is potentially dangerous. It should be planned in consultation with, and administered by, an anaesthetist experienced in managing difficult paediatric airways and in centres with access to an appropriate ICU [intensive care unit] as admission to PICU [paediatric ICU] may be necessary post-operatively.’ (British Inherited Metabolic Disease Group, 2013)

The warning about intubation in hospitals with appropriate access to an ICU does not feature in other national guidance.

4.2.10 A subject matter advisor told the investigation that the 7th national audit project (NAP7) of the Royal College of Anaesthetists examined Perioperative Cardiac Arrest. This report states that ‘of 165 hospitals caring for children, 144 (87%) did not have a PICU on-site, meaning transfer of critically ill children is required’ (Kursumovic et al, 2023). The investigation found that in March 2023, of 136 hospitals in England, 130 had an adult critical care unit, and 20 had paediatric critical care beds available (NHS England, 2023).

4.2.11 The British Inherited Metabolic Disease Group guidance (2013) describes why intubation carries risks and outlines risk factors associated with MPS. The investigation was told this guidance was written for planned procedures when advanced airway management may be required. However, the guidance does not refer to unplanned or emergency situations when a patient’s airway is likely to be difficult. The guidance refers specifically to liaison with anaesthetists, but not with other specialists (for example head and neck or ENT specialists) who may be required to support patients with a known difficult airway. The guidance also does not mention videolaryngoscopy.

4.2.12 The MPS Society told the investigation that they are currently setting up a team of experts (ENT, anaesthetists, respiratory, metabolic, surgical) to develop a consensus guideline in managing complex airways in MPS patients. This will include an Internationally recognised

airway management plan template that can be used by clinical teams to share information across; primary, secondary, and tertiary care. The patient and/or their carers will have a copy should communications fail, or an emergency occurs. This work is currently under development.

4.2.13 The investigation was told by national organisations that guidance for managing the care of a patient with an ‘anticipated’ difficult airway, for example people with MPS, would be welcome. This is because the effectiveness of enzyme replacement therapies means that more people with MPS are living longer and needing surgical intervention for other complications of their disease. It is therefore likely that, given their known anatomical changes to the airway, an airway management plan will need to be put in place before they have planned surgery.

4.2.14 An airway assessment plan (or ‘MPS passport’) for adults with MPS has been developed called the Salford Mucopolysaccharidosis Airway Score. This includes assessment of the airways and preparation for emergency tracheostomy. This is described as ‘an objective multidimensional score which may help to predict and manage difficult airways warranting further investigation and validation’ (Gadepalli et al 2021).

4.2.15 Current national guidance for managing a difficult airway does not consider fatigue of healthcare professionals. Fatigue may be caused by working patterns, for example 24-hour on-call shifts and long shifts. HSSIB is currently gathering intelligence to support a potential future investigation on the impact of fatigue on healthcare staff and therefore this has not been considered further in this report.

HSSIB notes the following safety action

Safety action A/2024/001:

The British Inherited Metabolic Diseases Group has amended the content of their guidance with specific reference to specialist guidance from the Royal College of Anaesthetists and the Difficult Airway Society in relation to videolaryngoscopy and incorporating reference to both planned and unanticipated/acute airway interventions.

A multidisciplinary approach to managing a difficult airway

4.2.16 A subject matter advisor told the investigation that in known anticipated difficult intubations, the clinical team might include expertise in ENT/head and neck surgery in case eFONA is required. A senior staff member at NHS England told the investigation that for planned surgical cases for people with a known difficult airway, consideration of ENT expertise

in the operating theatre is usually part of the decision making at multidisciplinary team meetings. However, it may be difficult to ensure that ENT expertise is available during emergency airway management.

4.2.17 The investigation was told by various healthcare professionals that specialist ENT availability on site is not always possible, especially out of hours, because there are not enough ENT specialists. ENT specialists may have to cover more than one hospital site within their geographical patch. In addition, some ENT doctors may specialise in areas such as conditions of just the ear, nose or throat, or skull base surgery and may not be 'expert' in eFONA.

4.2.18 Research studies have found that there were no significant differences between the length of time it took anaesthetists, head and neck surgeons and general surgeons to successfully ventilate a patient with eFONA Groom et al, 2019; Silverio et al, 2021).

4.2.19 The investigation was told of variability in the way staff and organisations respond in time-critical emergencies involving a patient with a difficult airway. A report of a combined working party of the British Association for Paediatric Otolaryngology, ENT UK, the Royal College of Anaesthetists and the Association of Paediatric Anaesthetists of Great Britain and Ireland (n.d.) aimed to establish clear guidance for the safe delivery of paediatric ENT surgery in the UK. The report specifically aimed to identify which children should be transferred to tertiary centres and which children could be safely treated closer to home. It states that all hospitals receiving emergencies should be able to manage […] 'Time critical / unstable condition (Any age): Major Haemorrhage Upper airway obstruction – stabilize an airway for transfer or remove a tracheal foreign body. Front of neck access / tracheostomy if necessary'. It goes on to state that 'Every hospital needs to be emergency safe for its local paediatric population'. The investigation was told that there is variation in how this guidance has been implemented nationally.

4.2.20 The investigation was told by a senior healthcare professional with responsibility for their regional operating delivery network (ODN) (NHS England, n.d.) that national guidance which refers to 'time critical' interventions "need a full multidisciplinary approach to local implementation". They described that every hospital in every region should have a local 'difficult airway' standard operating policy in place that describes clear allocation of roles, responsibilities, and contact pathways. They stated local policy should "dictate what contributions each specialty will make, what specialist equipment is available and where (for example videolaryngoscopy), if ENT is on site or not and what contributions ENT make in hours/out of hours". They went on to say that "as a network they bring all providers together … by specialty and work together to build a universal checklist which is standardised across the region to strengthen networks and pathways of care". They told the investigation that for other life threatening and time critical pathways in children developed by national organisations including Getting It Right First Time (GIRFT) and National Confidential Enquiry into Patient

Outcome and Death (NCEPOD), the role of policing local policy development has fallen to the regional operational delivery networks for surgery in children (SIC ODNs). Each SIC ODN will have an ENT working group bringing together a multi-disciplinary group of surgeons, anaesthetists and managers who could ensure and support such a policy is in place at each hospital.

4.2.21 One of the benefits of a universal checklist across a region is that it creates consistency for rotating staff (for example doctors in training) in the management of a difficult airway and other time-critical interventions. Examples of other time-critical interventions with universal checklists across the region included button battery and testicular torsion pathways.

Videolaryngoscopy

4.2.22 National guidance (Difficult Airway Society, 2015) refers to immediate access to a videolaryngoscope. Guidance also recommends that videolaryngoscopy should be considered as an option for all intubations of critically ill patients in ICU and emergency departments (Eds) (Higgs et al, 2017). Most recent guidance on prevention of unrecognised oesophageal intubation (meaning when the tube enters the gullet rather than the lungs) states videolaryngoscopy should be used for all intubations where feasible (Chrimes et al, 2022). The same is stated in Canadian guidance (Law et al, 2021) although not in other international guidance currently. Evidence in the studies states that videolaryngoscopy:

- reduces the risk of oesophageal intubation
- reduces failed intubations, including in people in whom laryngoscopy is predicted to be difficult
- provides a better view of the larynx
- reduces trauma and swelling of the soft tissues of the pharynx and larynx reduces dental injury.

4.2.23 The Cochrane review of videolaryngoscopy in adults (Hansel et al, 2022; Lewis et al, 2016) produced evidence of the benefits of videolaryngoscopy for intubation of all patients, not just those who are predicted to be difficult to intubate or who are being intubated in an urgent or emergency scenario. The investigation has seen research evidence and been told of the safety benefits of using videolaryngoscopy, which have been highlighted for over a decade (Aziz et al, 2011; Kalpan et al, 2006; Lewis et al, 2016; Malin et al, 2009; Noppens et al, 2010; Serocki et al, 2013). The national guidelines for management of unanticipated difficult intubation (Frerk et al, 2015) mandate ‘training of all anaesthetists in videolaryngoscopy and immediate availability of videolaryngoscopy’. Similar guidelines are now also applicable to ICUs and EDs (Higgs et al, 2017).

4.2.24 The investigation was told by healthcare professionals that videolaryngoscopy would most likely be used for patients with an anticipated difficult airway in emergency or secondary care settings. The investigation was also told by some staff that videolaryngoscopy is standard in their operating theatres, critical care units and EDs, and that it is used as the default first line for patients requiring intubation.

4.2.25 The investigation saw variability in the use and clinical adoption of videolaryngoscopy and training to support its implementation, and this was also found in a national survey (Cook and Kelly, 2017).

4.2.26 The investigation sought to understand some of the challenges described by healthcare professionals and national organisations of implementing the use of videolaryngoscopy as standard. The challenges included:

- The impact on resourcing would be greater than standard care because of the price differential between direct and videolaryngoscopes. This may be offset by staff time savings from improved intubation success rates, reduced length of stay, decrease the likelihood of postoperative admission to a critical care unit and fewer postponed procedures because of failed direct laryngoscopies (National Institute for Health and Care Excellence, 2018; Zhang et al, 2021).
- The design of some equipment was described as poor and that “you get what you pay for”. The investigation was told that some single-use videolaryngoscope blades were bulky, could break under pressure and their design was not always compatible with people that may have restrictions with opening their mouth. Subject matter advisors supported this view and commented on the environmental impact of some of the single-use equipment, which was described as “atrocious”. The investigation found limited evidence relating to design standards for single use videolaryngoscope blades. Research has noted that the International Organization for Standardization (ISO) standard (2020) applies to the device quality and not standards for patient safety and highlighted varied strength characteristics of disposable videolaryngoscope blades (Choi et al, 2021).
- The investigation was told of examples of staff not feeling competent and confident in using videolaryngoscopes and preferring to use traditional direct laryngoscopy. The investigation heard from staff that there is a tendency to lean towards a technique with which you “are most familiar”. The 4th National Audit Project’ and the citation to (Cook et al, 2011) report says that ‘choosing the safest technique for airway management may not necessarily be the anaesthetist’s most familiar. It may be necessary to seek the assistance of colleagues with specific skills, for example in regional anaesthesia or airway management’.
- The investigation was told that there are limitations to using videolaryngoscopy and that for a patient whose mouth is contaminated, for example with excessive vomit and blood, videolaryngoscopy would not be effective. However, research has found that even when a

patient's mouth was contaminated, videolaryngoscopy achieved an improved chance of a successful intubation than using direct laryngoscopy (Sakles et al, 2017).

- Some healthcare professionals expressed concern that if videolaryngoscopy was introduced as a universal standard, that there would be a skill degradation in direct laryngoscopy. The healthcare professionals said that there is a balance to be found between supporting the introduction of new technology and maintaining existing skills.

4.2.27 The interaction between people and devices/equipment has been identified as a contributory factor to patient safety events within previous HSIB investigation reports (Healthcare Safety Investigation Branch, 2023b; Healthcare Safety Investigation Branch, 2023c). In the latest human factors in anaesthesia: guidance for clinicians, departments, and hospitals there is a specific reference to the medical equipment procurement process:

'There is currently no mandate for manufacturers to release their human factors usability assessments to hospitals. The Working Party recommends that procurement departments routinely request to see these usability assessments and that manufacturers make these available'. (Kelly et al, 2023).

Recommendations are contained within the guidance.

4.2.28 An anticipated airway management strategy should be individualised, taking into consideration the specific concern about a patient's airway, the available skills mix in different hospital settings and the availability of equipment. The investigation recommends that the current DAS guidance is reviewed and amended to include guidance to support healthcare professionals when preparing to undertake an advanced airway procedure in a patient with a known potentially life-threatening difficult airway.

HSSIB makes the following safety recommendation

Safety recommendation R/2024/014:

HSSIB recommends that the Royal College of Anaesthetists works with the Difficult Airway Society and other key stakeholders to produce a framework on the management of a potentially 'life threatening' difficult airway for people with a known difficult airway who require advanced airway management. This work should consider the adoption of a common language which defines and explains principles for treating people with a known potentially 'life threatening' difficult airway who require advanced airway management. This could optimise the chances of survival for people who experience a life-threatening airway emergency.

HSSIB makes the following safety observations

Safety observation O/2024/010:

Healthcare organisations that commission elective (planned) surgical services for people with mucopolysaccharidoses (MPS) can improve safety by involving healthcare professionals from different disciplines who are experienced in airway evaluation and management, before, during and after a person's surgery.

Safety observation O/2024/011:

Healthcare organisations could improve safety of the management of difficult airways by procuring equipment that has evidence of safety by design and robust user testing and assessment.

4.3 Training and competence in the use of advanced airway management techniques

Training in videolaryngoscopy

4.3.1 The DAS (2015) guidelines recommend that videolaryngoscopes should be immediately available at all times and that all anaesthetists should be trained and skilled in their use. Training in the use and technique of videolaryngoscopy is specified in other literature (Higgs et al, 2017). The national guidance states that 'All anaesthetists should be trained to use a videolaryngoscope and must be skilled in the use of a videolaryngoscope' and that 'Those involved in critical care intubation should be appropriately trained in use of the videolaryngoscope(s) they may be called upon to use'. However, the investigation was told by healthcare staff that training is variable in both quality and frequency.

4.3.2 Consultant anaesthetic staff described how the use of videolayrngoscopy made it "easier" to observe and teach doctors in training and other healthcare professionals who are required to be competent in intubation. They said that this was because it enabled them to point out laryngeal structures in real time. Using a videolaryngoscope to teach the standard technique of laryngoscopy has been shown in separate trials to be better than standard teaching methods (Low et al, 2008; Marjanovik et al, 2019; O'Shea et al, 2015; Sainsbury et al, 2016).

4.3.3 The investigation observed the teaching of direct laryngoscopy and videolaryngoscopy. Videolaryngoscopy made it easier to see what the student was doing.

4.3.4 In research studies, trainees reported that their development as an anaesthetist was improved because of intensive exposure to videolaryngoscopes (Herbstreit et al, 2011; Low et al, 2008; Sainsbury et al, 2016).

4.3.5 Doctors in training told the investigation that using videolaryngoscopy improves their confidence in “getting the tube in right first time” and that they feel “safer” working in environments where videolaryngoscopy is used routinely. This was supported by operating department practitioners (ODPs) who felt they could work “better as a team”. These statements are supported by research which suggests that enabling other team members, including ODPs and anaesthetic nurses, to observe laryngoscopy and intubation improves their ability to assist the anaesthetist (Jones et al, 2018; Kelly et al, 2014).

Advanced airway training and skill retention

4.3.6 The investigation spoke to many anaesthetists and doctors in training who described that they had received training in advanced airway management techniques. However, the investigation was told there is variability in how training is delivered and how often skills are maintained. The investigation heard from healthcare professionals who had ‘airway workshop’ training twice a year. Others relied on the Resuscitation Council UK (2021) advanced life support training courses which are renewed every 3 years.

4.3.7 The investigation was told by anaesthetic doctors in training and other healthcare professionals that they had experience of unplanned (to them) scenario-based training for managing a time-critical airway scenario. The scenario-based training included the use and implementation of advanced airway management skills. This may happen up to three times a year and was described as “really realistic” and left staff feeling more prepared for a real airway emergency. The investigation was told that this type of scenario-based training is not standard in all hospitals. In addition, the investigation was told that this type of scenario-based training including simulation is time and resource intensive and not possible in some hospitals.

4.3.8 The investigation considered the research evidence for skills retention in healthcare professionals. It is reported in the literature that skill retention varies depending on the task; however, emergency airway management skills are reported to decrease between 4 and 6 months after training (Maddocks, 2020; Main and Anderson, 2022; Main and Anderson, 2023; Thim et al, 2022).

4.3.9 A General Medical Council (2014) review of ‘skills fade’ found no consensus on how much time should elapse between a healthcare professional undertaking training and a further assessment of their competence. The review concluded that, ‘based on the evidence it had collected, when a competency assessment should be completed depends on the skill and the

circumstances of initial acquisition and interim practice'. It also found there was consistent evidence that skills for high-risk procedures decline between 6 and 18 months after training, and resuscitation skills after 4 and 12 months.

4.3.10 Advanced airway management skills including eFONA were described by subject matter advisors as a "complex task". While the evidence for ongoing training and assessment of competency is limited, its implications may be particularly important for healthcare professionals who may have to perform complex tasks, albeit infrequently. The investigation heard from staff of the fear of reaching a CICO scenario and not having witnessed it in their career "to date". It also heard that "no training can prepare you for a real CICO scenario".

4.3.11 Hospital staff gave examples of being involved in scenario-based training as a multidisciplinary team (including simulation training). They reported that this improved teamwork and understanding of roles and responsibilities when in a difficult airway situation. One staff member told the investigation that in their experience, "teams that work together should train together"; this is supported by research (Siassakos et al, 2010). Research also reports improved awareness of other roles and responsibilities, decision making and teamwork through a shared visualisation of a patient's airway and the subsequent management (Flin et al, 2013).

4.3.12 The Guidelines for Provision of Anaesthetic Services (GPAS) (Royal College of Anaesthetists, n.d.a) (see 1.4.6) were updated in 2020 using their development process, which is accredited by the National Institute for Health and Care Excellence (NICE). NICE accreditation gives additional credibility to these guidelines, providing independent assurance that the guidelines are robust, and evidence based. HSSIB recommends that the GPAS are amended to reflect the competency and familiarity in all advanced airway techniques to include videolaryngoscopy and emergency front of neck airway (eFONA). This will provide every person responsible for managing a patient's airway with the skills and competence to use advanced airway rescue techniques in airway emergencies.

HSSIB makes the following safety recommendations

Safety recommendation R/2024/015:

HSSIB recommends that the Royal College of Anaesthetists makes changes to its Guidelines for the Provision of Anaesthetic Services (GPAS) requirements for all anaesthetists, to include guidance on:

- requirements for anaesthetists to have access to videolaryngoscopes in all locations in which anaesthesia is delivered and airway management takes place
- requirements for anaesthetists to be competent and skilled in the use of videolaryngoscopes
- requirements for anaesthetists to be regularly updated on airway rescue techniques, such as emergency front of neck airway
- requirements for anaesthetists and anaesthetic assistants to be regularly updated on other equipment that may be used in airway emergencies.

This will support anaesthetic staff to become familiar with and competent in the use of airway rescue equipment and techniques available locally.

Safety recommendation O/2024/016:

HSSIB recommends that the Royal College of Anaesthetists works with the Association of Anaesthetists and relevant key stakeholders to implement critical incident training for all anaesthetists and anaesthetic assistants. This should include consideration of scenario-based training and include the principles for the management of an expected or unexpected difficult airway using advanced airway techniques, including videolaryngoscopy and emergency front of neck airway.

4.4 Workplace culture and the introduction of new technology

4.4.1 The investigation was told by doctors in training about times when they had asked to use videolaryngoscopy, and the response was not always supportive of the use of technology. The doctors in training described examples of a “failure to embrace change, technology, and innovation”. One doctor in training described an “eye roll” (an expression of disapproval) when asking for a videolaryngoscope and that there was an undercurrent of “machoness … you don’t need to use that bit of kit, just use the standard”. Another doctor described their return from

maternity leave and receiving an eye roll when asking for a videolaryngoscope; the doctor was then asked, “Why, don’t you think you can do it on your own?”. They described that the impact of the comment “took a long while to shake”.

4.4.2 The integration of new technology into healthcare is a complex process and there can be a variety of reasons for resistance to its implementation. The investigation explored some of the reasons staff felt there was a resistance:

- Healthcare professionals often prefer to stick to tried and tested methods rather than embrace new ways of working. The investigation was told by doctors in training and ODPs that “older staff do not embrace the new technology” and described finding and learning new technologies challenging, highlighting challenges described in other literature (Imison et al, 2016; The Health Foundation, 2015).
- The introduction of new technology often requires significant up-front investment, and this may create a difficult balance between maintaining existing practices and investing in innovation (Appleby et al, 2014).
- The investigation was told that unless there is strong leadership advocating for change, many staff may default to established practices.

4.4.3 The investigation was told that operational delivery networks (ODNs) were established after concerns were raised nationally regarding inconsistency and variability in services. ODNs are focused on co-ordinating patient pathways between providers over a wide area to ensure access to specialist resources and expertise (NHS England, n.d.).

4.4.4 A key function of the core ODN team is to facilitate the bringing together of stakeholders from across the regions to lead on delivery of recommendations from national reviews and support opportunities for service development and wider regional collaboration. The investigation was told by a senior regional lead that in their experience the ODN had increased cross-organisational engagement and collaboration to support standardisation of safety-critical patient pathways, including managing a difficult airway, using evidence-based guidelines.

4.4.5 The investigation found that when healthcare providers take a collaborative approach to difficult airway management, this creates an overall improvement in pathways of care. Examples include when anaesthetic department leaders in hospitals support the implementation of national guidance to improve patient safety, and when regional networks work together to develop pathways of care.

HSSIB makes the following safety observation

Safety observation O/2024/012:

Healthcare providers can improve patient safety by supporting and encouraging anaesthetic staff, anaesthetic assistants and operating department practitioners to become familiar with and experienced in the use of airway rescue equipment and techniques available locally, including videolaryngoscopy.

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6. Appendix – Investigation approach

Evidence gathering

The investigation was completed between July 2022 and August 2023.

The investigation interviewed several members of staff who were involved in the reference event and met with additional staff from across the wider organisation.

The investigation visited the Trust involved in the reference event. The investigation observed the equipment, the supporting policies and procedures and processes used in providing basic and advanced airway management to people receiving care in both the emergency department and the operating department of the hospital. In addition, the investigation contacted and interviewed healthcare professionals from a tertiary centre involved in Ethan's care.

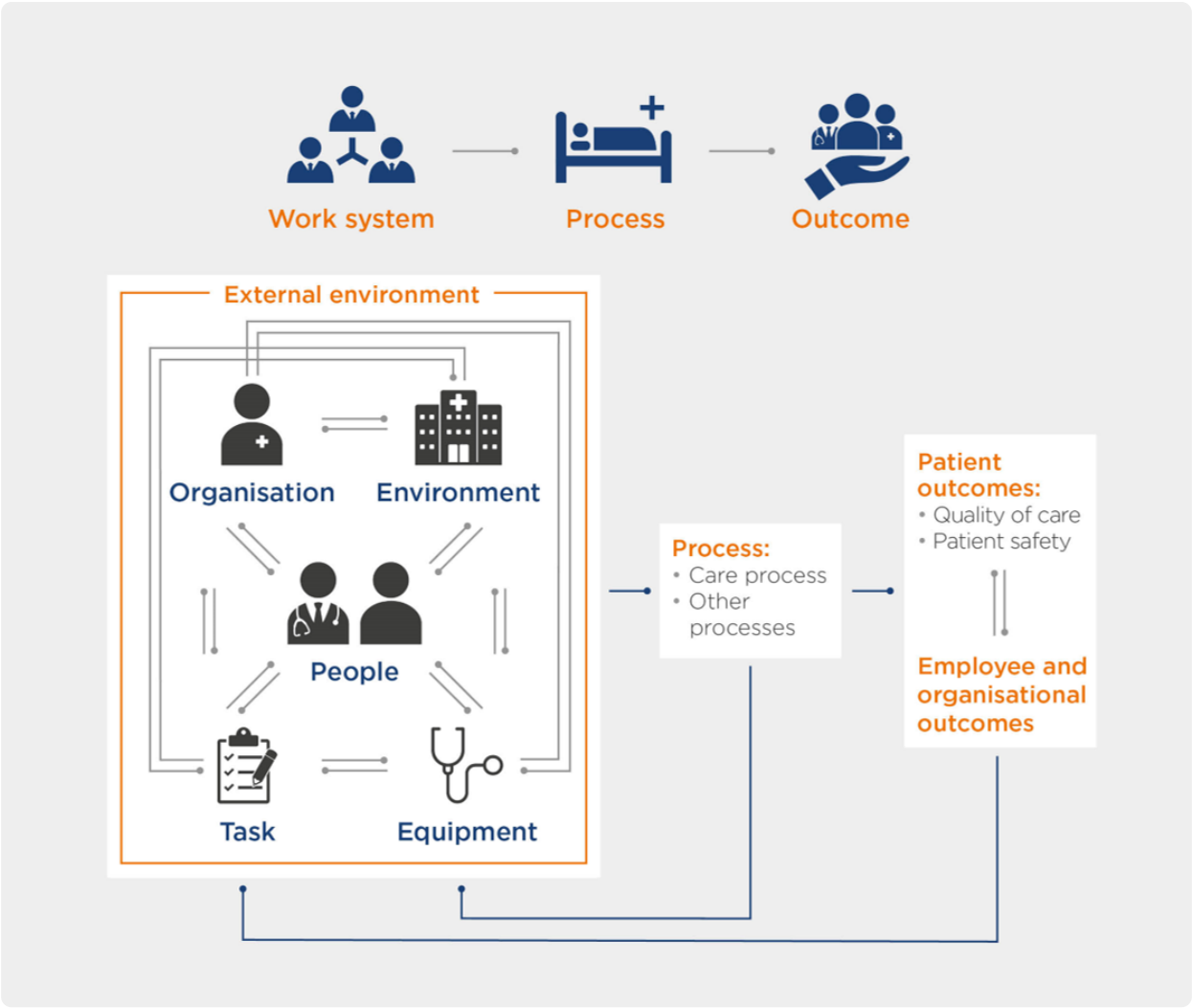
Other hospital sites including general hospitals, hospitals with an on-site paediatric intensive care unit (PICU) and a specialist tertiary centre were used for observational visits during the investigation. The investigation engaged with healthcare professionals responsible for basic and advanced airway management at these sites.

The investigation also engaged with national healthcare bodies in the areas being explored (see below). Further evidence was gathered from national policy and guidance, and research literature.

Analysis of the evidence

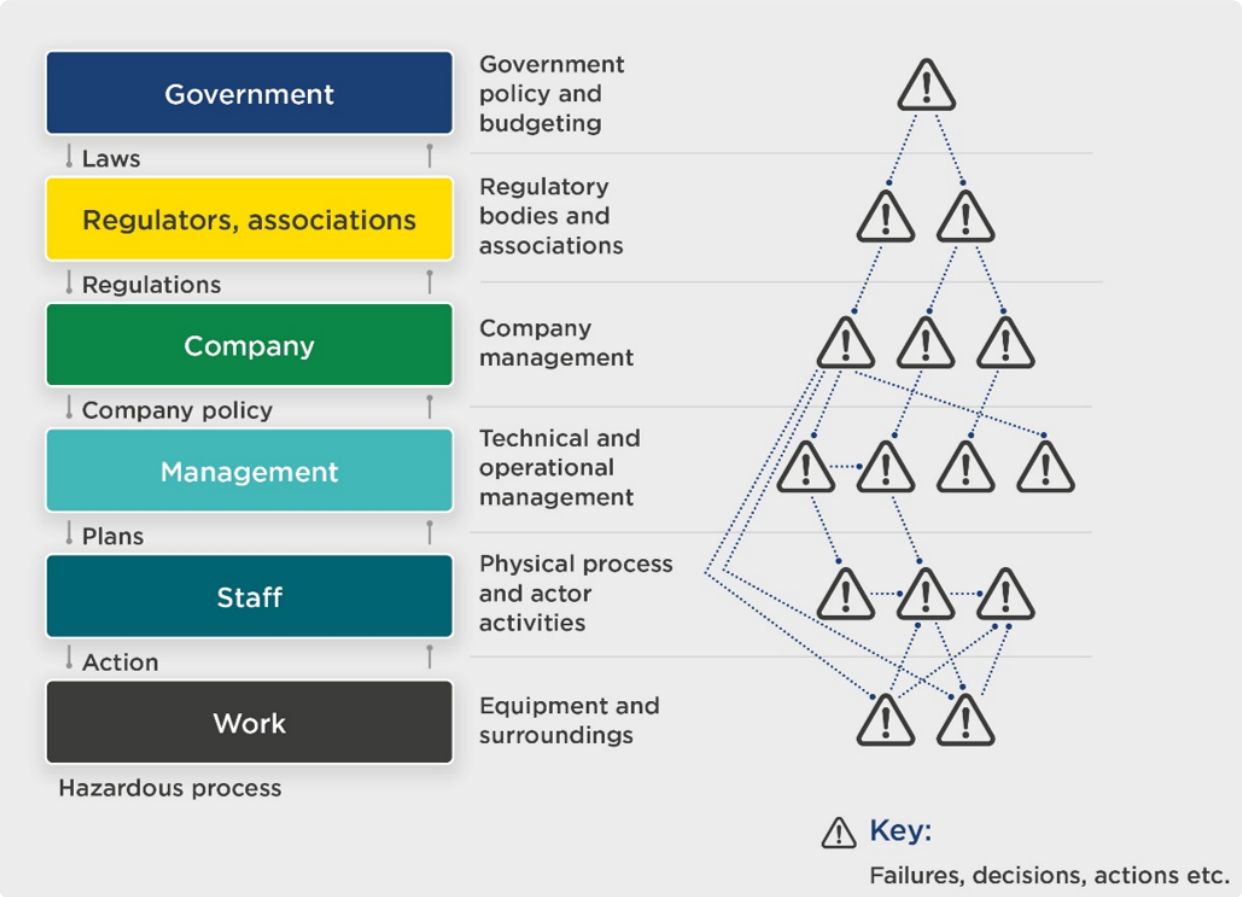
The investigation used the Systems Engineering Initiative for Patient Safety (SEIPS) (Carayon et al, 2006) to explore the reference event. This tool was used as a guide during site visits for collecting evidence and in analysing the data gathered. SEIPS provides a human factors framework for understanding the work system (that is, the external environment, organisation, internal environment, tools and technology, tasks, and persons), work processes (including physical, cognitive and social/behavioural aspects), and the relationship between these and the resulting outcomes in healthcare (see figure 5).

Figure 5 A representation of the SEIPS framework



In addition, the AcciMap model (Svedung and Rasmussen, 2002) was used to analyse the reference event information and support the direction of the investigation. The analysis focuses on identifying relationships between the different levels of the system, which include government policy and budgeting; regulatory bodies and associations; local area management; physical processes and actor activities (what staff, people, organisations, systems did); and equipment and surroundings. The contributory factors are arranged into a series of levels representing the different parts of the health and care system. The analysis focuses on identifying connections between the different levels of the system (see figure 6).

Figure 6 A representation of the AcciMap method



Stakeholder engagement and consultation

The investigation engaged with stakeholders to gather evidence during the investigation. This also enabled checking for factual accuracy and overall sense-checking. The stakeholders contributed to the development of the safety recommendations and safety observations based on the evidence gathered.

Stakeholders included:

- Royal College of Anaesthetists
- Difficult Airway Society
- Association of Anaesthetists
- Association of Paediatric Anaesthetists of Great Britain and Ireland
- National Institute for Health and Care Excellence
- British Inherited Metabolic Diseases Group
- National Clinical Director for Critical and Perioperative Care, NHS England
- Society for Mucopolysaccharide Diseases (MPS Society)

- subject matter advisors in advanced airway management, from the UK and other countries in advanced airway management
- subject matter advisors in fatigue and occupational psychology
- Medical Advisor to Highly Specialised Services at NHS England
- tertiary centres
- a retrieval service.

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