ADVANCES IN MULTIDISCIPLINARY TRACHEOSTOMY CARE AND THEIR IMPACT ON THE SAFETY AND QUALITY OF CARE IN THE CRITICALLY ILL

BA MCGRATH

PhD 2018

ADVANCES IN MULTIDISCIPLINARY TRACHEOSTOMY CARE AND THEIR IMPACT ON THE SAFETY AND QUALITY OF CARE IN THE CRITICALLY ILL

BRENDAN A MCGRATH

A thesis submitted in partial fulfilment of the requirements of the Manchester Metropolitan University for the degree of Doctor of Philosophy by Published Work (Route 2)

Faculty of Health, Psychology and Social Care

Department of Nursing

2018

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

Brendan A McGrath

MB ChB FRCP FRCA DICM EDIC PGCertMedEd AHEA FFICM MAcadMEd

Consultant in Anaesthesia & Intensive Care Medicine
University Hospital South Manchester

Honorary Senior Lecturer, Institute of Inflammation & Repair
University of Manchester

Domain co-lead, NHS Adoption & Improvement, Greater Manchester
Academic Centre for Acute Tissue Injury and Trauma (GM-CAT)

Trevor McGill Visiting Professor
Boston Children's Hospital & Harvard University

National Tracheostomy Lead Clinician, NHS England

Contents

Section 1 - Introduction
- 1.1 History and evolution of tracheostomy
- 1.2 Anatomical considerations
- 1.3 Tracheostomy problems
- 1.4 Multidisciplinary tracheostomy care
- 1.5 Defining quality of tracheostomy care
- 1.6 Aims of the thesis

Section 2 – Narratives, Publications and Critical Appraisal
- **2.1 Background**
  - a. Narrative
  - b. National ICU airway problems (Paper 1)
  - c. Ward Tracheostomy problems (Paper 2)
  - d. Critical appraisal
- **2.2 Defining the problem**
  - a. Narrative
  - b. Why is airway care such a problem in ICU? (Paper 3)
  - c. Critical appraisal
- **2.3 Designing resources and solutions**
  - a. Narrative
  - b. Multidisciplinary emergency guidelines (Paper 4)
  - c. Critical appraisal
- **2.4 Evaluating the impact of healthcare improvements**
  - a. Narrative
  - b. Targeted education and infrastructure changes (Paper 5)
  - c. Introducing the GTC into 4 diverse NHS hospitals (Paper 6)
  - d. Critical appraisal
- **2.5 Defining quality of tracheostomy care**
  - a. Narrative
  - b. Scoring systems to assess tracheostomy tube position (Paper 7)
  - c. Benchmarking quality for airway device management (Paper 8)
  - d. Critical appraisal

Section 3 - Future research strategies
- 3.1 Narrative
- 3.2 Improving Tracheostomy Care (current grant-funded project)
- 3.3 Resource use research and cost-of-illness assessment
- 3.4 Benchmarking and evaluation of emergency algorithms: did they work?
- 3.5 Evaluating the effect of institution-wide reporting culture on tracheostomy related critical incidents

Section 4 – Conclusions
- 4.1 Summary: National NHS-wide strategy for tracheostomy QI

References

Appendix

Detailed Contents

Contents

Abstract

Structure

Acknowledgements

Section 1 - Introduction

1.1 History and evolution of tracheostomy

1.2 Anatomical considerations

1.3 Tracheostomy problems

1.4 Multidisciplinary tracheostomy care

1.5 Defining quality of tracheostomy care

1.6 Aims of the thesis

Section 2 – Narratives, Publications and Critical Appraisal

Includes RDPUB forms and statements providing a clear indication of my contribution to each publication.

2.1 Background: why do we need to improve care? How do we measure the safety and quality of care provided?

a. Narrative: why do we need to improve care? How do we measure the safety and quality of care provided?

b. National ICU airway problems (Paper 1)
Thomas AN, **McGrath BA.** Patient safety incidents associated with airway devices in critical care: a review of reports to the UK National Patient Safety Agency. *Anaesthesia.* 2009 Apr;64(4):358-65.

c. Ward Tracheostomy problems (Paper 2)
McGrath BA, Thomas AN. Patient safety incidents associated with tracheostomies occurring in hospital wards: a review of reports to the UK National Patient Safety Agency. *Postgrad Med J.* 2010 Sep;86(1019):522-5.

d. Critical appraisal: reported critical incidents as a methodology for informing healthcare quality improvements

e. Critical appraisal: investigating locations in which patients come to harm

2.2 Defining the problem

a. Narrative: why is airway care such a problem in ICU?

b. Why is airway care such a problem in ICU? (Paper 3)
McGrath BA, Calder N. Tracheostomy and laryngectomy emergency management – implications for critical care. *British Journal of Intensive Care*. 2013; Autumn:77-80.

c. Critical appraisal: multidisciplinary challenges for airway and tracheostomy management in ICU

d. Critical appraisal: understanding the scale of the problem

e. Critical appraisal: did my work identify themes that were consistent with that from other investigators working in this field?

2.3 Designing resources and solutions

a. Narrative: designing resources and solutions

b. Multidisciplinary emergency guidelines (Paper 4)
McGrath BA, Bates L, Atkinson D, Moore JA; National Tracheostomy Safety Project. Multidisciplinary guidelines for the management of tracheostomy and laryngectomy airway emergencies. *Anaesthesia.* 2012;67(9):1025-41.

c. Critical appraisal: methodological critique of the guidelines paper

2.4 Evaluating the impact of healthcare improvements

a. Narrative: evaluating the impact

b. The impact on patient safety incidents of introducing targeted education and infrastructure changes (Paper 5)
McGrath B, Calder N, Laha S, Perks A, Chaudry I, Bates L, Moore J, Atkinson D. Reduction in harm from tracheostomy-related patient safety incidents following introduction of the National Tracheostomy Safety Project: Our experience from two hundred and eighty seven incidents. *Clin Otolaryngol.* 2013 Volume 38, Issue 6, pages 541–545.

c. Introducing the GTC into 4 diverse NHS hospitals (Paper 6)
McGrath BA, Lynch SJ et al BMJ Qual Saf Healthcare Paper. *BMJ Quality Improvement Reports. 6(1):u220636. [Online].*

d. Critical appraisal: critical incidents as a measure of the effectiveness of interventions

e. Critical appraisal: minimising potential bias when using critical incidents as an outcome measure

f. Critical appraisal: developing additional surrogates for the quality of care

2.5 Defining quality of tracheostomy care

a. Narrative: defining quality

b. Scoring systems to assess tracheostomy tube position (Paper 7)
BA McGrath, K Lynch, R Templeton, K Webster, W Simpson, P Alexander and MO Columb. Assessment of scoring systems to describe the position of tracheostomy tubes within the airway – the Lunar study. *Br J Anaesth* (2017) 118 (1): 132-138.

c. What are the best outcome measures for benchmarking quality for airway device management in ICU: Ventilator associated pneumonia? (Paper 8)
Wallace FA, Alexander PD, Spencer C, Naisbitt J, Moore JA, **McGrath BA.** A comparison of ventilator-associated pneumonia rates determined by different scoring systems in four intensive care units in the North West of England. *Anaesthesia*. 2015 Nov;70(11):1274-80.

d. Critical appraisal: defining the quality of tracheostomy care

Section 3 - Future research strategies

Future initiatives to improve the Safety & Quality of Care for tracheostomy patients in the ICU

3.1 Narrative
3.2 Improving Tracheostomy Care (current grant-funded project)
3.3 Resource use research and cost-of-illness assessment
3.4 Benchmarking and evaluation of emergency algorithms: did they work?
3.5 Evaluating the effect of institution-wide reporting culture on tracheostomy related critical incidents

Section 4 – Conclusions

4.1 Summary: National NHS-wide strategy for tracheostomy QI

References

Figure and Table legends and sources

Appendix

Abstract

Tracheostomy is one of the first recorded surgical procedures and refers to an incision into the windpipe at the front of the neck, classically performed by surgeons to relieve airway obstruction. A tracheostomy tube can be inserted to maintain airway patency. The majority of tracheostomies are now performed the critically ill, typically whilst dependent on invasive respiratory support. Analysis of tracheostomy-related critical incidents helped to understand the frequency, nature and severity of problems that can occur at initial placement or during subsequent use. If problems occur, significant harm may rapidly develop, especially in the critically ill. Recurrent themes that contributed to avoidable mortality include poor emergency management and limitations in infrastructure, equipment provision, staff training and education. Many of the problems identified are amenable to prospective, multidisciplinary quality improvement strategies. This thesis describes my published work in this area.

An underlying challenge to improving care lies in the fact that care requires input from many clinical disciplines. Complex patients need care in specialised settings that are not always adequately trained and supported in delivering safe tracheostomy care. My research has evaluated the impact of a co-ordinated multidisciplinary approach using bespoke resources, staff education, infrastructure changes and patient champions to direct healthcare improvements. I have critically appraised my bespoke resources and evaluated and justified the use of a variety of quality and safety metrics to define better care, both at patient-level and using institutional process measures, reflecting better coordination of care, contributing to significant cost savings.

Further opportunities to build understanding of the nature of tracheostomy problems in ICU and the success of quality improvement initiatives will be discussed. Future aims are to not only improve care but also to perform a detailed economic analysis and capture knowledge on how to best implement necessary changes rapidly in today's complex NHS.

The structure of the thesis

This PhD by publication thesis is based on a collection of key papers I have published between 2009 and 2016. These papers describe my work in the field of tracheostomy care and are grouped into themes:

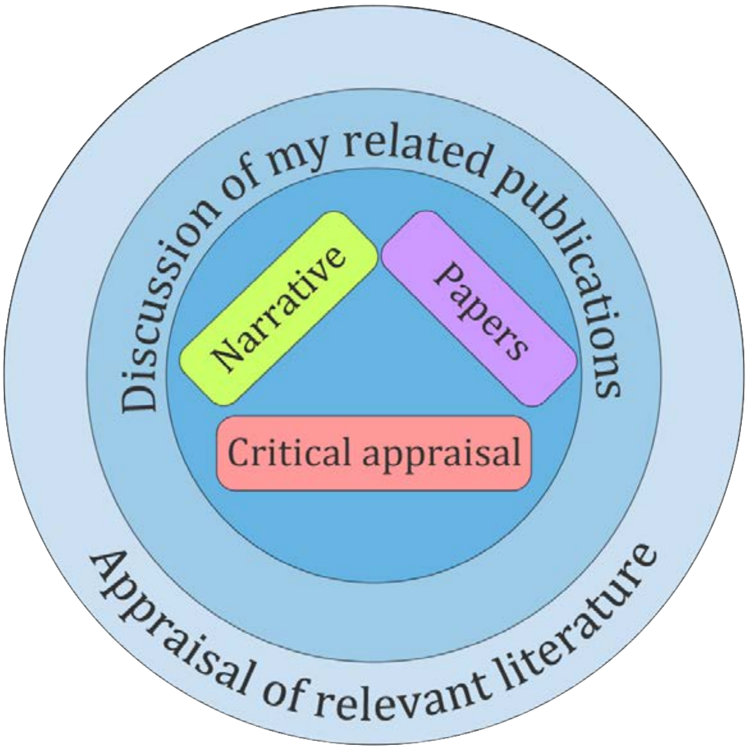
- Background
- Defining the problem
- Designing resources and solutions
- Evaluating the impact of healthcare improvements
- Defining the quality of care

Linking narratives are provided with the papers that define the context of the work and how the paper fits into the 'story' that my body of work describes. When writing the thesis, it became clear that the critical appraisal of my published works sometimes linked into subsequent sections, as the limitations of some of the early works are addressed by subsequent papers. For this reason, the relevant sections of the critical appraisal are located after the appropriate papers.

Introduction
Linking narrative
Papers
Critical Appraisal
Future research strategies
Conclusion

The sections of the thesis are colour coded. If the reader prefers to read the thesis in a more 'traditional' layout, then the appropriate sections can be read together in turn.

The critical appraisal sections will focus firstly on the papers presented in this thesis. I will briefly discuss any of my related publications that are relevant to the presented works, followed by an appraisal of the wider literature in order to place my presented papers in context.



Thesis key points

The thesis summary presented overleaf in Figure 1 summarises the key points arising from each themed section, both from the narrative and from the related critical appraisal. This figure is reproduced alongside the conclusions in Section 4.

Figure 1. *Thesis key points*

Theme	Linking narrative	Critical appraisal
Background Paper 1 & Paper 2	Retrospective analysis of national critical incident database of reported tracheostomy problems in the NHS	Although imperfect, incident analysis can identify themes and compare locations. Suitable for relatively rare events.
Defining the problem Paper 3	Invited editorial offering expert opinion on the problems that tracheostomy care poses for the multidisciplinary ICU team.	The caseload, physiology, environment, staffing, airway pathology & devices in ICU are different, but effective teamwork can improve care.
Designing resources & solutions Paper 4	Multidisciplinary emergency guidelines	Medical simulation has an important role in development, evaluation and refinement of airway management algorithms.
Evaluating the impact Paper 5 & Paper 6	Exploring different methods to measure the impact of multidisciplinary resources to improve care	Critical incident analysis is a reasonable outcome measure. Trends and system-wide process measures are useful.
Defining quality Paper 7 & Paper 8	Developing and evaluating systems to define and measure quality of tracheostomy care in the ICU	Quality indicators beyond the basic care of the tracheostomy tube itself can demonstrate effective bedside, multidisciplinary and system-wide care.

Selection of papers and journals

The papers presented in this thesis summarise the key publications that have supported my work as outlined above. They are selected from a larger body of work that I have published over the last 10 years. The papers have been selected as they 'tell the story' of my development as a researcher as I have explored the problems with tracheostomies, placed these into context in my clinical area of expertise (ICU), involved the multidisciplinary team and patients in developing resources and then evaluated the effect and impact of my work.

The papers were aimed at different journals, all with different readership and different impact factors (IF). Whilst wishing to demonstrate that my work was considered of a high enough standard for publication in relatively high impact journals in my field, I also strived to ensure that my papers would be read by a relevant 'target audience'; and this audience could change from paper to paper. A brief rationale for the selected journals is presented below:

1. Anaesthesia - as the official journal of the Association of Anaesthetists of Great Britain and Northern Ireland, this journal is widely read by my target audience of Anaesthetists and Intensivists. IF 4.7 (2017).
2. Post Graduate Medical Journal - this journal is widely read by the Physicians for whom my ward-specific tracheostomy incident paper and recommendations would be relevant. IF 1.6.
3. British Journal of Intensive Care - whilst the IF journal is low (<1.0) it is widely read by ICU doctors, nurses and is a constant fixture in many ICU offices and break rooms. This was important to me as I wanted to make the case for improvements in tracheostomy care to the multidisciplinary staff at the bedside and felt that this journal was an appropriate medium.
4. British Journal of Anaesthesia - this journal has an IF of 6.3 and is the no.1 ranked journal for Anaesthesia. Publishing my work in the BJA demonstrated that my papers were of a standard appropriate to the highest ranked journal in my professional sphere.
5. British Medical Journal: BMJ Quality - this relatively new journal has an IF of 4.0 and published high quality QI publications for a general multidisciplinary audience.
6. Journal of the Intensive Care Society - Similar to the BJIC, the relatively low IF of 2.2 is offset by the wide-ranging multidisciplinary readership, appropriate for my MDT research.

Acknowledgements

This thesis would not have been possible without the support and advice of a number of colleagues, family members and friends. I am also extremely grateful for the academic and financial support afforded to me by the Difficult Airway Society as part of their DAS Scholar programme. I would particularly like to thank the following people:

For academic advice

- Dr Chris Wibberley, Manchester Metropolitan University
- Prof Paul Dark, University of Manchester
- Dr Andrew Bentley, University of Manchester
- Dr Tim Felton, University of Manchester
- Prof Jaideep Pandit, University of Oxford & the Difficult Airway Society
- Prof Andrew Smith, University of Lancaster

All of my co-authors, especially

- Dr Dougal Atkinson
- Dr John Moore
- Dr Lucy Bates
- Dr Cath Doherty
- Dr Peter Alexander
- Dr Malachy Columb
- Dr Tony Thomas

For everything else

- Emma, Cerys and Bethan McGrath xxx

Section 1

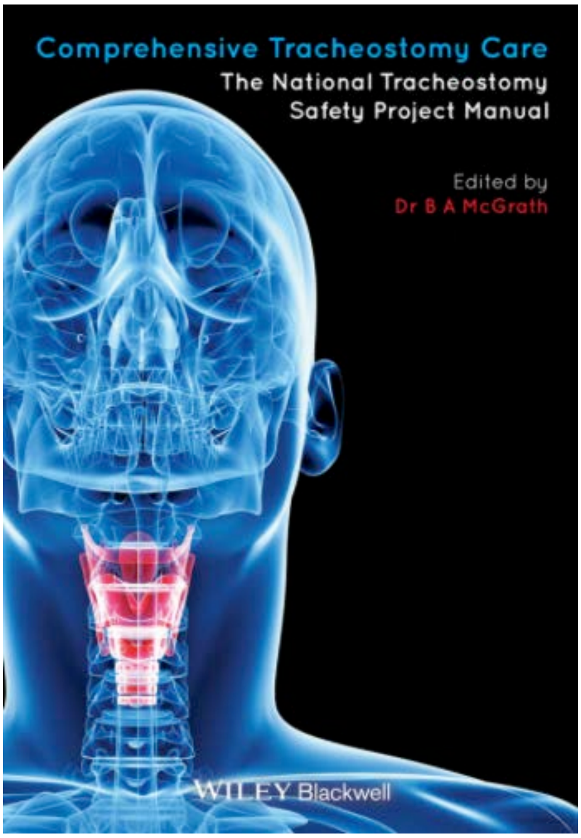
Introduction

Chapter 1 - Introduction

1.1 History and evolution of tracheostomy
1.2 Anatomical considerations
1.3 Tracheostomy problems
1.4 Multidisciplinary tracheostomy care
1.5 Defining quality of tracheostomy care
1.6 Aims of the thesis

The introductory chapters explain some of the key principles and elements of tracheostomy and tracheostomy care. The reader will better understand some of the approaches to improvements described later in this thesis.

This introduction is based on the introductory chapters from: McGrath BA Comprehensive Tracheostomy Care – the National Tracheostomy Safety Project Manual, 1st Ed. John Wiley & Sons, Published Feb 2014



1.1. History and evolution of tracheostomy

What is a tracheostomy?

A tracheostomy is an artificial opening made into the trachea through the anterior (front part of the) neck. This may be temporary or permanent. A tracheostomy tube is usually inserted, providing a patent opening. The tube enables airflow to enter the trachea and lungs directly, bypassing the nose, pharynx and larynx.

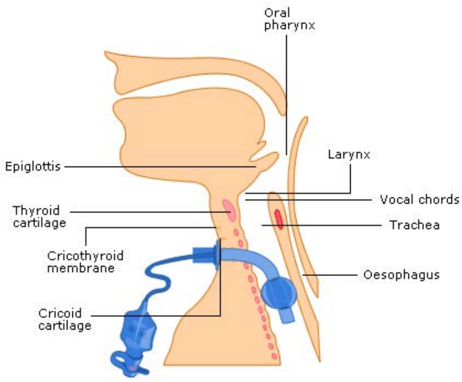


Figure 1.1 (above left) shows a tracheostomy tube in situ.
Figure 1.2 (above right) details a sagittal section through the neck and shows a cuffed tracheostomy tube passing through the anterior neck into the trachea.

The 'Upper airways' can be defined as the nose, mouth, larynx, pharynx and proximal (extra-thoracic) trachea, and these act as a conduit for inhaled or exhaled respiratory gases to the lungs. The 'Lower airways' comprise the intra-thoracic part of the trachea and the multiple divisions of bronchi and bronchioles that deliver gas to and from the alveoli in the lung. Airway obstruction leads to failure of oxygen delivery to the lungs and subsequently to the rest of the body and is rapidly fatal.

The history of tracheostomy

Tracheostomy is one of the earliest described surgical procedures, with descriptions found on ancient Egyptian clay tablets dating back to 3600 BC. Instruction in the surgical technique can be found in *Ebers's Papyrus*, dating back to about 1550 BC, but also in Sanskrit Holy Scriptures, the *Rig Veda*, dating back to 2000 BC (Olszewski and Miłoński, 2007). The Greek ruler, Alexander the Great is also reported to have performed a surgical tracheostomy in the fourth century B.C. using the tip of his sword to open the windpipe of a choking soldier (Szmuk et al., 2007). There was scepticism recorded in the writings of second century Greek medical writers Galen and Aretaeus around the ability of cut cartilage to heal, and tracheostomy was probably not widely performed throughout the Middle Ages. However, El Zahrwai (known to Europeans as Albucasis) described successful closure of an incised larynx on a slave girl, confirming that an incised trachea could indeed heal (Al-Zahrāwī et al., 1973).

ANTONIO MVSA BRASAVOLA
dalla litografia del Farina pubblicata dal Petrucci nelle sue vite di ferraresi celebri.

The first 'modern' surgical tracheostomy is commonly credited to Italian physician Antonio Brasavola, publishing his account in 1546 (Goodall, 1973). The patient was suffering from a laryngeal abscess and recovered from the procedure. Throughout the Renaissance period, technical advances were recorded by prominent surgeons and anatomists, including recommendations to use a silver tube inserted into the tracheostomy to maintain the patency of the artificial airway. Julius Casserius recommended a curved silver tube with several holes along its course whilst working as Professor of Anatomy at the University of Padua. The British physician George Martine reported using a double lumen tracheostomy tube in 1730 and increasing accounts of successful use of tracheostomy to relieve upper airway obstruction appeared in the literature. Jean Charles Felix Caron is believed to have performed the first recorded tracheostomy in a child in 1776, relieving obstruction in a 7-year-old boy who had inhaled a bean (Rajesh and Meher, 2017; *Tracheotomy*, (no date).

Accounts discussing the failure of tracheostomy were also published, including that describing the death of George Washington who died in 1799, probably from upper airway obstruction due to epiglottitis or an abscess. His physicians considered a tracheostomy but were reportedly reluctant to 'have a go' on someone so eminent (Brickell, 1903)! The famous surgeon Chevalier Jackson described modification to the procedure in 1909, making it safer to perform with markedly reduced long-term complications, especially for children.

Figure 1.4. Chevalier Jackson demonstrating a tracheostomy on a rag doll in his car, around 1925.

The 1952 polio epidemic saw tracheostomies used in the first intensive care units in Copenhagen, Denmark (Figure 1.5). Bjørn Ibsen pioneered this technique and thus allowed positive pressure ventilation to be delivered to patients, thereby reducing mortality from bulbar polio from around 85% to less than 15%. These advances in treatment using prolonged mechanical ventilation were seen as the birth of Intensive Care Medicine. Reisner-Sénélar, 2011.

Figure 1.5. A patient from the Copenhagen polio epidemic being ventilated via a tracheostomy

Indications for tracheostomy

Historical procedures were usually undertaken to provide emergency 'surgical airways' to relieve obstruction to the upper airway, caused by trauma or tumour. Whilst this indication remains, the advent of modern intensive care has seen a demand for prolonged mechanical ventilation. This is usually best achieved via a tracheostomy if the patient requires ventilation for more than around 10 days. Industry responded to this demand and developed kits that could insert tracheostomies safely at the bedside in the Intensive Care Unit (ICUs), meaning that patients did not need to be transferred to the operating theatre, and indeed a surgeon was not required at all. The utility of bedside 'percutaneous' tracheostomy has introduced a new cohort of patients with tracheostomies that can be considered as having 'medical' problems, rather than the original cohort with upper airway obstruction or undergoing head and neck surgical procedures. The majority of tracheostomy procedures are now performed percutaneously in ICUs rather than by surgeons (McGrath et al., 2012; Martin et al., 2014).

In modern medical practice, the indications have widened both for temporary and permanent tracheostomy. Indications for tracheostomy can be considered as:

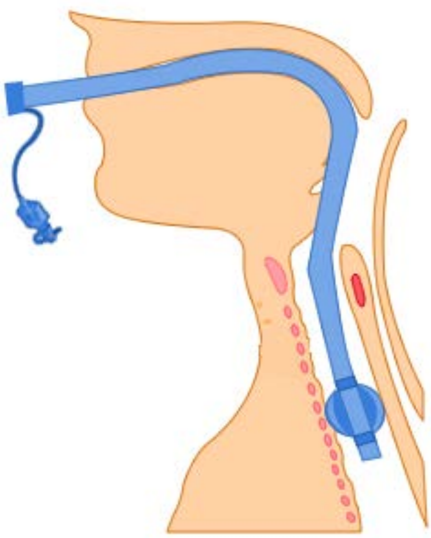
a. to secure and maintain a patent (clear) airway in actual or potential upper airway obstruction
b. to facilitate weaning from artificial ventilation in acute respiratory failure and prolonged ventilation
c. to enable long-term mechanical ventilation of patients, either in an acute ICU setting or sometimes chronically in hospitals or in the community

d. to secure and maintain a safe airway in patients with injuries to the face, head or neck and following certain types of surgery to the head and neck

e. to facilitate the removal of bronchial secretions where there is poor cough effort with sputum retention: direct suctioning of the trachea can be performed by introducing a catheter via the tracheostomy

f. in an attempt to protect the airway of patients who are at high risk of aspiration, that is patients with incompetent laryngeal and tongue movement on swallowing e.g. neuromuscular disorders, unconsciousness, head injuries, stroke etc. A tube with a cuff is inserted which can keep some secretions or aspirated material out of the airways that would otherwise enter the lungs.

There is no convincing data that can guide clinicians as to the timing of tracheostomy (Veenith et al., 2008; Young et al., 2013; Gomez Silva, 2012). Critically ill patients requiring prolonged mechanical ventilation in the ICU



require an invasive tube to be inserted into the airway. This is usually via the mouth, across the vocal cords and into the proximal trachea (See *Figure 1.6 left – a cuffed oral endotracheal tube in situ)*. Prolonged use of an ETT can cause problems with the larynx and the upper airway, and the tube is unpleasant to tolerate. Balancing the risks of managing an airway with prolonged endotracheal tube (ETT) intubation, versus the risks of tracheostomy (procedural and post-placement) is difficult. For specific circumstances, such as extensive elective head and neck surgery, the decision can be straightforward.

Risks of prolonged ETT and tracheostomy

Risks of prolonged ETT:

Unpleasant to tolerate

Prolonged sedation required

Difficult to re-institute respiratory support without re-intubation

Upper airway trauma

Damage to vocal cords

Breaches larynx, risks aspiration

Blockage and displacement

Risks of tracheostomy:

Invasive procedure

Bleeding and airway loss during procedure

Stoma infection or breakdown

Scarring, tracheomalacia, stenosis

Blockage and displacement

Damage to adjacent structure

There are over 5,000 surgical tracheostomy procedures performed annually in head and neck surgical practice in England. Estimates of around 10-15,000 percutaneous tracheostomies performed each year in England's critical care units were confirmed by the 2014 NCEPOD report (McGrath et al., 2012; Martin et al., 2014). Tracheostomies are also becoming more commonplace on the general wards of the hospital. This is partly due to pressures on intensive care beds and the increasing drive to de-escalate care quickly, along with increasing numbers of patients benefiting from temporary tracheostomies. These groups include those with chronic respiratory or neurological problems. Increasing numbers of patients with tracheostomies are being cared for on wards outside of specialist locations (typically ENT or Maxillofacial wards, or sometimes neurosurgical or neurology wards) or critical care infrastructure.

This has implications for the safety of patients who may be cared for on wards without the necessary competencies and experience to manage this challenging cohort and local measures need to be in place to ensure that safe routine and emergency care can be provided.

Classification of tracheostomy

Tracheostomy may be temporary or long term/permanent, and may be formed electively or as an emergency procedure. They may also be classified by their method of initial insertion – either surgical or percutaneous.

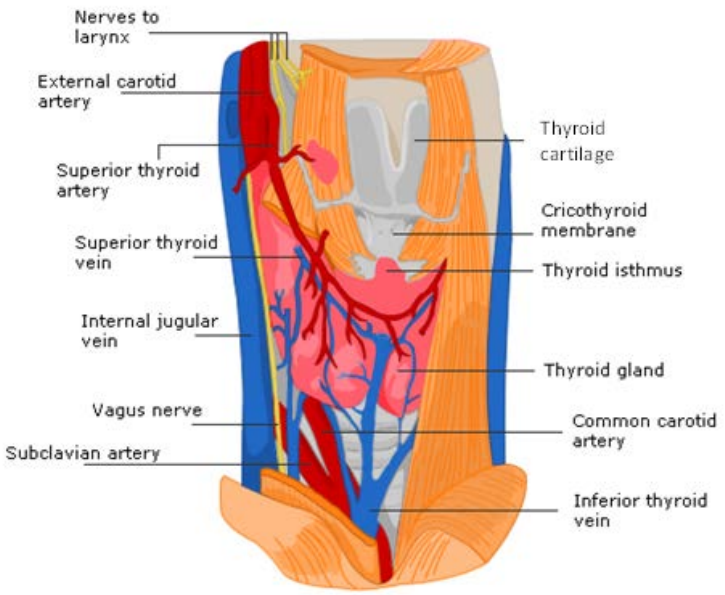
Temporary tracheostomies will be formed when patients require long/short term respiratory support or cannot maintain the patency of their own airway. They can also provide a degree of 'protection' of the airways against aspiration if the swallowing or neurological control mechanisms of the larynx or pharynx are damaged (commonly in head injuries or neurological diseases). Certain maxillofacial or ENT surgical procedures require a temporary tracheostomy to facilitate the procedure. These tubes will be removed if and when the patient recovers.

Long term/permanent tracheostomies are used when the underlying condition is chronic, permanent or progressive. This includes carcinoma of the naso-oropharynx or larynx. Dependent on the stage of the disease either a tracheostomy or a laryngectomy will be performed. Some patients need chronic respiratory support or long-term airway protection and this requires a long term/permanent tracheostomy.

1.2. Anatomical considerations

Anatomy relevant to tracheostomy

There are a variety of tracheostomy techniques but they all aim to enter the trachea around the gap between the second and third tracheal rings. Emergency access to the airway can be achieved through the relatively avascular cricothyroid membrane. The trachea is deeper into the neck the more caudally it travels and in some patients it is difficult to feel the trachea at all.



There are many important structures that lie in the neck in close proximity to the trachea. These can be damaged, or cause haemorrhage, while performing a tracheostomy. The thyroid isthmus is often resected during a surgical tracheostomy, but this is not possible during a percutaneous procedure (*Figure 1.7 above – anatomy relevant to tracheostomy*). Similarly, bleeding vessels are more amenable to ligation and diathermy using a surgical technique. The percutaneous technique probably causes less tissue trauma and may make bleeding less likely, but the only way to stop any resultant bleeding is by applying pressure. This can be externally applied or caused by a tamponading effect from the tube within the newly dilated tissues.

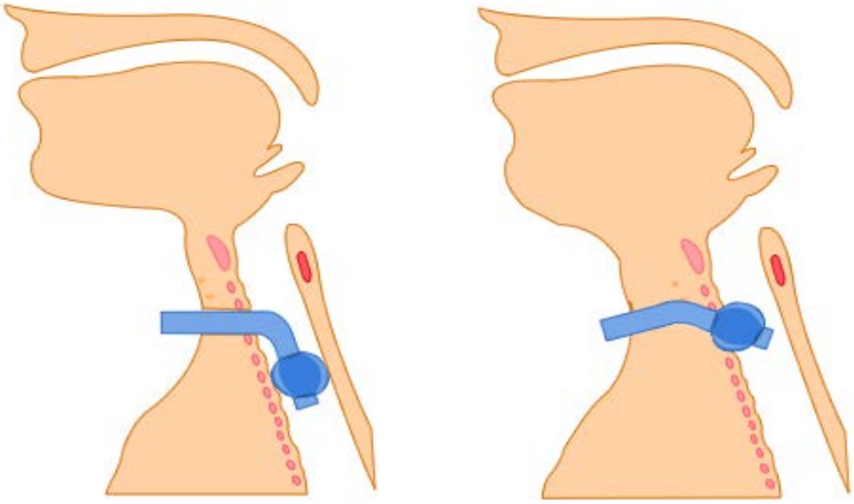


Figure 1.8: tracheostomy position in the obese neck (above).

In large or obese patients, it can be seen in the figure above that the distance between the skin and the trachea can be significant. This may require specialist tracheostomy tubes to ensure a safe and correct 'fit.'

Laryngectomy

Laryngectomy involves removal of the larynx (voice box) and the resulting end-stoma can closely resemble a tracheostomy. This is potentially a cause of life-threatening confusion for healthcare staff, as there is no longer a communication between the face/nose (upper airways) and the lungs. Oral, pharyngeal or laryngeal carcinomas are usually squamous cell carcinomas and can be treated by radiotherapy and/or surgery, depending on the site and the general condition of the patient. Surgical resection of the tongue base or epiglottis may not necessarily involve removal of the larynx and is sometimes referred to as a *supraglottic laryngectomy*. It is sometimes possible to resect only one half of the larynx for localised disease with a *hemilaryngectomy*. However, if a *total laryngectomy* is required, this involves complete surgical removal of the larynx, which disconnects the upper airway (nose and mouth) from the lungs. This is a permanent and irreversible procedure (although partial laryngectomies are possible). The trachea is transected (cut) and then the open end is stitched onto the front of the neck. Once this has been performed, the patient will never be able to breathe or be oxygenated or ventilated through the upper airway again.

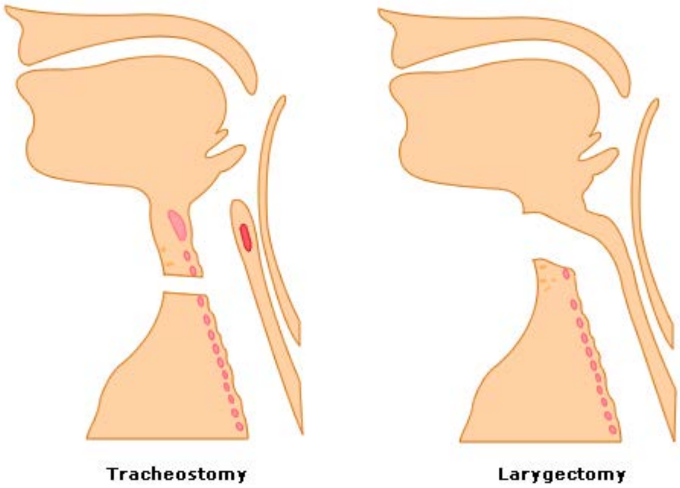


Figure 1.9: The differing anatomy of a tracheostomy (shown on the left) and laryngectomy (on the right).

As shown in Figure 1.9, a tracheostomy still has a potentially patent upper airway. As a number of tracheostomies are performed because of actual or anticipated difficulty with the upper airway, so upper airway patency cannot be guaranteed.

The anatomy relevant for laryngectomy is similar, except that the result is an end stoma: the trachea terminates at the front of the neck and is no longer in continuity with the upper airways. It can be very difficult to tell the difference, especially if a carer or responder is not familiar with laryngectomies.

Techniques for inserting a tracheostomy

Surgical tracheostomy

This technique is usually carried out in an operating theatre where conditions are sterile and lighting is good. It is possible to perform a surgical tracheostomy at the bedside in the ICU. General anaesthesia is commonly used, however surgical tracheostomies can also be carried out under local anaesthetic. A surgical opening is made into the skin and the tissues of the neck are dissected down to the trachea. The trachea is entered by forming a slit or a window into which a tube is placed (Frost, 1976). The tube may then be sutured to the skin and/or secured with cloth ties or a holder.

Percutaneous tracheostomy

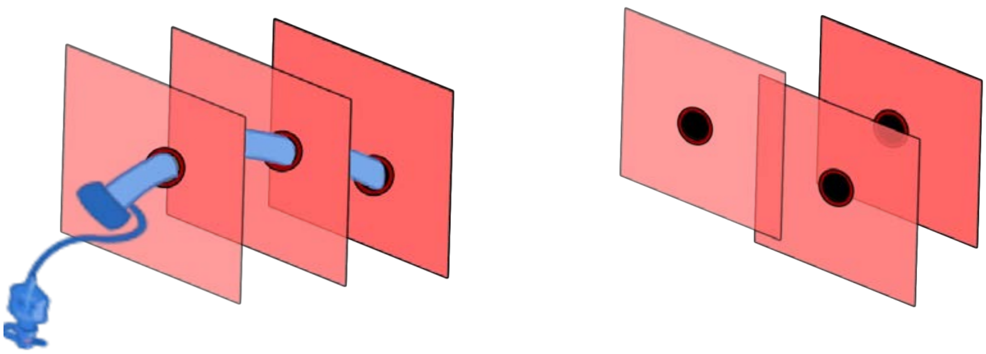
This is the most commonly used technique in critical care as it is simple, relatively quick and can be performed at the bedside using anaesthetic sedation and local anaesthetic. Moving critically ill patients to the operating theatre can be challenging, so a safe, bedside procedure often makes this the technique of choice in the critically ill. The procedure involves the insertion of a needle through the neck into the trachea followed by a guide-wire through the needle. The needle is removed and the tract made gradually larger by inserting a series of progressively larger dilators over the wire until the stoma is large enough to fit a suitable tube (Seldinger technique, Figure 1.10). The tube is then secured by cloth ties, sutures or a holder (Van Heurn and Brink, 1996).

Figure 1.10: Percutaneous tracheostomy insertion into a model via the Seldinger technique.

There is less dissection and cutting than with a surgical technique and this may cause less tissue trauma and bleeding. The tissues are stretched or dilated. However, the only way to stop any bleeding if it does occur is via the tamponading effect of the tube in the stretched tract. Most centres will opt for a surgical tracheostomy if a patient has bleeding problems or a large vessel near the puncture site, as this allows more options for controlling potential bleeding (diathermy, ligation). Some patients do not have an easily palpable trachea and a surgical approach may also be safer for these patients. It is possible to perform hybrid techniques where a small amount of blunt dissection is performed prior to puncturing the trachea with a percutaneous set. Alternatively, following formal surgical exposure, a percutaneous set is used to enter the trachea if the trachea is difficult to access.

Introducing a bronchoscope into the airway does have its drawbacks. Depending on the size of the endoscope, an endotracheal tube of at least 7 mm internal diameter is usually required. This doesn't leave much room for ventilation and a degree of hypoventilation can be expected during the procedure. There is also the risk of damaging the endoscope during initial puncture of the trachea, although disposable endoscopes are now available which may address part of this problem.

Figure 1.11: If a percutaneously inserted tracheostomy tube becomes displaced, the recently dilated tissues can 'spring' into their original positions, making reinsertion difficult.



One significant difference with percutaneous tracheostomies in the first few days after the stoma is created, the tract will take 7-10 days to mature, compared with 2-4 days for a surgical tracheostomy. If a percutaneously-inserted tracheostomy tube becomes displaced in this early period, the tissues are more likely to 'spring' back into their original places, whereas the cut and sutured surgical tract is more likely to remain patent. This has implications for attempting to re-insert a new tracheostomy tube into a newly created percutaneous stoma. Despite the wealth of literature and claims about the various benefits of one technique over another, most clinicians from all specialties will agree that after the first week or so, what you have is a tracheostomy stoma and it doesn't really matter how it was formed. Better follow up of tracheostomies may reveal subtle differences in the future (Susanto, 2002).

Physiological changes with a tracheostomy

As well as changing the airway anatomy, the airway physiology is altered when a patient has a tracheostomy inserted. Depending on the type of tube and presence of a cuff, the upper airway may be isolated completely. The tracheostomy will generally remain until the indication for insertion has resolved. In some instances however, the tracheostomy will be permanent. A laryngectomy is a permanent surgical change to the airway anatomy. Some of the physiological changes are advantageous to us as clinicians treating these patients. Others necessitate extra vigilance and care.

Upper airway anatomical dead space can be reduced by up to 50%.
This can be advantageous when weaning patients from mechanical ventilation. The dead space takes no part in gas exchange and adds to the work of breathing. Reducing this can help patients with critical respiratory reserves get off a ventilator.

The natural warming, humidification and filtering of air that usually takes place in the upper airway is lost.
This is one of the biggest dangers with a tracheostomy or laryngectomy. Secretions will become thick and dried and can easily obstruct a stoma or tube. This situation is made worse if there are copious secretions.

The patient's ability to speak is removed.

This is a big problem for the patient and can lead to distress and anxiety. Sometimes, we can use aids such as speaking valves to help patients vocalise, but attentive nursing staff are probably the most valuable source of help. Communication boards can be useful too.

Sense of taste and smell can be lost.

This can reduce appetite and general wellbeing of the patient. Patients' report this as a significant problem that can be easy to overlook when managing their 'medical' problems.

Altered body image

This is an important factor as it can have a major psychological impact. If possible the patient should have careful preoperative explanation. If this is not possible the patient must receive explanation and support postoperatively. The patient should be informed that scarring would be minimal when the tracheostomy is removed and the stoma has healed and, that speech will return (as long as the vocal cords remain intact). On average, the stoma will close and heal within 4-6 weeks. However, this may vary from patient to patient depending on factors affecting wound healing.

The ability to swallow is adversely affected.

Most people with a new tracheostomy will have a naso-gastric tube or similar feeding route and regimen established. The cuff of the tracheostomy or the tube itself interferes with the swallowing mechanics of the larynx. These muscles can waste if not used (during prolonged ventilation) and require careful rehabilitation and assessment. The Speech and Language Therapist (SALT) is an essential member of the multi-disciplinary team (McGrath and Wallace, 2014a).

1.3. Tracheostomy problems

Because of the nature of underlying medical conditions that often lead to the requirement for a tracheostomy, patients who receive a tracheostomy often have poor survival prospects. A review of over 23,000 American inpatient records where a tracheostomy was performed demonstrated that only 80% survived to hospital discharge, with as few as 60% surviving if they had significant co-morbidities (Doherty and McGrath, 2016). The 2014 UK NCEPOD report confirmed an overall mortality rate at the index tracheostomy admission of around 17% (Martin et al., 2014).

While tracheostomies are increasingly commonplace, patient safety incidents associated with their use are unfortunately also increasing. The first of my papers presented in this thesis examined national patient safety incidents and reviewed over 1,700 airway incidents reported to the NPSA between 1st January 2005 and 31st December 2008, including over 30 deaths (Thomas and MacDonald, 2016). When a clinical incident occurs relating to a tracheostomy, the chance of some harm occurring is between 60 and 70%, depending on the location in which the patient is being cared for.

Incidents may be classified as:

- incidents at the time of performing the tracheostomy (e.g. airway loss; damage of adjacent structures; bleeding)
- blockage or displacement of the tracheostomy tube after placement
- equipment incidents (lack of equipment or inappropriate use)
- competency (skills and knowledge) incidents
- infrastructure (staffing and location) incidents
- late complications (e.g. tracheomalacia; stenosis; infection of stoma)

The majority of these incidents are due to the same recurring themes and the resources I have subsequently developed and describe herein are specifically aimed at addressing these (McGrath, O'Donohoe, et al., 2012; McGrath, Bates, et al., 2012; McGrath and Calder, 2013; McGrath and Wallace, 2014a; McGrath, Wilkinson, et al., 2015; McGrath et al., 2016).

Laryngectomy problems

The laryngectomy patient has had the normal upper airway humidification mechanisms bypassed, in the same way as a tracheostomy patient has. They are at risk of blockage of the trachea with secretion or blood. The airway is often more secure than with a temporary tracheostomy, as the trachea is stitched onto the front of the neck. It can still become compromised however, particularly within a few days of surgery. Laryngectomy stomas are usually simple open stomas without a tube inserted. There are a variety of covers, valves and humidification devices available, which can make distinguishing between a tracheostomy and laryngectomy very difficult. Tubes are sometimes inserted into laryngectomy stomas, especially when they have just been created; the patient needs invasive ventilation or requires repeated suctioning.

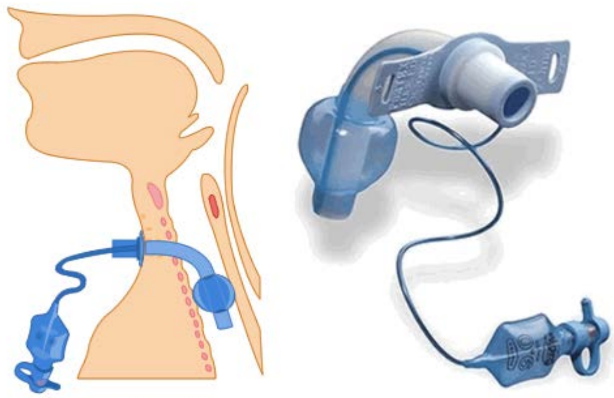
One of the commonest problems with a laryngectomy, particularly in an emergency, is that responders fail to appreciate that the patient has actually had their larynx removed. It can be difficult to tell the difference at the bedside between a laryngectomy and a surgical tracheostomy, particularly close to major surgery. There are many incident reports of patients following a laryngectomy who are mistakenly given oxygen via the face or who have had attempts at managing their upper airway fail because there is no connection between the face and lungs. Likewise, following radical head and neck surgery, carers have failed to manage a patient's upper airway after *assuming* that they had had a laryngectomy when in fact they had not.

Different types of tracheostomy tubes

The different types of tubes available can seem confusing. Essentially tubes can be described by the presence or absence of a cuff at the end, by the presence or absence of an inner cannula, or by the presence or absence of a hole or 'fenestration'. Tubes can be made of different materials and be different diameters and lengths. Most modern tubes are made from medical grade polyvinyl chloride, polyurethane, silicone or a combination of these materials. Some are lined with special films to reduce the 'biofilm' that may develop inside the lumen. There are illustrations and diagrams of the different functions of the range of tubes available via the e-learning section of the website I have developed to host my published resources: www.tracheostomy.org.uk.

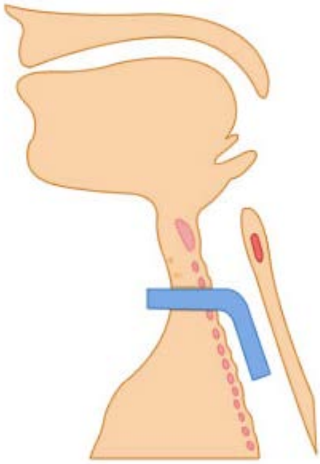
<u>Cuffed tubes</u>

Cuffed tubes have a soft balloon around the distal end of the tube that inflates to seal the airway (Figure 1.12, below). Cuffed tubes are required when positive pressure ventilation is required or in situations where airway protection is essential to minimize aspiration of oral or gastric secretions (although all cuffs are not an absolute barrier to secretions). If the tracheostomy tube lumen is occluded when the cuff is inflated, the patient will not be able to breathe around the tube, assuming the cuff is correctly positioned and inflated within the trachea.



Un-cuffed tubes

Un-cuffed tubes do not have a cuff that can be inflated inside the trachea and tend to be used in longer-term patients who require on-going suction to clear secretions. These tubes (Figure 1.13, right) will not allow sustained effective positive pressure ventilation, as



the gas will escape above the tracheostomy tube. It is essential that patients have an effective cough and gag reflex to protect them from aspiration, as there is no cuff to 'protect' the airway. Un-cuffed tubes are rarely used in acute care.

Another type of un-cuffed tube is the minitrach tube. These are typically 4 mm internal diameter and have no cuff. They are primarily designed to allow airway toilet (suction) but can facilitate delivery of oxygen. They are too small to provide any ventilation or removal of carbon dioxide and so can only be considered an emergency method of oxygenation. Minitrachs are sometimes used when preparing to decannulate a patient. The minitrach can remain in the stoma and keep it patent in case a tracheostomy tube needs to be re-inserted. Minitrachs can also be inserted through the cricothyroid membrane. Specialised insertion kits are available for this, either electively or in an emergency.

Fenestrated tubes

Fenestrated tubes have an opening(s) on the outer cannula, which allows air to pass through the patient's oral/nasal pharynx as well as the tracheal opening. The air movement allows the patient to speak and produces a more effective cough. However, the fenestrations increase the risk of oral or gastric contents entering the lungs. It is therefore essential that patients who are at high risk of aspiration or on positive pressure ventilation do not have a fenestrated tube, unless a non-fenestrated inner cannula is used to block off the fenestrations.

Figure 1.14: Fenestrated tubes can be cuffed or un-cuffed; the various inner tubes are shown

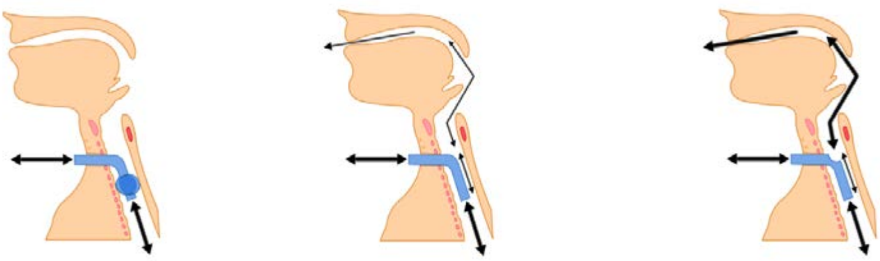


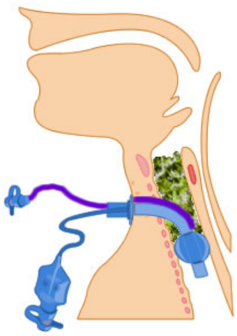
Figure 1.15 (above) demonstrates different airflow patterns with different tubes inserted. Left cuffed (no airflow via upper airways), centre uncuffed (some airflow), right uncuffed and fenestrated (most airflow).

Double cannula tubes

Double cannula tubes have an outer cannula to keep the airway open and an inner cannula, which acts as a removable liner to facilitate cleaning of impacted secretions. Some inner cannulae are disposable; others must be cleaned and re-inserted. Patients discharged from a specialist area with a tracheostomy should have a double lumen, ideally un-cuffed, cannula in place (Martin 2014). This type of tube is the safest to use outside the specialist environment, although to reduce the incidence of tube occlusion, the inner cannula must be regularly cleaned. If an un-cuffed tube becomes blocked, it is more likely that a patient can breathe past the tube via their upper airway, making these tubes inherently safer for non-specialist locations. If there is a high risk of aspiration or need for long-term ventilation, then a cuffed tube may be required long-term.

Tubes with sub-glottic suction

As part of a bundle of care, sub-glottic suction may reduce the incidence of a ventilator associated pneumonia occurring in those patients who require mechanical ventilation via a tracheostomy tube (Martin, 2014). *(Figure 1.16, left).* Tubes are now available from various manufacturers that will allow continuous or intermittent suction of any material that accumulates above the inflated cuff of a tracheostomy tube. Again, when the patient leaves the specialist environment, these tubes should be changed for more simple devices. The extra tubing has the potential to confuse carers, especially when responding to an emergency.



Adjustable flange tracheostomy tubes

These tubes are used in patients who have an abnormally large distance from their skin to their trachea, and a standard tube would not fit properly. There are now dedicated kits for inserting these tubes. Standard tubes may not be the correct size for many critical care patients and increasing numbers may require these tubes. Clinical examination, ultrasound and endoscopic inspection before and after a tracheostomy procedure may help to decide which patients require these types of tubes.

Particular indications for an adjustable flanged tube are:

- patients with very large neck girth including the obese
- oedema caused by burns classically or a capillary leak syndrome (sepsis etc.)
- actual or anticipated oedema after surgical procedures (including tracheostomy itself)

Figure 1.17: Adjustable flange tracheostomy tubes

Choice of tracheostomy tube

Tube obstruction can occur at any time and double-cannula tubes should be used where possible as standard to reduce the risks of obstruction. The disadvantage is that these tubes have a reduced internal diameter, which has implications for gas flow. There is also the problem of repeated disconnection from a ventilator, which can cause de-recruitment of the lung with disadvantages for gas exchange in the critically ill. These factors have to be balanced against the increased risks of tracheostomy tube obstruction with single lumen tubes, and the possibility of requiring a tube change if the patient is to be moved to a non-critical care area. A tracheostomy tube should not be changed for 7-10 days if possible after a percutaneous procedure (McGrath, O'Donohoe, et al., 2012; McGrath, Bates, et al., 2012).

Factors influencing temporary tracheostomy tube choice

Respiratory function

Most temporary tracheostomies inserted to assist with ventilation will be inserted while a patient is in an intensive care unit and still requiring some degree of positive pressure ventilation. This will require the use of a cuffed tracheostomy tube (although it is recognised that long term mechanical ventilation can be delivered through an un-cuffed tube in certain circumstances).

Abnormal airway anatomy

Upper airway endoscopy following percutaneous insertion suggests that a standard tracheostomy tube may be anatomically unsuitable in as many as one third of adult patients. Obese patients may require a tube with an extended proximal length, while patients with fixed flexion abnormalities may not easily accommodate tubes with a fixed angulation. Localised airway pathology, such as tracheomalacia, granuloma formation etc. may on occasion necessitate the use of a tracheostomy tube that has a longer distal length than standard.

Compromised airway, protection and weaning problems

Patients can be weaned to decannulation without any need to change from the cuffed tracheostomy tube that was initially inserted. In some cases however, it may be useful to consider options such as downsizing to an un-cuffed or fenestrated tube, or a tube with the option for sub-glottic aspiration of airway secretions. The introduction of a speaking valve may also aid swallowing and secretion control (see next section).

Speaking

Consideration of whether the patient is able to speak, whether it is desirable for them to speak (laryngeal training) or indeed if they want to attempt speech can dictate the type of tube inserted. If the patient has significant 'mouth breathing' then they may benefit from a smaller tube to allow more air to pass around the tube. If a larger tracheostomy tube is required or desired (e.g. the patient requires intermittent cuff inflation and mechanical ventilation), then a fenestrated tube may be a better choice.

Obstructed / absent upper airway

Patients with an obstructed or absent upper airway are at particular risk should a tracheostomy become obstructed or misplaced. This has implications for both the choice of tracheostomy tube as well as the method by which the stoma is fashioned.

Clinical environment

Obstruction of a cuffed tracheostomy tube is a potentially life-threatening emergency. Wherever possible a dual cannula tube (i.e. a tube with an inner cannula) should be used, particularly for patients cared for outside of a specialist environment who may not have immediate access to clinicians with emergency airway skills. Ward staff can change inner tubes easily and quickly to relieve obstruction with secretions.

The location that patients will be managed in will also influence the choice of tube. Simpler tubes without additional sub-glottic suction ports and channels will reduce the potential for confusion. If the patient is going to be discharged to a facility outside of a hospital environment, then consideration should be made to how easily the carers can manage with the device that is inserted. This will include balancing the risks of using a cuffed tube.

1.4. Multidisciplinary tracheostomy care

Around 25 years ago, tracheostomy was limited to head and neck surgical patients undergoing surgical procedures. Such patients were managed almost exclusively on specialist or more general surgical wards by surgical nursing and medical staff. The landscape has changed in 2017 such that around two-thirds of hospital in-patients with tracheostomy are primarily managed by non-surgical teams, usually from intensive care medicine or respiratory backgrounds (Martin et al., 2014; McGrath and Wilkinson, 2015b). This change has also coincided with developments in the delivery of healthcare in general whereby the increasingly complex needs of patients and their families call for a multidisciplinary team to achieve optimal patient outcomes. Team working models have been described that can be used to address the needs of patients and challenges associated with healthcare systems, addressing the mechanisms needed to establish a paradigm shift in achieving high-quality patient care through effective teamwork (McComb and Hebdon, 2013; van Hoof et al., 2015).

Tracheostomy care is one of the best examples of this multidisciplinary care, with many different medical, nursing and allied health teams being required to deliver coordinated and effective care. There have been calls in the literature for better coordinated management of tracheostomy patients since the early 1990s (Ladyshewsky and Gousseau, 1996; Harkin, 1998; Reibel, 1999; Rumbak et al., 2004; Gilbert, 1987) There then followed published examples and accounts of successful multidisciplinary teams that comprised various staff members. The makeup of the teams typically included speech and language therapists, physiotherapists and nurse specialists, with early teams usually led by medical staff from head and neck surgical, neurology or critical care backgrounds. The role of such teams typically included:

- To set, review and monitor the weaning regimen (from mechanical ventilation) for each patient.
- Setting goals for cuff deflation, use of speaking valve and capping off the tubes
- To identify patients who need tracheostomy changes, either routine changes or downsizing/changing the type of tracheostomy tube in line with the weaning process
- To identify patients who need further investigation by other specialties
- To monitor and audit tracheostomy care.

The challenges of organising healthcare in the modern systems are considerable. Continual improvements in medical technologies and treatments, greater levels of knowledge and awareness amongst patient populations (including their families), and increasing demands for the variety of sources of healthcare available make keeping up-to-date and 'expert' in all areas of theory, practice and the literature in specific fields increasingly difficult. The development of multidisciplinary teams have mirrored these developments and have seen a transition in many fields away from the 'all knowing' individual leading a patient's care.

The value of team working was described in the NHS Plan, from 2000 (NHS, 2000). The need to break down barriers between staff was emphasised so as to tackle inefficiencies in working practices. The report notes:

> *'Old-fashioned demarcations between staff mean some patients see a procession of health professionals… Information is not shared and*

> *investigations are repeated ... Unnecessary boundaries exist between the professions which hold back staff from achieving their true potential.'* (NHS,2000:27) *'Throughout the NHS the old hierarchical ways of working are giving way to more flexible team working between different clinical professionals.'* (NHS,2000:82)

A team can be defined as:

> *'A group of individuals who work together to produce products or deliver services for which they are mutually accountable. Team members share goals and are mutually held accountable for meeting them, they are interdependent in their accomplishment, and they affect the results through their interactions with one another. Because the team is held collectively accountable, the work of integrating with one another is included among the responsibilities of each member'* (Mohrman et al., 1995).

In recent years, several institutions from around the world have reported local initiatives to improve standards of tracheostomy care. Some of the earliest work came from Frank et al, reporting on the multidisciplinary team management approach to the treatment of patients with severe neurogenic dysphagia in Germany and Switzerland (Frank et al., 2007). The team comprised physiotherapists, speech pathologists, nurses and medical staff. They implemented a swallowing therapy and decannulation programme for patients and demonstrated significant reductions in time to decannulation. In the UK, Hunt and McGowan described an expanded specialist team comprising a physiotherapist, speech pathologist, nurse and anaesthetist working together at a national neurology hospital in London (Hunt and McGowan, 2005). This group were able to demonstrate an impact on length of hospital stay for complex patients with tracheostomies by better coordination between their disciplines.

Cameron et al. reported significant improvements in quality and safety in a Melbourne tertiary hospital. Their service was led by Speech and Language Pathologists who were joined by physiotherapists, dieticians, occupational therapists, nursing staff and medical staff from anaesthesia, critical care and head and neck surgery (Cameron et al., 2009). Cameron et al. saw such teamwork as a powerful enabler to rapidly address the needs of complex spinal injury patients and to better coordinate their care. They described all of the individual team members still delivering essentially the same care to the patient, but when this care was delivered in tandem with that from different specialties, care was more efficient and therefore effective. Staff reported more satisfying interactions with their peers and team performance was judged through audit of hospital lengths of stay, which reduced significantly.

ENT-led multidisciplinary teams reported similar improvements in harm metrics and length of stay, exemplified in a series of articles from St Mary's Hospital in London. Led by Professor Tony Narula, the team demonstrated an impact on patient safety incidents and provision of essential bedside equipment for tracheostomy patients on a head and neck surgical unit (Hettige et al., 2008; Cetto et al., 2011).

Recognition of the different and sometimes diverse skills that different staff groups have around tracheostomy care is one of the key themes to my body of work, described herein. Recognising this, I have gone to great lengths to learn from, share with, adapt and incorporate the views and resources of a wide variety of healthcare professional groups into my work. The National Tracheostomy Safety Project (NTSP) exemplifies this approach, by developing truly multidisciplinary resources that are applicable to all. The NTSP working parties that I chaired and led, have overseen the creation and interpretation of new knowledge around tracheostomy care, described in my research papers. The NTSP outputs have been praised in the UK by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) and recognised by peers internationally: the NTSP forms one of the cornerstones of the Global Tracheostomy Collaborative (GTC), an international Quality Improvement Collaborative.

The final piece of the multidisciplinary puzzle was to include the views and opinions and experiences of patents and their families, who have been at the heart of all the work I have done around tracheostomy care. This ensures that all of my work has remained focused on the people that matter most in improving the safety and quality of care provided.

1.5. Defining quality of tracheostomy care

The King's Fund defines high-quality care in three parts: clinical effectiveness, safety and patient experience (King's fund, 2017). All of these areas have been considered in detail over the course of the body of work that comprises this thesis.

The initial focus of my work was to concentrate on improving patient safety. My work established a baseline for understanding recurrent themes that contributed to measurable harm reported in patient safety incidents. This led to further work understanding incident rates and influenced the NCEPOD report 2014 '*On the right trach?*' in addressing and understanding the nature, frequency and severity of tracheostomy-related critical incidents (Martin et al., 2014). Several of my papers demonstrate meaningful improvements in the safety of patient care, measured by the severity of reported incidents. Understanding and interpreting critical incidents as a tool for measuring safety is discussed in detail in the critical appraisal.

The patient experience is central to what we do in healthcare and this is exemplified in the work of the Global Tracheostomy Collaborative, described in my later papers. Understanding what is important to patients can often reveal a difference from the focus of clinicians. For example, patients will often report that the worst thing about their tracheostomy is not being able to eat, drink or vocalise and not be at all interested in the infrastructure and equipment concerns that their healthcare staff be concerned about (McGrath and S. Wallace, 2014a).

By attempting to improve the patient experience and addressing patient safety issues, multidisciplinary teams and systems have a symbiotic influence on clinical effectiveness. Early reports from tracheostomy multidisciplinary teams described teams working together to influence surrogate markers of the quality of care delivered. For example; Norwood's multidisciplinary team reported a significant decrease in the number of patients discharged to the ward with a tracheostomy tube, and a reduction in the number of complications for ward-based patients (Norwood et al., 2004) More recently, Tobin and Santamaria reported on their intensivist-led tracheostomy team in the ward setting, describing a significant trend to reduced decannulation times. This translated into significant reductions in total hospital length of stay (LOS) and hospital stay after ICU discharge. They found improved decannulation rates across the period of the study, with the effect of the team intervention improving over time (Tobin and Santamaria, 2008).

Cameron's group in Australia introduced a tracheostomy review and management service (TRAMS), also demonstrating improved outcomes. Patients left acute hospital care sooner, vocalised earlier, and were decannulated earlier, with associated cost savings (Cameron et al., 2009). Similar reductions in incident rates were reported by Narula's London group and from Pandian's group at Johns Hopkins Hospital, Baltimore, US (Hettige et al., 2008; Cetto et al., 2011; Pandian et al., 2012).

However, although these strategies led to improvements in the care of tracheostomy patients locally, they have not been implemented on a wider scale (Hettige et al., 2013). This is partly due to the lack of a robust evidence base and the dearth of large-scale trials. The majority of the evidence is limited to retrospective reviews, small uncontrolled case series, and expert opinions (R. Mitchell et al., 2012; R. B. Mitchell et al., 2013; Hettige et al., 2013).

One of the key drivers behind developing the Global Tracheostomy Collaborative was to address the issue that tracheostomy care improvement initiatives are often applied at the institutional rather than the patient level. Conducting high-quality clinical trials in this space may be difficult or impossible, un-ethical or not practical to implement (Hettige et al., 2013). Quality Improvement Collaboratives (QICs) in healthcare consist of a group of hospitals working together to rapidly disseminate improvement strategies, create a sense of urgency around improvement, track their outcomes and share data and work together for the purpose of improving care for everyone.

Defining quality in tracheostomy care involves defining standardised outcome metrics. This allows hospitals to evaluate their performance reliably and accurately, measure the impact of implemented changes and potentially allows benchmarking between comparable sites. Metrics which have been proposed in the literature include length of ICU stay (Gruenberg et al., 2006), in-patient stay (Eibling and Roberson, 2012), time to decannulation (Heffner, 1993), the frequency and severity of tracheostomy-related clinical incidents (Hettige et al., 2008; McGrath and Thomas, 2010), and overall mortality rate (Cetto et al., 2011). This thesis describes how these proposals have been evaluated as surrogate markers of quality in tracheostomy care, along with some of their limitations.

1.6. Aims of the thesis

This thesis aims to present a cohesive body of work relating to advances in multidisciplinary tracheostomy care. By describing systematic evaluation and interpretation of relevant patient safety incidents, the thesis summarises key issues and describes new prospective quality improvement strategies that were developed or adopted into the NHS. Through detailed evaluation of the impact of new ways of working at the forefront of international multidisciplinary tracheostomy care, the thesis aims to communicate clearly to the specialist and non-specialist reader the impact that this body of work has had on the safety and quality of care in the critically ill patient population.

The thesis specifically aims to:

- Provide an introduction to the non-specialist reader about tracheostomies, explaining the history and evolution of the procedure and the associated devices.
- Define the problems with airways and tracheostomies on a national scale in our ICUs and hospital wards by exploring critical incident reports.
- Describe landmark multidisciplinary emergency guidelines.
- Explain the importance of multidisciplinary care in managing patients with tracheostomies and defining quality of tracheostomy care
- Outline the implementation of guidelines and strategies to improve care by targeted education and infrastructure changes. Testing these resources in four diverse NHS hospitals.

- Explore and critique potential systems and metrics to assess the quality of bedside tracheostomy care.
- Present a critical appraisal of my body of work, reflecting on the research methodologies I have undertaken and how my research sits when compared to international research on the subject.
- Describe future research strategies in this complex and important area of healthcare, including presenting a national NHS-wide strategy for tracheostomy quality improvements.

Section 2

Publications, narratives and critical appraisals

This section details my publications relevant to this thesis. Each paper is accompanied by a two-page narrative describing the rationale and relevance of the paper.

An RDPUB form is provided for each paper, including statements providing a clear indication of my contribution to each publication.

2.1. Background

Why do we need to improve care? How do we measure the safety and quality of the care provided?

2.1.a. Narrative: Why do we need to improve care?

Patients with tracheostomies often have complex underlying healthcare needs that cross traditional healthcare boundaries. Tracheostomy care has been under increasing scrutiny with successive reports from the United States, United Kingdom, and Australasia highlighting measurable harm in up to 30% of hospital admissions (Thomas and McGrath, 2009; McGrath and Thomas, 2010; Martin et al., 2014; Doherty and McGrath, 2016).

One of the methodologies employed in understanding the problems in a particular field of healthcare is analysis of reported critical incidents. In the UK's NHS hospitals, any local incident is reported and investigated locally. Reported incidents are then typically sent to the data-warehouses of the National Reporting and Learning Service (NRLS), formerly part of the National Patient Safety Agency (NPSA). Application to the NRLS to search the database is possible, with a relevant research question and the relevant approvals.

The basis for this paper was a keyword search that my co-author had previously tested in a smaller dataset. This keyword search was highly sensitive (retrieving all relevant airway incidents) but not specific (retrieving many irrelevant incidents). Over half of the 2,327 retrieved incidents were rejected, leaving 1,085 that could be analysed. These incidents represented a snapshot of airway-related critical incidents reported in England and Wales over a 2-year period from October 2005. Both authors classified these incidents into pre-agreed categories described in Table 1, using a bespoke Microsoft Access database that was developed in collaboration with a knowledgeable colleague from the Medical Physics department at Salford Royal Hospital. Thematic analysis and exploration of the data were undertaken using pivot tables in Access and statistical comparisons were made in IBM SPSS Statistics.

We reported that whilst attention had previously been focused on insertion of airway devices, over 80% of airway incidents occurred after insertion, and that these incidents could lead to significant harm. Recurrent themes around staffing, training, adequate infrastructure and appropriate equipment provision were made. A lack of monitoring equipment was identified and we made a recommendation that the same standards of care be applied to ICU airway management as to airway management in operating theatres. We highlighted the potential for improving the reporting of patient safety incidents and also made recommendations to improve the safety of airway devices in critical care.

This first paper presented in this section highlights the problems that airway devices and tracheostomies in particular can pose in critical care. These incidents described some of the worst harm, much of which appeared entirely preventable by prospective system-wide improvements. For the second paper in this series, the same two authors examined tracheostomy-specific reports. This time we examined reports originating outside of the ICU on hospital wards.

Despite ward patients being less sick than the critically ill, these patients were coming to more significant harm, often leading to subsequent ICU admission. Harm was likely due to staffing, educational, monitoring and equipment limitations in these ward areas (Hashimi et al., 2012).

Importantly, we also identified that communication around the 'ownership' of patients with tracheostomies was poor and fragmented and that essential details around the nature of the patient's airway could not be rapidly communicated to those responding to emergencies. This new knowledge was key to our development of tracheostomy bedhead signs and the strategies around creating designated 'cohort' wards to provide safe areas for patients with altered airways. It was also clear that comprehensive, accessible training resources were urgently needed. These findings catalysed the development of the National Tracheostomy Safety Project and the development of many guidelines and resources in response to the problems I had identified.

One of the significant limitations of analyses of this nature is that staff tend not to report incidents for a whole host of reasons. Estimates suggest only around 10% of incidents are reported (Sari et al., 2007). However, this approach is still one of the best tools available for analyzing large datasets and offers a likely snapshot of problems related to airway management on a national scale, reported for the first time. The pattern of our findings was reproduced in later reports and these papers were cited by many authors in the UK and abroad when considering improvements in airway care in ICU (M. Jackson et al., 2014; McGrath and Wilkinson, 2015a; McGrath, Wilkinson, et al., 2015).

The use of reported patient safety incidents as a tool for assessing the impact of healthcare interventions is developed and discussed later in this thesis. See section 2.4.d.

2.1.b. Paper 1.

National ICU airway problems

Thomas AN, **McGrath BA.** Patient safety incidents associated with airway devices in critical care: a review of reports to the UK National Patient Safety Agency. *Anaesthesia.* 2009 Apr;64(4):358-65.

Link to paper - http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2044.2008.05784.x/abstract

Citations as of 21st June 2017

- Google Scholar 83
- Web of science 52
- Scopus 53
- Tweeted by 6
- 38 readers on Mendeley
- Altmetric score 6

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 64
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Patient safety incidents associated with airway devices in critical care: a review of reports to the UK National Patient Safety Agency. Anaesthesia, 2009, 64, pages 358–365

4. Candidate's contribution to the research output
(State nature and approximate percentage contribution of each author)

Study conceived by Dr Thomas and protocol jointly developed between both authors.
Classification, analysis and writing of paper 50% contribution each.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
AN Thomas	Anthony N Thomas	tony.thomas@srft.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

2.1.c. Paper 2.

Ward Tracheostomy problems

McGrath BA, Thomas AN. Patient safety incidents associated with tracheostomies occurring in hospital wards: a review of reports to the UK National Patient Safety Agency. *Postgrad Med J.* 2010 Sep;86(1019):522-5.

Link to paper - http://pmj.bmj.com/content/86/1019/522.long

Citations as of 21st June 2017

- Google Scholar 43
- Web of science 19
- Scopus 20
- On journal website
  - Abstract views 3,983
  - Full text views 474
  - PDF full text downloads 593

Mendeley and Altmetric scores unavailable

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Patient safety incidents associated with tracheostomies occurring in hospital wards: a review of reports to the UK National Patient Safety Agency.
BA McGrath & AN Thomas. Postgrad Med J 2010;86:522-525.

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Conceived by BAM. Joint data analysis and interpretation. 75% manuscript writing and submission BAM.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
AN Thomas	Anthony N Thomas	tony.thomas@srft.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

2.1.d. Critical appraisal: Reported critical incidents as a methodology for informing healthcare quality improvements

In the 50 years since Flanagan first published `The critical incident technique' in 1954, analysis of reported critical incidents has been adopted and adapted to a variety of high-risk industries, including healthcare (Flanagan, 1954). An incident was defined by Flanagan as, 'any observable human activity that is sufficiently complete in itself to permit inferences and predictions to be made about the person performing the act.' He goes on to define a critical incident as an incident that occurs, '…in a situation where the purpose or intent of the act seems fairly clear to the observer and where its consequences are sufficiently definite to leave little doubt concerning its effects.' (Flanagan, 1954)

Flanagan's critical incident technique consisted of collecting direct observations of human behavior during incidents, which had special significance and met systematically defined criteria. Flanagan used psychological principles to evaluate the subject's potential usefulness in solving subsequent practical problems. His work was originally designed to develop procedures for use in the selection and classification of aircrew personnel in the US Air Force. The technique was adapted for selection and classification of employees in many other industries and settings before being translated into identification and classification of reported incidents and events in retail, industrial and healthcare settings (Kemppainen, 2000).

Analysis of healthcare critical incidents is not an exact science however (Runciman, 1993). Where other qualitative methodologies place stronger emphasis on describing events in real-life settings, critical incident studies are usually more focused on exploring solutions to practical problems (Kemppainen, 2000). Building on the original work, methodologies are more typically aimed at identifying facts and reducing personal opinions, judgments and generalizations. One caveat that Flanagan offered in his original work was that observations can become fact when a large number of independent observers offer the same descriptions of a behaviour (Flanagan, 1954).

Reporting and analysis of critical incidents in the NHS drew increasing attention throughout the 1990s, culminating in the government white paper 'An organisation with a memory', published in 2000 (Donaldson, 2000). The paper recognised that advances in knowledge and technology had immeasurably increased the complexity of our health care systems, with unique combination of processes, technologies and human interactions. With that complexity comes inevitable risks and when things go wrong in healthcare, the stakes are high. In his foreword, the then Health Secretary, Alan Milburn, noted that no one pretends that adverse health care events can be eliminated from modern health care. The challenge however, is to ensure that the lessons of past experience be properly learned, and that the NHS learns from its own experiences, so that the risk of avoidable harm to patients is minimised. Amongst the report's recommendations was the creation of a new national system for reporting and analysing adverse health care events, the National Patient Safety Agency (NPSA). Within this system stood the National Reporting and Learning Service (NRLS) which was essentially a data warehouse. The NRLS was established in England in 2003, becoming the largest repository of healthcare incidents in the world. The NRLS was originally designed to facilitate analysis of serious and frequently occurring events. The NRLS developed and issued national patient safety warnings based on these analyses and disseminated safety information and solutions in an attempt to prevent such events recurring

(Howell et al., 2015). One example of a relevant patient safety alert was an alert around confusion between tracheostomies and laryngectomies which had led to entirely preventable harm for 'neck breathing' patients (NPSA, no date).

Patient safety incident reports are submitted by NHS staff using local reporting systems; each NHS organisation is then expected to submit these reports to the NRLS using an electronic submission process. The free text description of the incident is provided together with a classification, which includes details of the location from where the incident was reported (Thomas and McGrath, 2009). Reports are submitted from NHS Hospitals and institutions in batches, with typically between one week's and several months' data provided at any one time (Shaw et al., 2005). Access to the searchable NRLS database is granted by the NPSA following application with a proposal and search strategy.

The stimulus for my initial work analysing nationally reported airway-related patient safety incidents was personal and local experience of airway misadventure. It was clear to me that whilst these life-threatening or catastrophic airway incidents were rare, each hospital, ICU, theatre area or ward was likely to experience at least one of these significant events every few months. The nature of these events could be predicted to some degree, as the same categories of incidents were common in our region. The commonest theme for ICU incidents seemed anecdotally to be a lack of appropriate airway equipment on the ICU and so I undertook a regional audit in 2006, published later that year (McGrath and Saha, 2006).

From this paper, I was able to draw more meaningful conclusions from the pooled data, prompting me to investigate similar strategies to explore relevant themes at a national level.

Some have questioned the utility of national incident reporting systems to draw meaningful conclusions about relatively rare events. Rabøl's Danish study concluded that rare events are difficult to detect due to deficiencies in data mining and that healthcare efforts are better spent solving known safety problems at a local level (Rabøl et al., 2016). However, Lord Ara Darzi, the former Chief Medical Officer, amongst others, challenged this conclusion (Howell et al., 2016). One of the initial drivers towards the creation of the NRLS in England was the very rare but fatal misadministration of vincristine; an incident that occurred 14 times in different hospitals without any shared learning (Franklin et al., 2014). The NRLS collated relevant incidents and recognition of the problem led to critical design solutions to prevent against future events. Airway incidents were thought to be more frequent than vincristine incidents and so we adopted a similar strategy and approached the NRLS.

Is this methodology adequate to detect relevant incidents?

In critiquing my incident analysis papers, I have considered the following points:

- Did the keyword search strategy identify all of the relevant incidents?
- What about incidents that were not reported?
- Could the incident theme groups have been categorized differently? Would this have led to different conclusions and different work streams and resources as a result?

The strategy for the keyword search was tested to ensure that all relevant incidents were retrieved. We initially reviewed the free text description of 12,240 patient safety incidents submitted in the 6 months from August 2006 to February 2007 and identified 207 airway incidents reported in this sample. It was clear from this review that the text descriptions of airway incidents contained repetitive words. These could be grouped by repeated letter sequences and all of the identified airway incidents contained at least one of the sequences (Thomas and McGrath, 2009). The keyword search applied to our sample was refined until this retrieved all of the manually identified airway incidents, satisfying us that our search strategy was accurate and reproducible.

The question of whether all relevant incidents were reported is a common one for analyses such as these. In one investigation by Sari, 324 patient safety incidents were reviewed that occurred in 230 patients admitted to a tertiary NHS hospital. Of these, 270 (83%) patient safety incidents were identified by retrospective case note review only, 21 (7%) by the hospitals own in-house critical incident reporting system only, and 33 (10%) by both methods (Sari et al., 2007). Routine incident reporting systems may be poor at identifying patient safety incidents, particularly those resulting in harm.

Local staff will have decided whether or not to report incidents for many reasons, including the reporting system provided (Harris et al., 2007), fear of the consequences of reporting incidents (Vincent et al., 1999) and perceptions as to how incidents would be used to improve patient care (Thomas and McGrath, 2009). We estimated that only around 10% of all airway incidents that occurred were actually reported, a consistent estimate from similar reports (Needham et al., 2004; Valentin et al., 2006).

Howell and Darzi examined the 5,879,954 incident reports submitted to the NRLS in the first decade of its existence, from 2003 (Howell et al., 2015). They found that 70.3% of incidents produced no harm to the patient and 0.9% were judged by the reporter to have caused severe harm or death. Interestingly, they concluded that hospital characteristics did not significantly influence overall reporting rates. They found no association between size of hospital, number of staff, mortality outcomes or patient satisfaction outcomes and incident reporting rates. Incident reporting culture did seem linked to outcomes insofar as hospitals where staff reported more incidents also reported reduced litigation claims. Similarly, where clinician staffing was increased, fewer incidents reporting patient harm were registered. Certain specialties report more near misses than others, and doctors tended to report more harm incidents than near misses. The authors also conducted a number of staff surveys which they analysed qualitatively, concluding that open environments and reduced fear of a punitive response increases incident reporting (Howell et al., 2015).

So whilst our analysed incidents would only have represented a convenience sample of all incidents that occurred in England and Wales in the two-year study period, we can conclude that this sample was representative. By comparison with similar analyses from other fields, we know that airway incidents are less common than ICU medication incidents (Thomas et al., 2009) or equipment incidents (Thomas and Galvin, 2008) but that airway incidents are associated with more patient harm, again consistent with other studies (Needham et al., 2004; Valentin et al., 2006). It is therefore likely that these relatively rare but significant airway events were reported and captured by our search strategy using the NRLS database.

The categories of incident were not decided *a priori* but became fairly clear as the data were analysed. Similar themes had been identified by airway researchers using prospective and different methodologies (Cook, Woodall, Frerk, et al., 2011; Cook et al., 2012; Martin et al., 2014; Cook et al., 2016). We believe that the classification of incidents into themes around education for staff, equipment provision and infrastructure support, allowed us to develop appropriate resources to help improve care and target these problem areas.

Conclusions

Although imperfect, analysis of reported critical incidents is an appropriate methodology for informing healthcare quality improvements. Evolution of my research through local, regional and national work reinforced these themes and led to later development of resources to address recurrent deficiencies in care.

2.1.e. Critical appraisal: Investigating locations in which patients come to harm

It was clear from my own work and from others that incidents occurred in any location that patients with tracheostomies were cared for. It was important to try and understand the nature of these locations, the pattern of incidents and also whether there were any differences in incident severity occurring in different locations. By exploring these potential differences, I hypothesised that I might need to adapt specific learning resources for different staff groups working in different locations.

In order to more fully understand the effect of location on critical incidents, I undertook further analysis of my original data from the two papers presented in this section of the thesis. These small studies were presented at meetings of the Anaesthetic Research Society and published in abstract form in the British Journal of Anaesthesia (Templeton et al., 2011; McGrath and Thomas, 2011; M. Jackson et al., 2014).

Firstly, I compared harm associated with tracheostomy incidents that occurred on hospital wards with that arising from critical care incidents. I identified and analysed the post-placement tracheostomy incidents reported to the NRLS between October 1, 2005, and September 30, 2007, using key letter searches as described above (Thomas and McGrath, 2009; McGrath and Thomas, 2010). Incidents were collected from both ICU and ward environments. Incidents were then stratified into three strata; completely or partially displaced and obstructed and classified as harm or no harm.

Outcomes were defined as the frequencies and types of harm occurring. Analyses included the Mantel–Haenszel test for stratified data and Fisher's exact test for within-stratum comparisons. The expanded Fisher–Freeman and Armitage trend tests were used for within location analyses. The results are presented below as frequencies and odds ratios (ORs) with 95% confidence intervals (CIs), with significance defined at p<0.05 (two-sided).

I identified 494 post-placement tracheostomy incidents and classified these by location into 'Intensive Care/ High Dependency' (n=218) or 'Hospital ward' (n=276). The overall risk of harm was significantly greater in the ward setting (pooled OR 7.1; 95% CI 3.7–14.7; p<0.001 Mantel–Haenszel test). Results stratified for incident are shown in Table 2.1. There was a significant trend (slope 15%; 95% CI 7–23) to increasing risk of harm across the strata in the ICU setting from complete through partial displacements to complete obstruction.

This analysis demonstrated that ward patients have a significantly higher chance of coming to harm when a tracheostomy incident occurs when compared with critical care patients (McGrath and Thomas, 2011).

Table 2.1. *Tracheostomy patient safety incidents stratified for incident and by location. Adapted from McGrath & Thomas* (McGrath and Thomas, 2011).

n=494 incident	Ward		ICU		Odds ratio (95% CI)	Fisher's exact P-value
	Harm	No Harm	Harm	No Harm		
Complete	112	3	51	35	25.6 (7.4–134.0)	<0.0001
Partial	29	3	66	22	3.2 (0.9–11.6)	0.077
Obstructed	122	7	39	5	2.2 (0.5–8.7)	0.18
Expanded Fisher's P-value	0.18		0.0011			
Trend P-value	0.31		0.0003			

To explore this relationship further, I compared the *severity of harm* occurring in these two locations when a tracheostomy incident occurs.

Post-placement tracheostomy incidents were stratified as above into the three ordered strata: completely or partially displaced and obstructed. Outcomes were then scored in ascending ordered categories of severity from 1 to 6, matched to the incident severity classifications described by the NPSA. The effects of location, incident, and outcome were analysed using log-linear analysis of multi-way contingency tables. Linear mixed model analysis using maximum likelihood estimation of the log-transformed scores was performed with the Kruskal–Wallis test, with Mann–Whitney U test used as backup. The Cuzick test was used for trend in ranks. Results are presented as geometric mean with 95% confidence interval (CI). Significance was defined at $p<0.05$ (two-sided) with Bonferroni corrections as appropriate. A total of n=494 incidents were classified by location into ICU (n=218) or ward (n=276) as above. Harm scores were significantly higher for ward incidents vs ICU (log-linear P=0.011). There was a significant trend, with increasing severity scores, from complete through partial displacement, to tube obstruction (Cuzick's P<0.001). The interaction of location and incident demonstrated significant differences in harm scores occurring with a completely displaced tracheostomy on the ward (2.14 (95% CI 2.03–2.25)) vs ICU (1.55 (1.42–1.69)), Mann–Whitney's U P<0.001 (Templeton et al., 2011). See Figure 2.1 below.

While ward patients would be expected to be less dependent than ICU patients, they come to greater harm when a tracheostomy incident occurs. Different levels of staffing, observation, equipment, and infrastructure may account for the difference in severity arising from the completely displaced tracheostomy incidents. Respiratory distress with a partially displaced or obstructed tracheostomy may alert staff, whereas complete displacement may result in a delayed diagnosis if not immediately observed. In ICUs, complete displacement may be more likely to result in a trial without the device if the patient is in a weaning phase, whereas ward patients usually require a long-term tracheostomy, necessitating replacement. Airway intervention (such as replacing the tracheostomy) is classified as 'harm' in the reporting system, which may partly explain the observed differences (Templeton et al., 2011) .

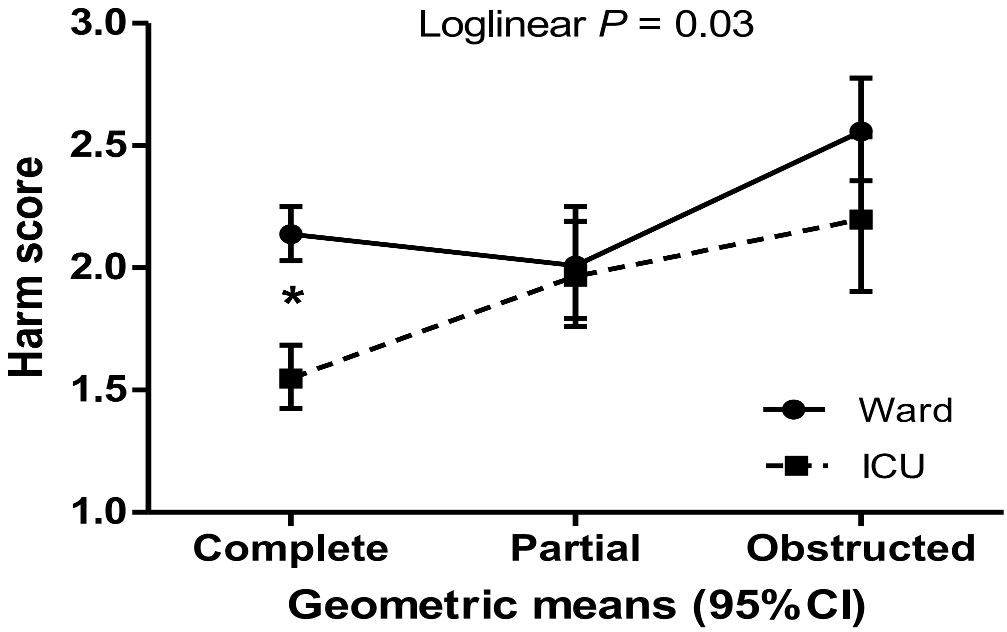


Figure 2.1. *Interaction of incident and location. Adapted from (Templeton et al., 2011).*

How do the numbers for incident location I calculated compare with prospective series?

The 2014 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report prospectively collected data concerning over 2,500 patients with new tracheostomies (Martin et al., 2014). Local reporters were recruited and completed prospective adverse incident reporting forms. An independent panel of NCEPOD reporters also reviewed a convenience sample of over 400 case notes. From this analysis, a breakdown of incidents from wards or ICU was calculated.

NCEPOD noted that harm occurred in 23% of ICU patients managed with a tracheostomy and in 31% of ward patients. Patients managed on the wards also came to more significant harm. NCEPOD cited underlying factors such as a lack of staffing, observation, equipment, and infrastructure to allow a timely response to deal with evolving incidents. In short, ward patients were having incidents that remained undetected and when staff were alerted, their response was delayed and often inadequate.

Understanding in detail the nature and severity of harm that occurred in different locations allowed my work with the National Tracheostomy Safety Project to develop resources and target specific staff groups.

Conclusions

Further detailed analysis of the data presented in these two papers has allowed a deeper understanding of the effect of incident location on the nature and severity of tracheostomy patient safety incidents. Unrelated prospective observational studies by other authors confirmed and validated my initial findings.

2.2. Defining the problem
Why is airway care such a problem in ICU?

2.2.a. Narrative: Why is airway care such a problem in ICU?

This paper was an invited editorial, published in the British Journal of Intensive Care, written with my co-author, a consultant Head & Neck surgeon. The paper highlights the multidisciplinary nature of problems we encounter in the ICU and was one of the first publications to highlight the development of the Global Tracheostomy Collaborative as a potential solution to address some of the known problems around tracheostomy care.

This paper builds on the raw critical incident data I had examined and attempts to describe the likely nature and scale of the problem, and put this into context. At the time of writing, accurate UK figures for the number of tracheostomy patients were not available. The rationale behind our estimates is explained in the following critical appraisal.

The paper reflects on the moves in many UK ICUs towards more multispecialty and even multidisciplinary staffing, affecting both senior and trainee levels. The implications of these changes are that advanced airway skills may not be reliably available (Higgs et al., 2016). Staff are increasingly faced with patients who have deranged baseline physiology, complex conditions and are increasingly obese; patients who are disproportionately more likely to experience airway problems and presenting challenges to airway safety in ICU (Cook, Woodall, Frerk, et al., 2011; De Jong et al., 2015).

Others have reflected these concerns. The 4th National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society (NAP4) highlighted the difficulties, and sometimes failings, of airway management in ICU, describing ICUs as a place of 'increased airway danger' (compared to the operating theatre) (Cook, Woodall, Frerk, et al., 2011). Airway management in the critically ill patient may be required on the ICU itself, but also almost anywhere else in the hospital environment. Many of these locations are remote and none are designed with airway management primarily in mind. Some airway interventions on ICU are planned but most are reactive and emergent. The multidisciplinary team that manages airway and tracheostomy emergencies is often called urgently to a rapidly deteriorating patient.

This paper acts as a 'link' between my earlier works understanding the nature and severity of tracheostomy related patient safety incidents and identifying some of the strategies that might benefit this patient population, described and evaluated in my later work.

2.2.b. Paper 3.

Why is airway care such a problem in ICU?

McGrath BA, Calder N. Tracheostomy and laryngectomy emergency management – implications for critical care. *British Journal of Intensive Care*. 2013; Autumn:77-80

Article available in print only

0 citations

Altmetric data not available from this journal

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

(3)

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Tracheostomy and laryngectomy emergency management - implications for critical care.
BA McGrath & N Calder.
British Journal of Intensive Care, Autumn 2013, p93-97

4. Candidate's contribution to the research output
(State nature and approximate percentage contribution of each author)

Article conceived by BAM. Literature review and manuscript 75% BAM.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
N Calder	N. Calder	ncalder@hotmail.com

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

2.2.c. Critical appraisal: Multidisciplinary challenges for airway and tracheostomy management in ICU

The paper I have presented builds the case for better multidisciplinary airway and tracheostomy care. However, the case I made was based largely on the critical incident reports and when reflecting on this paper, I believe that a more physiologically based argument for improving care could have been made that would increase the impact and relevance of the paper. In this section, I will discuss the relevant patient factors, physiological problems and environmental issues that are also relevant to this paper and the patient population that it describes. Many of these factors are applicable to airway management in general, as well as more specifically to tracheostomy care.

Patient factors

Patient factors often contribute to difficulty in ICU airway and tracheostomy management. Patients are often hypoxic, obtunded, combative or all three, meaning that airway assessment is difficult. The vast majority of patients will have unstable physiology even before any anaesthetic agents are administered to facilitate airway or tracheostomy management. Physiological problems include pre-existing hypoxia, ventilation-perfusion mismatch that impairs preoxygenation, hypovolaemia and increased risks of myocardial impairment. This lack of cardiorespiratory reserve increases the risk of profound hypoxia, hypotension, arrhythmia, cardiac arrest and death which is associated with airway interventions (Mort et al., 2009; Leibowitz, 2009).

Airway management needs to be decisive and successful in order to prevent physiological decline. Rapid desaturation from a hypoxic baseline creates time pressures for the team managing these airway emergencies and further complicates management in the ICU. Even when airway management is successful, subsequent positive pressure ventilation causes cardiovascular compromise and may be poorly tolerated (Jaber et al., 2006).

The incidence of patients with known airway difficulty is also higher in the ICU, with such patients admitted for monitoring and management including intubation, extubation, later tracheostomy or observation. This group incudes those with difficult native upper airways and existing artificial airways such as tracheostomies. Astin's UK survey reported that 1 in 20 UK adult ICU admissions were for management of a primary airway problem including post-tracheostomy, and 1 in 16 patients admitted had a predicted difficult airway (Astin et al., 2012). More pertinently, 1 in 4 of the ICUs surveyed declared that they had at least one patient currently admitted with a primary airway problem and 40% were managing at least one patient with a predicted difficult airway.

Physiological problems for airway management in the ICU patient

Critical illness and its management can also render an anatomically 'normal' airway 'difficult' with fluid resuscitation, capillary leak syndromes, prone ventilation and long periods of intubation all contributing to airway oedema and distortion. Compounding these 'difficult airways' are the physiological disturbances that principally affect the cardiovascular and respiratory systems. This can lead to cardiovascular instability, hypoxia and death.

Mort reported 60 cardiac arrests occurring during 3,035 out-of-theatre intubations, or approximately 2% of all such intubation attempts, over a 12 year period in a single tertiary centre (Mort, 2004b). All intubations were performed by an airway operator with a minimum of 6 months anaesthetic training. Eighty-three percent of those patients who suffered a cardiac arrest experienced severe hypoxaemia ($SpO_2 < 70\%$) during airway management. This included all those patients who required three or more intubation attempts. The most hypoxic patients required an average of almost 4 attempts at intubation, while those without hypoxia were nearly all intubated first time. This emphasises the importance of having the right team and right equipment available to manage the airway promptly, with the goal of 'first pass' success. These principles have been adopted into the guidelines I have developed for emergency tracheostomy care.

Environmental considerations for ICU airway management

Importantly, but little discussed in the literature, is the lack of skilled assistance on the ICU when managing airways. When comparing the exposure and experience of staff who work in operating theatres and ICUs, the latter may be exposed to airway management every few months with the former having daily exposure. This may impact on the delivery of prompt, safe, skilled airway management, especially if difficulty occurs and non-standard plans are required. ICU staff may however be much more familiar with tracheostomy care, troubleshooting and management than other staff within a typical hospital, perhaps with the exception of staff who work on head and neck surgical units.

These multifactorial issues can have an effect on the outcomes of airway management in critically ill patients, including those with tracheostomies. Airway management is required to facilitate tracheostomy insertion in the 10-19% of ICU patients who require a tracheostomy (Fischler et al., 2000; Blot et al., 2005; Nathens et al., 2006). Further, if a tracheostomy complication occurs (which may be expected in 23-30% of all hospital inpatients (Martin et al., 2014) airway management is required and can be expected to be difficult.

Failure to intubate is much more likely in these critical situations in the ICU than during routine intubation for elective surgery. In ICU, failure at the first intubation attempt can be expected in 10-12% of intubation attempts, significantly higher than during routine anaesthetic practice (Schwartz et al., 1995; Mort, 2004a; Martin et al., 2011). Complications and cardiac arrests increase significantly with increasing numbers of intubation attempts and cardiac arrest during airway management on ICU is not infrequent (Mort, 2004a).

My NPSA incident reviews demonstrated that over 80% of ICU airway incidents occurred after intubation or tracheostomy placement (Thomas and McGrath, 2009; McGrath and Thomas, 2010). Post placement, all invasively ventilated ICU patients are subject to procedures, complex nursing interventions and regular repositioning. This requires a high degree of vigilance to maintain the airway device in situ. In contrast to anaesthetic practice in operating theatres, success is dependent on the performance of the multidisciplinary team rather than one anaesthetist. Airway displacement and subsequent re-intubation is a constant threat in the critically ill and is associated with high complication rates, including mortality (McGrath and Wilkinson, 2015b).

These problems are magnified in those patients managed with tracheostomies; typically around 10-19% of level 3 ICU admissions in Europe and the US (Fischler et al., 2000; Blot et al., 2005; Nathens et al., 2006). The very requirement for tracheostomy marks these patients out as ones who occupy a disproportionately high number of ventilator bed days (McGrath, Ramsaran, et al., 2012; McGrath and Templeton, 2012; McGrath and Wilkinson, 2015b). This group also experience greater frequency of complications, with the 2014 UK NCEPOD report into tracheostomy care reporting complications in 23.6% of tracheostomised ICU patients. Nearly 30% of patients experienced multiple complications (Martin et al., 2014). In keeping with previous reports, tube displacement, obstruction, pneumothorax and major haemorrhage were the commonest themes (Templeton et al., 2011; McGrath and Wilkinson, 2015b).

Conclusion

The caseload, physiology, environment, staffing, airway devices and airway pathologies in the critically ill are significantly different to those encountered in routine anaesthetic practice. Patients with tracheostomies are at a particular risk of developing complications, with the vast majority of incidents occurring post placement. The focus of guidelines for airway management in general and for tracheostomy care were not historically readily applicable to the critically ill and did not take into account the needs and complexities of the multidisciplinary ICU team (McGrath, O'Donohoe, et al., 2012). The paper I have presented here sets the scene for the necessary resources that were required to improve routine and emergency multidisciplinary airway management in the ICU, especially that of patients with tracheostomies. It also highlights the need for further quality improvements to stop emergencies happening in the first place – the focus of my later work.

2.2.d. Critical appraisal: Understanding the scale of the problem

One of the problems in critical incident analyses that I had conducted is that there is limited denominator data available with which to try to understand the scale of the problem and to identify relative frequencies of incidents. At the time of writing the paper presented in this section, the number of tracheostomies managed in England's Intensive Care Units (ICUs) was unknown. Understanding the scale of the problems I had identified was important in devising strategies to address the multidisciplinary challenges for tracheostomy management in the ICU that I had identified. I have therefore described and discussed some of my related work that supported the paper I have presented in the thesis.

As background work for the presented paper, I conducted a small study to determine the numbers of percutaneous and surgical tracheostomies managed in critical care units in the North West of England with the aim of extrapolating from the Greater Manchester critical care network admissions database ('MIDAS') to estimate approximate national numbers (McGrath, Ramsaran, et al., 2012).

I interrogated the MIDAS database for all ICU admissions between January 1st 2010, and January 25th 2012 in order to determine frequencies of percutaneous and surgical tracheostomies, along with bed days. Other national sources of data came from Hospital Episode Statistics (HES): a data warehouse containing details of all admissions to NHS hospitals in England (Hospital Episode Statistics, 2013) The Intensive Care National Audit & Research Centre (ICNARC) collects data submitted from units participating in its Case Mix Programme. HES and ICNARC data in the public domain and I used these data to determine the numbers of critical care units, beds, and admissions in England. Neither HES nor ICNARC collect data concerning the patient's airway.

Eight Trusts comprising a total of 154 ICU beds in 17 separate ICUs spread across 11 hospital sites submitted data to MIDAS for 16,589 admissions covering 99,037 bed days (Table 2.1 below). There are 241 ICUs in England in 2012. By extrapolating the MIDAS figures from 17 ICUs to 241 ICUs), I estimated that 14,200 (95% CI 6,800 – 21,600) tracheostomies were managed annually in England's ICUs. There were 169 176 ICU admissions recorded by HES in 2009/2010. I therefore estimated 15,000 (9,000–21,000) annual tracheostomies by extrapolating the tracheostomy rate per admission.

Table 2.2. *Expected tracheostomy patients and rates, based on extrapolating MIDAS data from the North West of England ICUs. 'Tracheostomy' refers to all surgical and percutaneous procedures. Adapted from McGrath, Ramsaran et al., 2012.*

	Mean	95% CI
Admissions per ICU per year	612	439–786
Total bed days per patient	6.0	4.9–7.6
All tracheostomies per ICU per year	58.9	28.3–89.6
Percutaneous tracheostomies per ICU per year	55.8	26.2–85.3
Tracheostomy bed days per ICU per year	707	344–1070
Tracheostomy bed days per patient	11.6	7.6–15.5
Tracheostomy rates per admission (%)	8.9	5.4–12.4

Whilst this is a crude estimate and assumes a uniform pattern and provision of tracheostomy care around the country, by estimating the approximate numbers of tracheostomies managed in England's ICUs, I was able to identify the likely scale of the problems with tracheostomy care. Extrapolating these data from the North West region is reasonable, as the

MIDAS dataset included a diverse range of general and specialist Trusts, hospitals and ICUs, reflecting the rough makeup of the UK picture. This extrapolation seemed especially reasonable, given lack of nationally reported data around tracheostomies at the time.

Confidence in my estimate came from using two different methods, which produced similar results. HES recorded around 5,700 surgical tracheostomies performed in theatres during 2009/2010 and our estimates suggest that the majority of tracheostomies in England are performed and managed in critical care by intensivists, rather than surgeons. This was a significant finding at the time of publication as tracheostomies had been seen as the preserve of head and neck surgeons. These were the first data to suggest that was not the case, and highlighted the knowledge gap that existed for these patients, and characterised the evolving patient demographic that was receiving tracheostomies in England.

Furthermore, not only were more tracheostomies being performed on our ICUs, but those patients were usually ones who had a much longer length of stay. Much of this period involved mechanical ventilation, which means a greater risk of complications: the patient is at a worse baseline, is dependent on support and oxygen for breathing and is more likely to have intercurrent organ failures than a ward-based patient. This means that incidents are likely to develop more rapidly and potentially cause more harm.

I used the MIDAS database described above to determine that there was a mean of 64 tracheostomies per ICU per year (60 percutaneous, 4 surgical) over a 2 year period in the North West of England. A total of 84,623 bed days for 16,589 admissions were then analysed. The tracheostomy remained for a mean of 12.0 days (range 1.0–24.9 days), with advanced respiratory support delivered via tracheostomy for a mean of 9.1 days (range 3.1–23.0 days) (McGrath and Templeton, 2012).

Crudely extrapolating from HES, I estimated 16,238 tracheostomies were managed in England during 2009/10 (15,382 percutaneous) totalling 194,856 bed days. ICNARC data comprises of admissions with complete data, but also incomplete (probable admission) datasets. I could therefore similarly estimate from ICNARC that each ICU in England can expect to manage between 48 and 51 tracheostomies per year (46–48 percutaneous). HES recorded 315,173 ICU advanced respiratory support bed days for the year 2009/10. Extrapolating these data, we estimate 147,766 of these days were spent receiving advanced respiratory support via a tracheostomy (46.9 %).

The different methods used to collect national ICU bed information in England makes this direct extrapolation potentially flawed. However, the makeup of the North West's ICUs is broadly representative of the national picture and the MIDAS database is of high quality (McGrath and Templeton, 2012).

How do the patient numbers I estimated compare with prospective series?

It remains surprisingly difficult to find national data on the number of patients managed with tracheostomy. What detailed data that have been reported suggest that 7–19% of all patients admitted to an ICU will be managed with a tracheostomy, and that up to 90% of these tracheostomies are currently performed by percutaneous routes (Veenith et al., 2008; Young et al., 2013). This figure varies with the admission diagnosis, individual units, and to some extent, the country (Fischler et al., 2000; Blot et al., 2005; Nathens et al., 2006; McGrath, Ramsaran, et al., 2012; McGrath and Wilkinson, 2015b).

The prospective NCEPOD report collected comprehensive national level data from all hospitals in England and Wales in 2013 over an 11-week period in Spring. The final report extrapolated figures for this period and estimated around 12-14,000 tracheostomies were performed, with two-thirds of these performed percutaneously in ICUs. (Martin et al., 2014).

Conclusion

An important step in building the case for developing actionable resources to improve multidisciplinary tracheostomy care was to devise novel strategies to estimate the likely scale of the problem. The denominator figures which I believed were key to understanding the scale of the problems with tracheostomy care were estimated using a variety of methodologies from the best data available at the time. Subsequent prospective national studies found these figures to be accurate, and further validated my chosen methodologies for understanding the scale of the problems.

2.2.e. Critical appraisal: Did my work identify themes that were consistent with that from other investigators working in this field?

Further validation of my methodology and strategies for understanding the 'bigger picture' came from other investigators using my published work to plan their own investigations. In this section, I appraise the wider literature that has attempted to understand the nature and scale of tracheostomy problems in critical care, some of which used my published works presented in this thesis as key background to their studies. Subsequently, I have been invited to comment in published editorials about my own work and that which followed from other groups. Some of these published editorials related to my presented papers are discussed below.

The 2014 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report in tracheostomy care scrutinized the patient journey from initial treatment decisions through tracheotomy to post-procedural care (Martin et al., 2014). This was a prospective national study into United Kingdom tracheostomy care, reporting the most comprehensive analysis of in-patient care to date. Key findings highlight recurrent deficiencies in the organization of care, staff training and support, and the inconsistent use of monitoring and safety equipment, essentially reinforcing the conclusions from our original work from 5 years earlier.

A summary of the report was described in our published commentary in the US journal Otolaryngology: Head & Neck Surgery (McGrath, Wilkinson, et al., 2015). The NCEPOD study findings are translatable to Western health care systems and our commentary provided a forum to disseminate this essential information internationally. The paper also served to highlight important safety initiatives from exemplar institutions and national and international quality improvement projects. This commentary describing and contrasting the NCEPOD study is summarized below:

The June 2014 NCEPOD report collected data from 219 UK hospitals (excluding Scotland) contributing 2,546 consecutive cases, providing the most detailed analysis of in-patient tracheostomy care to date. The primary aim was to explore factors surrounding the insertion and subsequent management of tracheostomies in the Intensive Care Unit (ICU) and ward environments. The study was designed by an invited multidisciplinary group of experts representing national stakeholder organizations and lay representation, alongside NCEPOD's clinical and research team. Adult patients undergoing a new tracheostomy insertion or a laryngectomy between February to May 2013 were included, with questionnaire data collected until decannulation, discharge, 30-day post-tracheostomy, or inpatient death. Two complete sets of case notes were randomly selected per hospital for peer review by a panel of recruited advisors.

Key findings from the NCEPOD report

Highlights of the report include identifying complications occurring in 23.6% of ICU patients and 31.3% of ward patients. In keeping with previous reports, tube displacement, obstruction, pneumothorax and major hemorrhage were the most common serious complications, with accidental tube displacement more common in ward-based patients (6.3% vs. 4.1%). Nearly 30% of patients experiencing one complication experienced further complications, indicating the vulnerability of this specific cohort of patients.

Organizational data showed that 80.6% of hospitals had a policy for management of blocked and displaced tubes and 27.9% did not provide an emergency training program. Whilst physiologically more stable than ICU patients, wards are not subject to the same levels of medical and nursing supervision and monitoring. Multidisciplinary care was more fragmented on the wards, with longer delays in referrals to Speech & Language Therapy (SLT) and other allied health professional groups.

There was variation in the number of locations within hospitals designated as areas to manage tracheostomy patients. Limiting these wards may reduce the nature, severity and frequency of tracheostomy-related incidents (McGrath et al., 2013). Organizational data revealed that capnography was available at 91.7% of ICU bed spaces but documented use for this potentially life saving technology was found in only 54.1% of cases. Post-insertion endoscopy was documented in 51.5% of patients. The reports highlighted that the correct use of monitoring has been shown to improve safety, and endoscopy may be an increasingly important method of ascertaining the correct position of the tracheostomy tube tip.

Almost 30% of patients included in this study were classified as obese or morbidly obese. However, adjustable length tracheostomy tubes were used in only 96/510 (18.8%) of these patients and in 185/1825 (10.1%) of patients overall. It remains difficult to predict which size tracheostomy should be inserted, but a relatively small tube inserted into a 'large' neck, intuitively increases the risk of tube displacement.

Data were available for 1,956 ICU discharges, which included a 17.5% inpatient ICU mortality. Of those decannulated, 48.6% were prior to ICU discharge with 98.8% success rates. Remaining patients were transferred to wards (78.1%), other ICUs (12.9%), or to rehabilitation facilities or other sites. Receiving wards often lacked the equipment and expertise to manage tracheostomies, frequently receiving patients outside of 'normal' working hours (47.4% after 18:00).

Conclusion

The NCEPOD study was unique in documenting outcomes of over two and a half thousand patients undergoing tracheostomy insertion and reports upon a consecutive snapshot of 'real world' care for NHS patients. The report reinforces some of what was known already from my earlier work. Importantly the NCEPOD report adds information on the education and composition of teams and systems that care for patients in ICUs and wards within the NHS. Similar healthcare systems outside of the NHS can learn from the findings of this report and look to implement prospective quality improvement strategies, discussed in later sections of this thesis, that have the capacity to improve the safety and quality of care for our tracheostomy patients (McGrath, Wilkinson, et al., 2015; McGrath and Wilkinson, 2015a).

2.3. Designing resources and solutions

2.3.a. Narrative: Designing resources and solutions

The paper presented in this section was the first to describe a uniform multidisciplinary approach to the management of tracheostomy emergencies. My previous work had demonstrated that whilst adult tracheostomy and laryngectomy airway emergencies are uncommon, they do lead to significant morbidity and mortality. I set up and chaired the National Tracheostomy Safety Project to address these issues and I led the working party that developed these guidelines over a 3-year period. This incorporated key stakeholder groups with multi-disciplinary expertise in airway management: the Difficult Airway Society, the Intensive Care Society, the Royal College of Anaesthetists, ENT UK, the British Association of Oral and Maxillofacial Surgeons, the College of Emergency Medicine, the Resuscitation Council (UK) the Royal College of Nursing, the Royal College of Speech and Language Therapists, the Association of Chartered Physiotherapists in Respiratory Care and the National Patient Safety Agency. Resources and emergency algorithms were developed by consensus, taking into account existing guidelines, evidence and experiences. The stakeholder groups reviewed draft emergency algorithms and feedback was also received from open peer review.

The final algorithms were something of a compromise, balancing the desire to describe a universal approach to managing emergencies to be followed by multidisciplinary first responders against the specific circumstances that may be encountered in specialist areas or the critically ill. The need for these algorithms had been identified through my previous work and the scene was set. I personally spoke at all of the relevant Colleges and stakeholder groups to explain the purpose and rationale behind the guidelines and all agreed to support and endorse the final algorithms.

The key principle behind these guidelines was to improve the management of tracheostomy and laryngectomy critical incidents. We had tested and refined these guidelines using High Fidelity simulation, which was unique for airway management algorithms (McGrath et al., 2014; Doherty et al., 2015).

The resulting algorithms were unique in guiding responders to address the commonest and most easily rectifiable problems with tracheostomy care in a sequential way, based on our analysis of incidents. Removal of a confirmed blocked or displaced tube was encouraged by multidisciplinary staff, breaking down barriers and giving 'permission' to junior staff to undertake potentially life-saving interventions that were previously considered a specialist skill.

Other novel features of the development process for the guidelines described in this paper include primary review by nominated representatives of key national bodies, followed by peer review by members of those bodies. This peer review took several forms, including presentation at specialist national meetings, open and direct invitations to view and feed back on the algorithms that were presented in draft form on the NTSP website. As a result, specific differences with other guidelines are evident. In our algorithms:

1. Waveform capnography has a prominent role at an early stage in emergency management.
2. Oxygenation of the patient is prioritised.
3. Trials of ventilation via a potentially displaced tracheostomy tube to assess patency are avoided.

4. Suction is only attempted after removing a potentially blocked inner tube.
5. Oxygen is applied to both potential airways.
6. Simple methods to oxygenate and ventilate via the stoma are described.
7. A blocked or displaced tracheostomy tube is removed as soon as this is established, not as a 'last resort'.

In addition, previous guidance for tracheostomy emergencies had generally not been published as an algorithm, making it difficult to follow in emergency situations. Where algorithms have been used, they were often complex and not easily followed when tested in simulated emergencies. No previous algorithms were colour coded and none had been presented paired with bed-head signs. Further, many previously published strategies offered no 'Plan B' if the initial measures failed to resolve the situation.

Finally, we believed that the emergency guidance developed by our group was applicable to all situations (critical care, ward patients, community patients, spontaneously breathing or ventilated patients, surgical and percutaneous tracheostomy). These guidelines have generated considerable interest amongst the multidisciplinary groups that manage tracheostomy patients which has led to them becoming relatively highly cited. The paper has remained amongst the top 10 cited, viewed and downloaded papers each year from the journal *Anaesthesia* from 2013 until the time of writing (last report from the journal in December 2016).

2.3.b. Paper 4.

Multidisciplinary emergency guidelines

McGrath BA, Bates L, Atkinson D, Moore JA; National Tracheostomy Safety Project. Multidisciplinary guidelines for the management of tracheostomy and laryngectomy airway emergencies. *Anaesthesia.* 2012;67(9):1025-41.

Link to article - http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2044.2012.07217.x/abstract

Citations as of 21st June 2017

- Google Scholar 69
- Web of science 30
- Scopus 41
- Tweeted by 94
- 111 readers on Mendeley
- Quoted in 1 policy source (National Institute for Health and Care Excellence, NICE, on 01 Sep 2015: ERBE flexible cryoprobes for bronchoscopic diagnosis and treatment)
- Altmetric score 72 (top 5% of all published works)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Multidisciplinary guidelines for the management of tracheostomy and laryngectomy airway emergencies
BA McGrath, L Bates, D Atkinson, JA Moore.
Anaesthesia 2012 Sep;67(9):1025-41.

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept - all authors. Content & algorithm BAM 60%, other authors 40%. Manuscript BAM 60%, other authors 40%. Endorsements from societies BAM.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
L Bates	LeBates	Lucy.Bates@boltonft.nhs.uk
D Atkinson	[signature]	dougal.atkinson@cmft.nhs.uk
JA Moore	[signature]	john.moore@cmft.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

2.3.c. Critical appraisal: Methodological critique of the guidelines paper

This section of the thesis will critique the methodology behind the 2012 multidisciplinary emergency guidelines paper, included as part of my presented works (McGrath, Bates, et al., 2012). I led the Working Party that developed these guidelines through close collaboration with a number of stakeholder national organisations. The development and finalisation of the guidelines was described in detail in the paper, but a significant amount of the early work in preparing draft algorithms for circulation and discussion involved the use of high-fidelity medical simulation. This marked a departure from more 'traditional' methods of guideline development and is still novel amongst published airway management guidelines.

In this section I will describe this novel use of high-fidelity medical simulation to test and develop the initial adult algorithms that formed the basis for this paper.

Simulation and airway management

Prompt clinical decision-making and decisive actions are required in airway emergencies, especially the critically ill. Knowledge, skills and practical procedures must be effected rapidly in challenging circumstances and a variety of simulation-based strategies have been developed to date to facilitate technical and non-technical learning in simulated airway scenarios (Lucisano and Talbot, 2012).

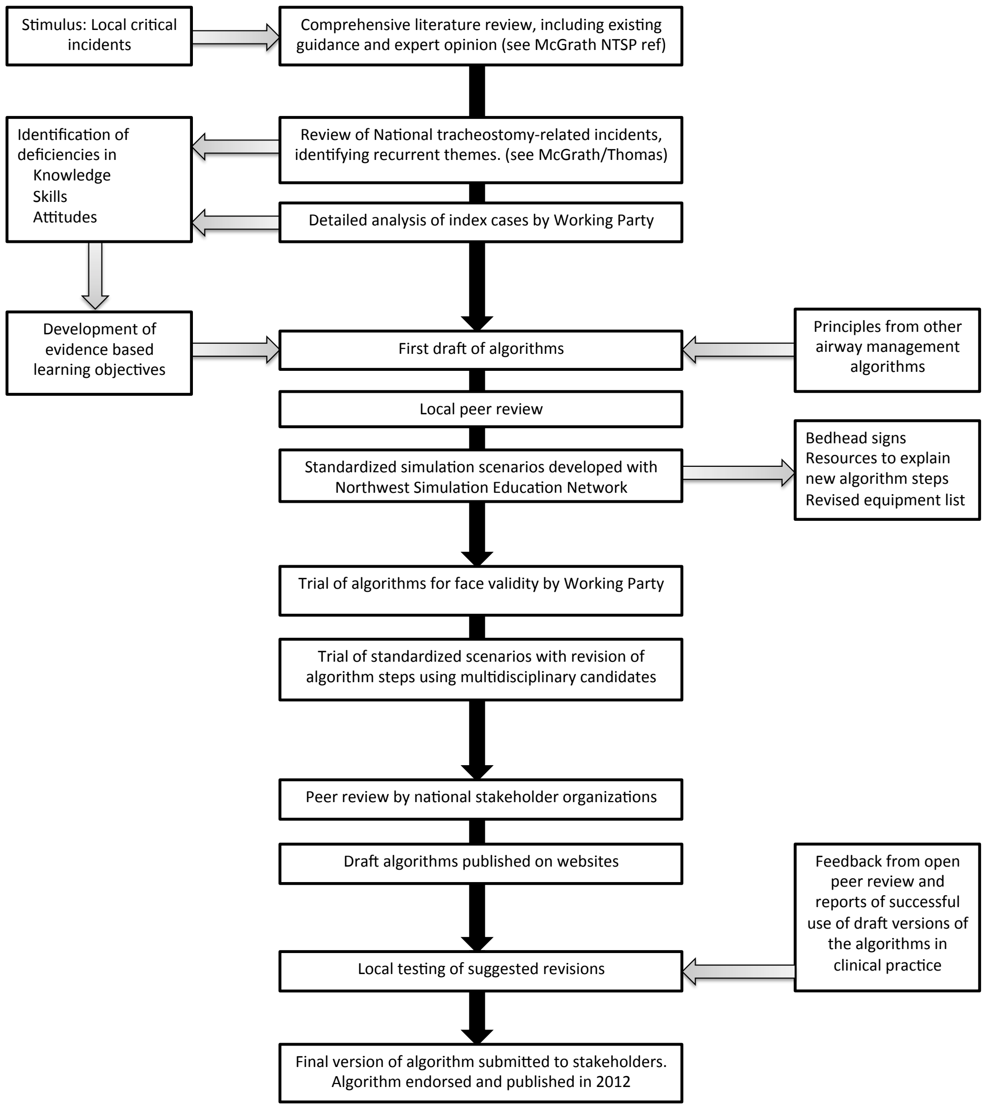
The NTSP was tasked with developing tracheostomy resources in an attempt to reduce adverse events. Whilst some responses could be considered organizational (availability of personnel and equipment) one key concept was the development of simple algorithms to guide responders in the emergency situation, based on the successful flow charts produced by international difficult airway societies. Previously published algorithms have demonstrated how effective emergency airway management requires careful advanced planning, rehearsal and performance of key steps in a logical order and a multi-disciplinary team approach in order to achieve a successful outcome (Caplan et al., 1990; Mallick and Bodenham, 2010; Crosby, 2011; Cook et al., 2016). National specialist airway societies are usually tasked with developing such guidance, identifying knowledge gaps, considering areas for future research and assessing the implications for education and training for the new guideline itself, including any technical procedures described. Most are developed by consensus following an extensive literature review and then drafted by experts or committees of experts (Crosby et al., 1998; American Society of Anesthesiologists Task Force on Management of the Difficult Airway, 2003; Henderson et al., 2004; Braun et al., 2004; Frova and Sorbello, 2009; Crosby, 2011; Difficult Airway Society Extubation Guidelines Group et al., 2012; Apfelbaum et al., 2013; Frerk et al., 2015). Emergency algorithms have been a key component in advances in the safety of airway management of the native airway (Peterson et al., 2005; Frova and Sorbello, 2009; Crosby, 2011; Amathieu et al., 2011).

Whilst medical simulation is used extensively to teach and rehearse delivery of individual key steps of algorithms and successful team working, there are no published evaluations of the development of such algorithms using simulation to trial and revise either individual elements or their order. Multidisciplinary tracheostomy emergency management lends itself to the use of medical simulation: there may be unfamiliar key steps and technical skills to acquire and the concept of working with two potentially compromised airways with responders from diverse nursing, medical and allied health backgrounds can be rehearsed in a variety of simulated scenarios. Our group recognised that ‘high fidelity’ medical simulation could be used to evaluate the most appropriate algorithm steps and their order to guide responders most effectively using standardised scenarios. By comparing algorithm revisions made using this simulation-based methodology with those made as a result of expert peer review, I wished to challenge the established development processes of existing airway management guidelines.

There is evidence that procedural simulation improves actual performance in clinical settings with respect to implementing ACLS protocols and acquiring clinical skills, translating into improved performance in clinical situations (Chopra et al., 1994; Mayo et al., 2004; Rosenthal, 2006; Wayne et al., 2006; Nishisaki et al., 2007). Properly conducted simulation scenarios can create predictable, consistent, standardized, safe, and reproducible learning objectives or activities (Okuda et al., 2009). These factors make simulation ideal for rehearsing clinical interventions during high-risk events and can be used to effectively re-create rare but significant patient scenarios, such as difficult airway management (Kory et al., 2007). The physiological and physical changes that occur in airway crises can be realistically modelled utilizing the capabilities of high-fidelity mannequins (Okuda et al., 2009).

The early development process of the NTSP algorithms

Figure 2.2. *Timeline detailing the key steps in developing the Emergency algorithms*



My co-authors and I recognised that feedback from simulated scenarios could not only be used to guide and assess performance of the candidates, but also in the development of the actual algorithms themselves. The development process is summarized in figure 2.2 above.

We constructed index tracheostomy emergency scenarios upon which a universal management approach could be designed. Simulation scenarios were informed by relevant nationally reported critical incidents, identifying themes relevant to blocked or displaced tracheostomy tubes (McGrath and Thomas, 2010; Cook, Woodall, Frerk, et al., 2011; McGrath, Bates, et al., 2012; Thomas and MacDonald, 2016). Peer review of scenarios was provided from colleagues from the NHS North West Simulation Education Network (www.northwestsimulation.org.uk), each highlighting a specific learning objective and resulting in four standard scenarios.

Actual events from reported incidents were compared and contrasted to what was considered as optimal practice by the group, noting significant actions, inactions or opportunities to intervene and also including examples of successful management. These steps formed the basis of the first drafts of the emergency management algorithms and could be considered as expert opinion informed by the literature review and our analysis of over 2,000 airway-related incidents (Thomas and McGrath, 2009; McGrath and Thomas, 2010). Two principles were adopted from previous UK Difficult Airway Society work and supported by our critical incident reviews: oxygenation of the patient takes priority (not necessarily securing the airway immediately and definitively, unless required for oxygenation) and that experienced assistance should be sought early (Henderson et al., 2004; McGrath, Bates, et al., 2012).

The first algorithms were written in October 2008 and key steps included directing responders to the awareness of two potential airways, use of capnography as a ‘gold standard’ in determining airway patency, removal of un-necessary and potentially harmful devices attached to the tracheostomy tubes, removal of the inner cannula and an attempt at suctioning the airway via the tracheostomy tube. These algorithms then directed responders to attempt increasingly invasive methods of oxygenating and ventilating the patient, should initial measures prove unsuccessful.

Trialling the algorithms using simulation

We invited staff from a range of disciplines working in our hospitals to participate voluntarily in the tracheostomy simulations, following explanation that we were evaluating the algorithms and seeking feedback. We tested and refined the algorithms in three phases, either in dedicated simulation suites or clinical settings, including emergency departments, wards, theatre suites and critical care units.

We recorded if the actions taken by participants resulted in:

1. Prolonged desaturation (SpO_2 <90% for >5mins – a standard definition of at-least 'temporary harm' applied by the NPSA incident reviews (Thomas and McGrath, 2009).
2. Significant inaction (e.g. pause of >1min, asking for help, continuing with the same algorithm step when faced with on-going deterioration)
3. Achievement of the scenario's key learning objectives
4. Successful management of the scenario (objective assessment combined with improvement in simulated physiological state)
5. Completing the scenario: Overall time taken to complete the scenario (defined as return to SpO_2 > 90% and achieving the learning outcome, candidate unable to continue or cardiac arrest occurring in the scenario)

A final cycle of peer review and endorsement by stakeholder organisations endorsed these final versions with no further revisions.

This extensive feedback and guideline development process is unique in devising airway management algorithms. The Working Party, led by myself, combined expert opinion with local opinion and then tested any updates in the algorithms on recreated, previously reported, simulated clinical scenarios. The result were unique, one-page algorithms that could be followed by a spectrum of medical, nursing and allied health professionals in a wide range of emergency scenarios. The final algorithms directed diverse responders to promptly manage index scenarios without significant delays, using clinically appropriate and familiar equipment and techniques and achieve the intended learning outcomes and goals. I have continued to evaluate the algorithms with a variety of staff groups and simulated scenarios (Doherty et al., 2015).

The relevance of simulation equipment

As we developed resources and tools for multidisciplinary staff to manage emergency situations, we were conscious that wider resources that would support this paper and the guidelines would be required. We envisaged that others in a variety of healthcare settings would teach these algorithms. This meant that the work we published had to be straightforward to teach, using readily available equipment.

My experience with teaching the required airway skills to follow the guidelines presented in this paper is consistent with published opinion, with basic skills able to be acquired using simple simulators (Grober et al., 2004), and with the high-fidelity simulators offering opportunities to achieve advanced educational objectives (Blair et al., 2007). However, whilst basic mannequins are certainly useful for teaching basic airway skills, mannequins should have adequate fidelity and be fit for purpose (Rosenthal and Owen, 2004; Jordan et al., 2007). Some available mannequins have unrealistic laryngeal anatomy, rigid structures and inability to simulate reversible airway obstruction (Rosenthal and Owen, 2004; Jackson and Cook, 2007). Studies have also reported varying performance from different types of mannequins when using supra-glottic airway devices (Parry and Owen, 2004; Howes et al., 2010), and more than one mannequin may be required to teach the complete set of skills required to achieve the goals of a given algorithm (Plummer and Owen, 2001; M. E. Rosenthal, 2006). One perceived advantage of using a variety of mannequins is that learners may adapt their skills to a particular mannequin, leading to a broader range of acquired skills (Rowe and Cohen, 2002). Standards in relation to simulators, environments and facilities have been slow in coming, with the result that published algorithms may be taught in a variety of methods using a variety of equipment and simulators (Fletcher et al., 2002).

Conclusion

Through the novel use of simulation to develop guidelines, I have attempted to 'close the loop' on tracheostomy-related emergencies by investigating recurrent themes leading to patient harm and by developing and evaluating resources designed to reduce harm in this vulnerable patient group. The role of high-fidelity medical simulation in recreating reported patient safety incidents and analysing key steps, missed opportunities and potential interventions was key in developing universal emergency management algorithms. Repeating standardised scenarios whilst following subtly different response algorithms allowed refinement of guided responses and this approach led to significantly more changes than those returned by expert peer review.

In conclusion, medical simulation has an important role to play in the initial development and subsequent refinement of airway management algorithms and this methodology can compliment or challenge the established methodologies for development or revision of similar guidelines.

2.4. Evaluating the impact of healthcare improvements

2.4.a. Narrative: Evaluating the impact

The first paper (Paper 5) presented in this section was the first to demonstrate improvements in care following the introduction of multidisciplinary educational resources for tracheostomy care. This work was conducted in four hospitals in Greater Manchester. I had previously published the NTSP multidisciplinary guidelines for the management of tracheostomy and laryngectomy airway emergencies in 2012 (McGrath, Bates, et al., 2012). I continued to lead a working party that developed resources to support the wider project that included e-learning modules, a freely accessible, comprehensive manual, educational videos, guidance on equipment and infrastructure considerations for healthcare providers and multidisciplinary educational courses for staff (available from the Advanced Life Support Group, www.alsg.org). We housed these resources on a website (www.tracheostomy.org.uk) and free smartphone applications.

The implementation of staff training was adopted by the 18 hospitals that comprise the Association of North Western ICUs (ANWICU) and I focused on four large tertiary sites for this 'before and after' study. Key steps involved in-house training of any staff who would be expected to care for neck-breathing patients, the use of NTSP bedhead signs, training in the use of the NTSP emergency algorithms, provision of bedside and appropriate resuscitation equipment and the designation of tracheostomy cohort wards within the 115rganization.

As this study was focused on improving safety, I chose severity of harm as my primary outcome measure. There are potential problems with this measure as incident reporting is prone to variations, especially if staff know that a project is examining incidents. This is an example of the Hawthorne effect; a term coined in 1958 by Landsberger to describe changes in outcome simply by participating in a study. In order to minimize this potential bias in this paper, we examined reported incident rates across the whole period and found these to be essentially unchanged. We also examined the proportions of incidents that resulted in various levels of harm, grouping this together into simple classifications and comparisons such as 'no harm vs some harm'. Other unmeasured factors may have accounted for the improvements observed, although we were not aware of significant changes in infrastructure or personnel over the course of the study.

In essence I was careful not to over-interpret the results of this study, but was pleased that we were able to demonstrate reductions in harm following implementation of our educational resources. My group went on to demonstrate improvements in safety following the introduction of tracheostomy multi-disciplinary team ward rounds at a tertiary hospital. (Lynch et al., 2015) and improvements in patient-reported outcome measures following the introduction of new techniques for Speech and Language Therapists. (McGrath and S. Wallace, 2014b; McGrath, Lynch, et al., 2015).

This led to implementing a system-wide package of care into four different diverse hospitals in South Manchester, presented as Paper 6. The sites comprised a tertiary teaching hospital, a university-affiliated district general hospital and two smaller district general sites. I was successful in securing grant funding from the Health Foundation to implement the resources of the Global Tracheostomy Collaborative (GTC) into these four diverse hospitals. This was the first time that this comprehensive package of educational and infrastructure resources had been implemented alongside targeted training for staff. The GTC used established quality improvement methodology to understand how to implement change in these sites and for the first time, the effectiveness of this package of improvements was evaluated using a patient-level database. I led this multidisciplinary project as Principle Investigator and we were able to achieve our objectives in all sites. There was variable engagement across sites and specialities, but we found that feeding back data to departments and individuals drove changes.

Paper 6 is presented in this section and demonstrates meaningful improvements in the quality and safety of care. We addressed some of the potential bias outlined above by using run-charts and trends in the nature and severity of reported incidents. These themes are further developed and discussed in section 4. I was particularly pleased to see significant trends over a 12-month period towards reduced length of hospital stay, reflecting better coordinated care, particularly in the ICU patients with tracheostomy. These data have been shared with the GTC and will inform future benchmarking amongst the global sites participating in the project.

Whilst the primary aim of the resources, interventions and quality improvements presented in these two papers has been to improve the safety of care for patients, much of the secondary aim has been to also improve the quality of care. Quality of care is difficult to measure and is dependant on many different factors (Hancock, 2015; Braithwaite et al., 2017). Quality is also very subjective. The most important people in all of these papers are the patients and their families and often their impressions of quality are very different to what clinical staff or hospital administrators believe to be important.

For example, in focus group work with patients, we discovered that the most important things patients want to do with their tracheostomy is:

1. To be able to speak
2. To be able to eat
3. To get the tube removed (decannulated) and get out of hospital
4. To have information about their tracheostomy provided

Families report:

1. A desire for simple information
2. A wish to understand how they can help manage the day to day care of the patient and their tracheostomy

Clinical staff report a wish for:

1. Better co-operation between teams
2. Better co-ordinated care
3. Access to technology to improve care
4. Easy access to low cost, accessible, bedside endoscopy

Hospital administrators report a wish to:

1. Reduce length of stay
2. Reduce adverse events (associated with cost and reputational harm)
3. Reduce the cost of care

In order to ensure the relevance of my research, I developed my methodologies to incorporate an evaluation of some of these surrogates for the quality of care. This takes the incident reporting which had previously been used to inform the problems and uses it to measure outcomes but builds on this to measure patient level metrics. These approaches are described in the presented papers and discussed in the critical appraisal sections which follow (Sections 2.4. d,e,f).

2.4.b. Paper 5.

The impact on patient safety incidents of introducing targeted education and infrastructure changes.

McGrath B, Calder N, Laha S, Perks A, Chaudry I, Bates L, Moore J, Atkinson D. Reduction in harm from tracheostomy-related patient safety incidents following introduction of the National Tracheostomy Safety Project: Our experience from two hundred and eighty seven incidents. *Clin Otolaryngol.* 2013 Volume 38, Issue 6, pages 541–545

Article link – http://onlinelibrary.wiley.com/doi/10.1111/coa.12177/full

Citations as of 21st June 2017

- Google Scholar 12
- Web of science 6
- Scopus 6
- Tweeted by 3
- 8 readers on Mendeley
- Altmetric score 3

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Reduction in harm from tracheostomy-related patient safety incidents
BA McGrath, N Calder, S Laha, A Perks, I Chaudry, L Bates, D Atkinson, JA Moore.
Clin Otolaryngol. 2013 Volume 38, Issue 6, pages 541–545

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept - BAM. Data collection, synthesis and analysis BAM 80%, other authors 20%. Manuscript BAM 70%, other authors 30%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
N Calder	N. Calder	ncalder@hotmail.com
S Laha	Shondipon Laha	shondipon.laha@lthtr.nhs.uk
A Perks	[signature]	anna.perks@srft.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Reduction in harm from tracheostomy-related patient safety incidents
BA McGrath, N Calder, S Laha, A Perks, I Chaudry, L Bates, D Atkinson, JA Moore.
Clin Otolaryngol. 2013 Volume 38, Issue 6, pages 541–545

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept - BAM. Data collection, synthesis and analysis BAM 80%, other authors 20%. Manuscript BAM 70%, other authors 30%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
I Chaudry	[signature]	irfan.chaudry@lthtr.nhs.uk
L Bates	[signature]	Lucy.Bates@boltonft.nhs.uk
D Atkinson	[signature]	dougal.atkinson@cmft.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Reduction in harm from tracheostomy-related patient safety incidents
BA McGrath, N Calder, S Laha, A Perks, I Chaudry, L Bates, D Atkinson, JA Moore.
Clin Otolaryngol. 2013 Volume 38, Issue 6, pages 541–545

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept - BAM. Data collection, synthesis and analysis BAM 80%, other authos 20%. Manuscript BAM 70%, other authors 30%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
JA Moore	[signature]	john.moore@cmft.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

2.4.c. Paper 6.

Introducing the GTC into 4 diverse NHS hospitals

McGrath BA, Lynch J, Bonvento B, Wallace S, Poole V, Farrell A, Diaz C, Khwaja S, Roberson DW. Evaluating the quality improvement impact of the Global Tracheostomy Collaborative in four diverse NHS hospitals. *BMJ Quality Improvement Reports. 6(1): bmjqir. U220636. W7996 [Online]*

Article link – https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5457966/

(0 citations –published May 23st 2017)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s): Brendan Anthony Preferred Title: Dr

Surname: McGrath

MMU e-mail address: brendan.mcgrath@stu.mmu.ac.uk Contact Number: 0161 291 642

Personal e-mail address: brendan.mcgrath@manchester.ac.uk Student ID Number: 16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Evaluating the quality improvement impact of the Global Tracheostomy Collaborative in four diverse NHS hospitals. BMJ Quality Improvement Reports 2016; u220636.w7996 doi: 10.1136/bmjquality.u220636.w7996
BA McGrath, J Lynch, B Bonvento, S Wallace, V Poole, A Farrell, C Diaz, S Khwaja, D Roberson

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept BAM. Methods and data collection all authors. Data analysis 80% BAM, 20% JL. Manuscript BAM 80%, other authors 20%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
J Lynch		james.lynch@tracheostomy.org.u
B Bonvento		barbara.bonvento@uhsm.nhs.uk
S Wallace		sarah.wallace@uhsm.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Evaluating the quality improvement impact of the Global Tracheostomy Collaborative in four diverse NHS hospitals.
BMJ Quality Improvement Reports 2016; u220636.w7996 doi: 10.1136/bmjquality.u220636.w7996
BA McGrath, J Lynch, B Bonvento, S Wallace, V Poole, A Farrell, C Diaz, S Khwaja, D Roberson

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept BAM. Methods and data collection all authors. Data analysis 80% BAM, 20% JL. Manuscript BAM 80%, other authors 20%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
V Poole	[signature]	valerie.poole@stockport.nhs.uk
A Farrell	[signature]	ann.farrell@tgh.nhs.uk
C Diaz	[Unable to contact - abroad]	cristina.diazcidrobbie@nhs.net

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Evaluating the quality improvement impact of the Global Tracheostomy Collaborative in four diverse NHS hospitals.
BMJ Quality Improvement Reports 2016; u220636.w7996 doi: 10.1136/bmjquality.u220636.w7996
BA McGrath, J Lynch, B Bonvento, S Wallace, V Poole, A Farell , C Diaz, S Khwaja, D Roberson

4. Candidate's contribution to the research output
(State nature and approximate percentage contribution of each author)

Concept BAM. Methods and data collection all authors. Data analysis 80% BAM, 20% JL. Manuscript BAM 80%, other authors 20%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
S Khwaja	[signature]	sadiekhwaja@gmail.com
D Roberson	[signature]	David.Roberson@childrens.harvard.edu

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

2.4d. Critical appraisal: Critical incidents as a measure of the effectiveness of interventions

A key element of assessing the impact of my interventions presented in this pair of papers was the use of reported patient safety incidents to assess changes in the safety of care. In this section, I will discuss the potential problems with using incidents as a metric and outcome measure.

Critical incident reporting systems were already established in the four hospitals that participated in this research project. That allowed me to use historical data as a baseline, to compare and benchmark with national data, and also to assess the impact of the interventions that we had introduced across these sites.

One of the significant potential confounders in assessing the impact of interventions using incident reporting trends is if a change in reporting culture occurs during the period of interest. A change in culture in just one ward or location could be enough to significantly influence the interpretation of incidents, especially if that location managed high volumes of the patient population or condition of interest. For my work, one concern was that targeted interventions aimed at ENT wards or ICUs could raise the profile of tracheostomy care, and by actively encouraging reporting of 'near misses' (such as a blocked tube was noticed and managed correctly) or non-clinical incidents (such as equipment was noticed to be not available at the bedside, but was not actually required) then the baseline reporting of such incidents could be influenced. This could lead to the conclusion that the intervention is influencing outcome when in fact the reporting culture could simply be changing.

This phenomenon was first described in 1958 by Landsberger when analysing earlier experiments from 1924–32 at the Hawthorne Works, a Western Electric factory near Chicago in the United States (Landsberger, 1958). The Hawthorne Works had commissioned a study to investigate if their workers would become more productive in higher or lower levels of light. They observed that workers' productivity seemed to improve when changes were made, regardless of what the change was, and slumped when the study ended. Landsberger suggested that the productivity gain occurred as a result of the motivational effect on the workers of the interest being shown in them, independent of the nature of the intervention. (Wikipedia contributors, 2017)

This "Hawthorne effect" (also referred to as the observer effect) has been characterised as a situation in which individuals modify an aspect of their behavior in response to their awareness of being observed. Various authors have characterised this phenomenon and attempted to quantify the influence of the Hawthorne effect on the results of an intervention. Confounding can occur if researchers fail to recognise the consequences of influencing a subject's performance. Performance can be influenced positively or negatively, due to the perception of a sympathetic or interested observer, subjects wishing to please an observer, or concerns that performance will be open to scrutiny, praise or criticism (Parsons, 1974; Kohli et al., 2009).

Clark suggested that that the uncontrolled 'novelty effects' of a new intervention that is subject to scrutiny can be responsible for around 30% of a standard deviation rise in performance, independent of the quality of the intervention (Clark and Sugrue, 2010) However, other researchers have used large datasets of reported critical incidents to assess the impact of interventions and trends in harm metrics in the NHS. They conclude, as I did, that my methodology was appropriate and robust. The rationale for this conclusion is discussed below.

Using the NRLS dataset to assess reporting culture in the NHS

The bulk of the evidence comes from evaluation of the NRLS dataset over the last 10 years, which includes nearly 6,000,000 reported incidents. With such a large library of reported incidents available in the NHS, it seemed inevitable that these databases would be used to assess the effectiveness of various interventions and quality improvement strategies on a national and local scale. High profile service failures within the NHS have raised public concern about preventable harm in healthcare, increasing the demand for transparency and accountability (Howell et al., 2015). It is therefore not unreasonable to expect that valid judgments about the risks to patients in one hospital compared to another could be made using collected incident reports.

Incidents have also been used by regulators for various reasons, ranging from quality improvement to implementation of punitive measures. As much of my work was designed around solving problems originally identified by critical incidents, it seemed logical to use those same systems to measure the effect of any interventions, but exploring the rationale behind this is worthy of critique.

The Care Quality Commission (CQC) is the principle regulator of NHS hospitals. The CQC currently assesses the rates of incident reporting for individual hospitals as part of their inspection regime. The reporting rate probably reflects not only the actual number of safety incidents, but also the reporting behavior and culture within a particular hospital. What is less clear is whether examining crude reporting rates distinguishes unsafe care or whether it merely reflects variation in reporting behavior. This 'reporting culture' has been examined by a number of authors, again using the NRLS reporting system. The two largest studies drew similar conclusions, although with different explanations. Hutchinson examined the first eighteen months of NRLS data and found no correlation between high reporting rates and poor hospital outcomes. However, the group concluded that the lack of correlation was almost certainly due to overall low reporting rates of incidents (Hutchinson et al., 2009). Hutchinson noted that the overall reporting rate was steadily increasing and reporting rates to the NRLS by 2013 had increased to over one million patient safety incidents a year. Later analysis of these data still demonstrates significant variation between hospitals in terms of reporting rates and culture (Howell et al., 2015; NPSA, 2016).

Conclusions

Whilst the mere participation of a site or clinical area in studies such as papers five and six presented in this section might be expected to influence the reported effects of any interventions, the impact of the Hawthorne effect is likely to be negligible in studies of this type. No significant relationships between overall reporting rates, hospital structure, interventions and outcomes were found by other authors who evaluated large NRLS datasets (Hutchinson et al., 2009; Howell et al., 2015). The measurement of critical incidents is considered to be a reasonable outcome measure for the papers presented in this section.

2.4.e. Critical appraisal: Minimising potential bias when using critical incidents as an outcome measure

In order to evolve my methodologies to support my conclusions, I adopted a number of refinements to the methods I used, based on reflections on my published works. This section describes the different approaches I have taken to validate our findings presented in Papers five and six, and to ensure that my conclusions are robust. The refinements that I discuss demonstrate evolution from earlier publications (Paper four) and include:

- Standardised assessment of incidents
- Examining trends in reporting
- Comparisons with historical and other datasets

Firstly, I ensured that more than one person – usually myself and at least one co-author, classified all reported incidents independently. We collected data from several different sites and by re-reporting and classifying incidents, we ensured that:

1. Variations in standards and local interpretations of local incidents are removed
2. Standardisation is applied in classification of incidents (for example, a tube that has to be replaced is always classified as 'temporary harm')
3. We can explore further variations in local assessment of the impact and severity of similar incidents, as a separate piece of work

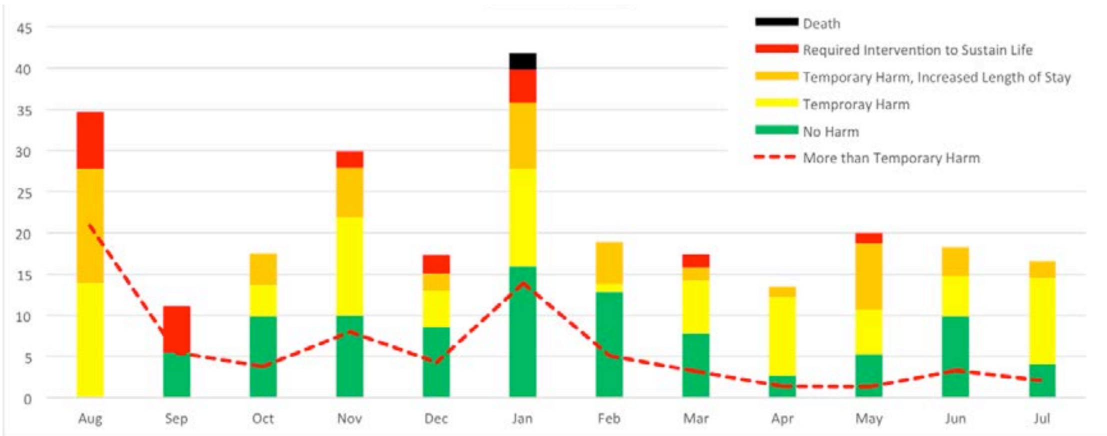
Another method I have employed of ensuring that meaningful incidents are captured for analysis is to focus on specific incident themes, rather than overall incidents. This approach has been advocated by others when considering critical incident analysis and allows targeted evaluations of specific interventions whilst minimizing the risks of bias from 'background noise' fluctuations in incident reporting, that may be influenced by participation in a particular programme, study or series of interventions (Sari et al., 2007; Roehr, 2012). This was the approach I took when choosing outcome measures for some of my observational and interventional studies. By focusing on particular themes of incidents or areas of interest, a more accurate refection of the impact of the intervention could be expected.

The initial methodology I employed in my first studies evaluating the effect of targeted training and educational resources was a fairly basic 'before and after' approach (Paper 4). I used pooled incidents from two periods either side of the interventions. The educational resources were applied across different clinical areas and across four sites. There was inevitable overlap and likely contamination either side of the interventions, but we attempted to minimise this by asking sites to self-declare when they considered each of the clinical areas to be 'trained', prior to analysis of the incidents. This approach allowed us to evaluate the impact on critical incident rates as a simple before and after study.

Accepting the potential limitation of this technique, I developed my methodology further to incorporate trends in incident reporting over time with my later work. For the BMJ Quality Paper (Paper 6) in which I describe the effect of a comprehensive package of quality improvements in four Greater Manchester sites, incidents were classified according to the month in which they occurred. Where a trend was apparent, I evaluated the magnitude of the effect by non-parametric linear regression plots that describe the median slope of the line that is drawn through the medians for each month. Median slopes are presented in Figure 2.3 overleaf, as the trend per unit (month) over the chart duration (12 months) with 95% confidence intervals (CI). If the CI limits did not cross zero, then the slope is considered statistically significant with an alpha level of 0.05.

Over the 12-month data collection period 296 tracheostomy patient admissions were tracked across the four sites. One hundred and twenty four adverse events were identified affecting 29.8% of patients. Analysis of monthly incident rates showed a steep increase (likely due to increased engagement, awareness and reporting as described above) before a steady reduction. However, the impact of these incidents ranged from no impact (equipment was not available at a bedside) through to one instance of death. Analysis of reported incidents over the duration of the project showed a significant reduction in the severity of harm by month (Chi Square $p<0.01$) demonstrated by the red line in the figure below. There was also a significant trend towards lower harm categories for incidents over the duration of the project (Chi Square test for linear trend, $r= -0.21$, $p<0.01$).

Figure 2.3. *Pooled incident rates per 1,000 tracheostomy bed days, by level of harm, during the 12-month data collection period.*



On a statistical note, these non-parametric methods were appropriate for our non-parametrically distributed data, but additionally, outliers also have less influence on these tests as they rely on ranking. All data points were retained for these analyses and it is inevitable when using hospital length of stay data that outliers will be encountered. Statistical tests of trend can also be influenced by the extremes of the data. In this case, this means the data from the first and last months of data collection. In order to take this into account, a sensitivity analysis was performed whereby the first and last month's data were removed and the trend test repeated. This secondary analysis did not affect the significance of the original result, but added weight to its robustness.

Comparisons with historical and other datasets

In order to further evaluate the impact of our work, I also made direct comparisons where possible with historical data. The outcomes from the four site QI project in Greater Manchester (the Shine project, Paper 6) were categorised independently into the NRLS/NPSA classifications of *No harm*, *Temporary harm*, *Temporary harm with increased Length of Stay* (LoS), *Intervention required to sustain life* and *Incident may have or did contribute to death*. Summative analysis was performed examining the trends of frequency and severity of incidents reported by month by the four sites during the project. Data were compared with historical regional and national data and to the contemporaneous Global Tracheostomy Collaborative dataset.

When considering the incidents in two categories ('more than temporary harm' for significant incidents and 'temporary harm/no harm' for low grade incidents) there was again a significant reduction in the severity of harm over the duration of the project (Chi square $p<0.01$, Chi square test for linear trend $r= -0.27$, $p<0.01$). Data were compared to historical outcome and incident data from 287 incidents reported from four teaching hospitals in the North West of England as part of my earlier quality improvement project carried out between 2008 and 2012, published in 2013 and presented in this thesis as Paper 5 (McGrath et al., 2013). Data were also compared with outcomes and incident data from the 2013 NCEPOD report into tracheostomy care, which examined over 2,500 consecutive tracheostomy insertions in England and Wales over an 11-week period.(Martin et al., 2014).

Table 2.3. *Comparison of rates of harm between the Shine (4 site) data and rates from the NW 2008-12 dataset for reported critical incidents. TH – Temporary Harm, LoS – Length of Stay.*

	Total	Death	Intervention	TH⇑ LoS	TH	No Harm
NW 2008-12	287	8 (2.8%)	34 (11.8%)	25 (8.7%)	140 (48.8%)	80 (27.9%)
Shine	123	1 (0.8%)	8 (6.5%)	20 (16.3%)	47 (38.2%)	47 (38.2%)

There was a significant difference between levels of harm in the historical NW dataset and those measured during the current Shine project (Chi^2 $p<0.01$), with a significant trend towards incidents resulting in no harm (Chi^2 test for trend $p<0.01$).

NCEPOD data were available as significant incidents (blockage, displacement, major haemorrhage, classified as more than temporary harm in the Shine and NW datasets) and less significant incidents (no harm or temporary harm only). Comparison between these more severe categories of incidents showed similar proportions resulting in significant harm. The major differences in the current Shine cohort were due to the significantly higher proportion of incidents that resulted in no harm (Chi^2 $p=0.047$). This is often the case with new QI projects and may imply an increased awareness of potential problems, earlier detection of problems before they escalate and more decisive and effective management of such incidents.

The tables below show the number of patients in each project for which a patient safety incident was recorded. Differences in reporting cultures in other global sites may account for the much lower GTC rate. Whilst patients in the Greater Manchester 'Shine' cohort (Paper 6) had a greater number of incidents reported, these were of lower harm severity.

Table 2.4. *Number of patients in each of the papers presented in this section for which a patient safety incident was recorded. Comparison is made with the NCEPOD dataset. See text for details.*

	Total	No Harm or TH	More than TH	%age of incidents resulting in more than TH
NW 2008-12 (Paper 5)	287	220	67	23.0%
Shine (Paper 6)	123	94	29	23.6%
NCEPOD	821	619	202	24.6%

Table 2.5. *Number of patient safety incidents occurring per patient in Paper 6, compared with NCEPOD (UK) and GTC (International) pooled data.*

Number of incidents per patient	Shine (4 sites) 296 patients	GTC 175 patients	NCEPOD 2,509 patients
0	211	147	1,875
1	63	19	442
2	16	7	140
3	4	2	40
4	1	0	11
5	1	0	1
Patients with no incident	211	147	1,875
Patients with any incident	22 (36.4%)	28 (16.0%)	634 (25.3%)
Total number of incidents	116	39	891

When compared to the NCEPOD dataset, there were significantly fewer complications in ward patients (21.2 vs 31.3%, p=0.034) and fewer complications in ICU patients (18.8 vs 23.6%, p=0.251) at the main site.

The NCEPOD study was limited to a maximum of 30 days data collection following the insertion of a new tracheostomy. If we compare a similar period for the lead site with LoS truncated at 30 days, there were greater improvements in performance when compared with the NCEPOD dataset.

Ward incidents were significantly reduced (20.0 vs 31.3%, p=0.034) as were ICU incidents (11.9 vs 23.6%, p=0.012).

These additional comparisons are presented and discussed in order to support and validate the conclusions I had drawn from the trends in severity of harm observed following the educational and quality improvement interventions implemented in these two papers.

Comparing adverse incident reporting rates

The longer the tracheostomy tube is in situ for, the likelihood for potential complications increases. As this review demonstrates, I have consulted widely on more effective methods of expressing and communicating harm metrics and have described these as incident rates per 1,000 tracheostomy bed days (TBDs, see Table 2.7 below). I have subsequently approached NCEPOD who have agreed to calculate similar rates for incidents in the NCEPOD report. This will form a useful national benchmark going forwards.

There were 39 incidents that occurred in 28 patients out of the 175 adult GTC patients during the study period, covering a total of 1,700 tracheostomy days. This equates to an incident rate of 22.94 per 1,000 TBDs. As with the NCEPOD dataset, these incidents were all significant (blockage, displacement, major haemorrhage) and can be considered in the category of temporary harm or greater. Considering the TDBs on which an incident occurred vs TBDs where no incident occurred, there was a significantly lower rate of incidents seen in the Shine cohort (Paper 6) than in the contemporary GTC dataset.

This method of presenting incident data may be useful in benchmarking sites with different lengths of stay in the future.

Table 2.6. *Incident rates per 1,000 Tracheostomy Bed Days (TBDs) in the Shine sites (paper 6) vs the international GTC dataset.*

	Shine (all 4 sites)		GTC dataset	
		Rate per 1,000 TBD		Rate per 1,000 TBD
TBD	6,154		1,700	
All incidents	123	20.0		
No harm	47	7.7		
Temporary harm	47	7.7		
TH increased LoS	20	3.3		
Intervention	8	1.3		
Death	1	0.2		
Incidents with harm	76	12.3	39	22.9

Conclusion

In conclusion, crude reporting of critical incidents is not significantly influenced by hospital characteristics. Studies have demonstrated no relationships between size of hospital, numbers of staff, mortality outcomes or patient satisfaction outcomes and reporting rates (Hutchinson et al., 2009; Howell et al., 2015). Whilst reporting rates alone should not be used to assess hospital safety, focusing on different types of safety incident and examining both prospective and retrospective trends is a useful method of determining the impact of interventions. This is especially the case if those interventions have been designed to address the concerns raised by the incident reporting themselves.

2.4.f. Critical appraisal: Developing additional surrogates for the quality of care

Whilst the primary aim of the resources, interventions and quality improvements presented in these two papers has been to improve the safety of care for patients, much of the secondary aim has also been to improve the quality of care. Quality of care is difficult to measure and is dependant on many different factors (Hancock, 2015; Braithwaite et al., 2017). Quality is also very subjective. These papers demonstrate development in my methodologies to incorporate an evaluation of some of these surrogate indicators for the quality of care.

As described in Paper 6, I was successful in securing a grant to join four hospitals in the North West of England to the Global Tracheostomy Collaborative (GTC). Membership of the GTC gave us access to a patient-level database that could track length of stay data. As I wanted to collect other metrics around the quality of care as defined and described above, I built an additional database to track additional metrics that I believed would act as surrogates of the quality of care.

These metrics had to be:

1. Measureable
2. Reliable
3. Representative of an underlying quality concern
4. Able to be used to benchmark care

In order to develop potential quality indicators around multidisciplinary tracheostomy care, we chose to investigate the following metrics:

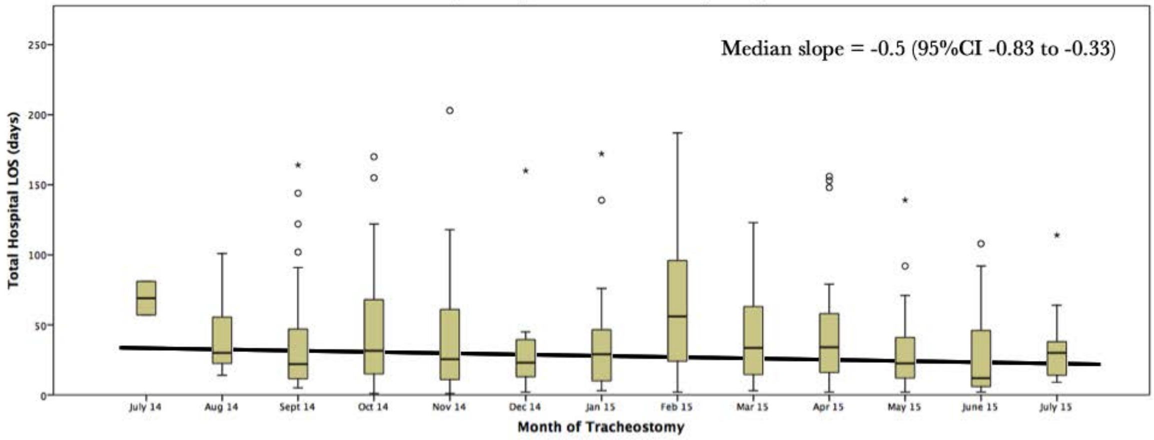
1. Time to first cuff deflation
2. Time to first oral intake
3. Time to full oral diet
4. Length of stay on ICU
5. Length of stay in Hospital
6. Total time that the tracheostomy remained in situ for

My hypothesis was that these metrics would act as surrogates for the quality of care provided. For example, a coordinated multidisciplinary approach meant that all of the necessary assessments and interventions could be obtained in a coordinated manner whilst the patient had the tracheostomy tube in situ. I have performed additional analysis on some of the headline metrics presented in Paper 6 to illustrate the potential impact that these measures may have. These measures are presented as trends by month and this approach is discussed later in this chapter.

Impact on Length of Stay trends

Enhanced multi-disciplinary care should lead to a more co-ordinated, efficient patient journey. Similarly, by preventing incidents that lead to harm, there are fewer delays in a patient's recovery. Pooled data from the four Shine sites presented in paper 6 was used to calculate median lengths of stay (LoS) for all patients. I found a significant trend month-by-month towards reducing LoS, with median hospital LoS reduced by 6 days over the 12 months of the project (95%CI 9.96-3.96, Figure 2.4 below).

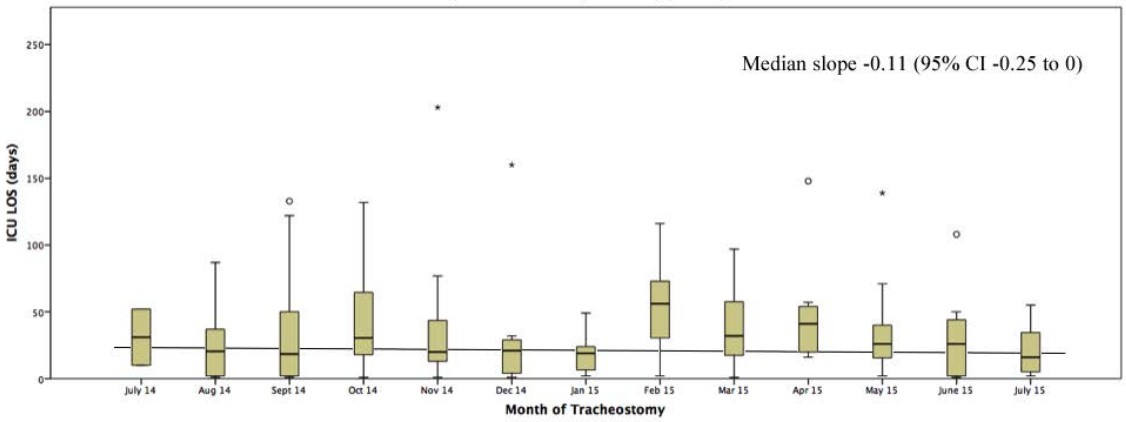
Figure 2.4. *Pooled Hospital LoS data for all sites over the 12-month data collection period (n=296).*



I included all patients in our analysis, allowing 31 days following the project to capture remaining patients. Eight patients had not achieved discharge at this point and their LoS as of 01/09/2015 was included in data analysis. Median LoS across the four sites was 30 days.

Detailed, validated ICU LoS data was available for one site presented in Paper 6, with 169 patient episodes. ICU LoS was significantly reduced over the duration of the project with a median slope of -0.11 (-0.25 to 0). This equates to a reduction in median ICU LoS of 1.3 days over the project (Figure 2.5 below).

Figure 2.5. *ICU LoS per month for Hospital 1 (n=169).*



Patient-focussed outcomes and the impact of the multidisciplinary team

In order to capture data that patients had told us was important to them, we conducted a communication and nutrition-based audit at our hospital site in parallel with the Shine project. These data were not presented in full in paper 6, but are discussed here to highlight the role that the multidisciplinary team can have in influencing care, which undoubtedly translated into influencing some of the headline harm and LoS metrics presented in the main paper.

Our additional analysis demonstrated that improved input from the Speech and Language Therapy (SLT) service led to reduction in the time taken to reach full oral diet from date of first cuff deflation. A patient questionnaire was also developed and completed by 40 patients during the project. This showed slight improvements in levels of anxiety, satisfaction, confidence in staff and staff communication. However, it largely highlighted that these problems seem to be accentuated in the tracheostomy population, even compared to other critically unwell patients.

From an early stage, it became apparent that local policies were not consistently being followed, referral to SLT was not always made after tracheostomy insertion and that it was often made after the decision to commence oral intake had already been taken. SLT provide a vital role in the care of tracheostomy patients as identified by the recent NCEPOD Report (Martin et al., 2014). At the largest Trust, the project team ensured that SLT provided regular assessment of swallow function (including Fibre-optic Endoscopic Evaluation of Swallow (FEES) both in critical care and wards); provided swallowing rehabilitation; assessed and taught patients to use a variety of communication aids; and participated in multi-disciplinary discussions surrounding wider treatment.

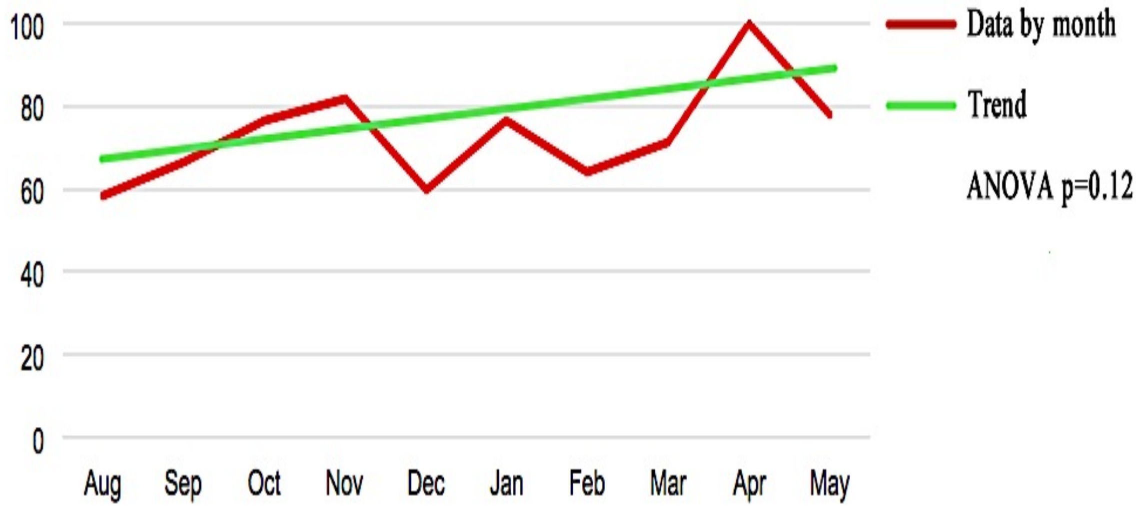
The project team and I believe that SLT input has been an important part of the improvements observed, including the reduction of adverse events and length of stay. However, the SLT audit allows us to demonstrate direct impact against some of the issues highlighted to us during patient and family consultations. We demonstrated that it was possible to ensure that every patient with a newly inserted tracheostomy was referred to SLT within 6-months of commencing the project. Further local goals were agreed, including for example delaying oral intake until a patient had been assessed by SLT.

Enforcing this target increases patient safety but has the potential to delay treatment and outcomes, in particular time to oral intake. To help reduce these delays the steering group set a further goal to improve the timeliness of SLT referral. Traditionally, oral intake before cuff deflation is high risk (although, with FEES it can sometimes be achieved safely). At the lead site the SLT team had a 48-hour target window from receiving a referral to initial assessment of the patient.

Reviewing metrics such as this during the weekly Tracheostomy Multidisciplinary Team (TDMT) ward rounds or departmental audit meetings can have a powerful positive effect in improving performance through feedback. This is also an example of how small, patient-focussed targets can contribute to wider system or process measures such as overall tracheostomy time or length of stay.

Within the SLT dataset there was no single metric to measure time to communication. It was felt that such a metric would be difficult to describe specifically and could be widely interpreted leading to inaccurate results. The dataset did include days to first use of speaking valves, which can be placed on a tracheostomy after successful cuff deflation to produce increased airflow through the upper airway on exhalation. This can result in improved vocalisation. During the project a non-significant (ANOVA p=0.12) monthly trend in increased percentage of patients with newly inserted tracheostomies who used speaking valves was seen (Figure 2.6).

Figure 2.6. *Monthly percentage of patients with newly inserted tracheostomies who used a speaking valve*



The use of speaking valves is dependent on a number of factors and, by design these carry an inherent risk (two adverse events specifically relating to the use of speaking valves were noted during incident data analysis). This risk is particularly high following head and neck surgery. Unfortunately we are unable to separate this dataset by type of surgery but we can separate surgically inserted tracheostomies (including head and neck surgery patients) from percutaneous tracheostomies (no head and neck surgery patients). Monthly analysis of the dataset for percutaneous tracheostomies showed non-significant trend toward earlier speaking valve use (Figure 2.7).

Similarly, the impact of the MDT could be measured by the time between first deflation of the tracheostomy tube cuff and the first oral intake by the patient. This showed a non-significant reduction over the 12 months of data collection in Paper 6 (Figure 2.8) suggesting that the interventions could be playing a role in earlier oral intake, but that this was not conclusive.

__Figure 2.7__. Box-Whisker plot of monthly days to first use of speaking valve for patients with newly inserted percutaneous tracheostomy.

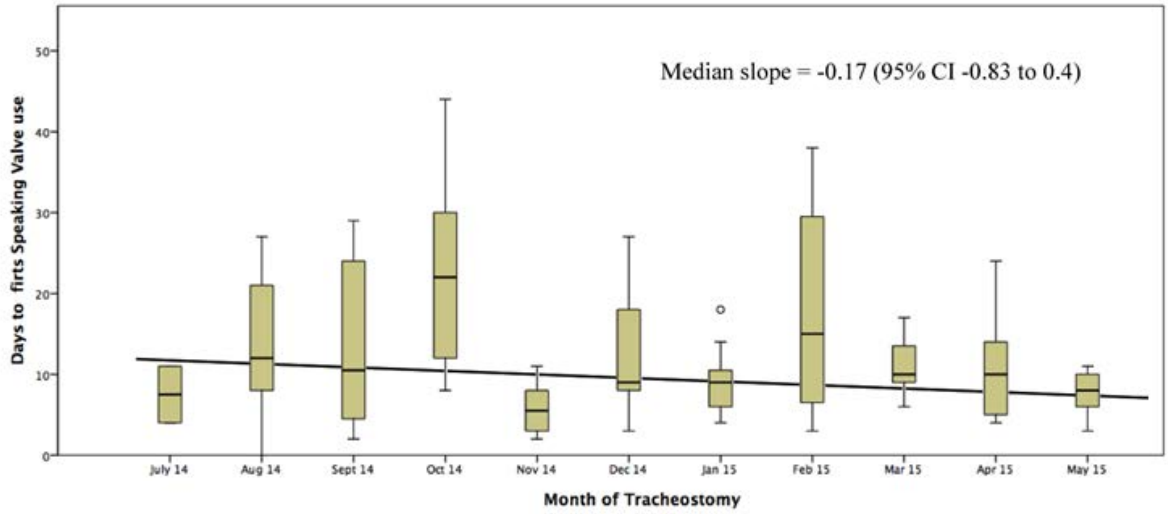
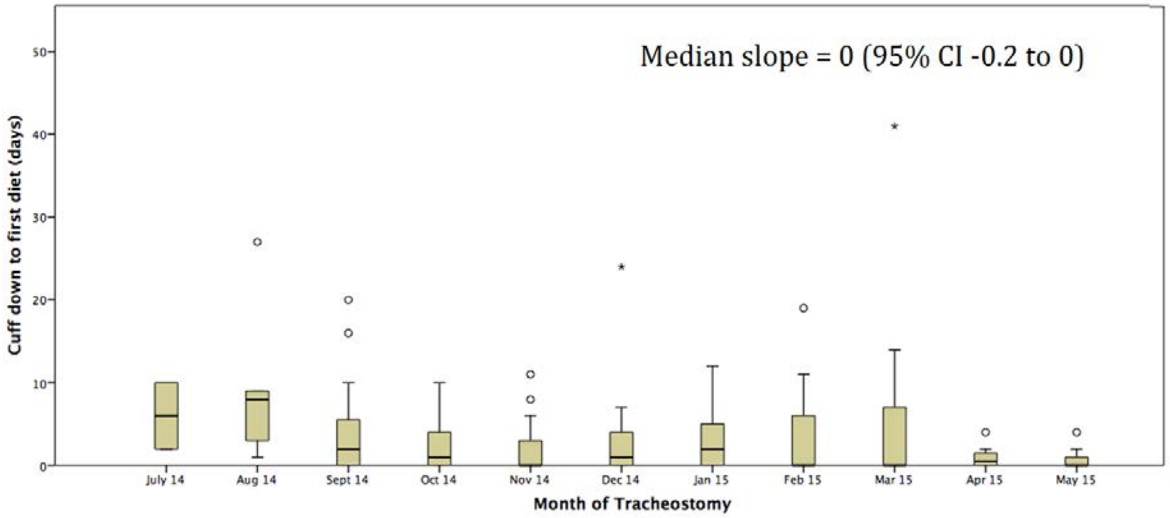
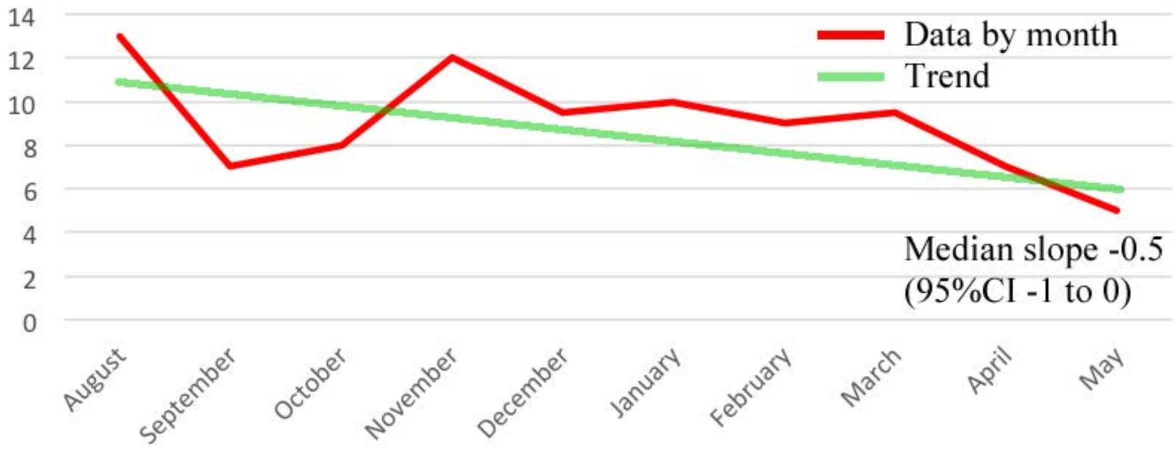


***Figure 2.8.** Box-whisker plot of monthly days between **first** cuff deflation and first oral diet for patients with newly inserted tracheostomy.*



When monthly median days from first cuff deflation to commencement of *full* oral diet (no enteral support) were analysed, a significant trend was identified. The median slope of -0.5 days/month is attributable to a reduction of 5 days across the 10 month SLT data collection period (Figure 2.9).

Figure 2.9. *Monthly trend in median days between first cuff deflation and* ***full*** *oral diet for patients with newly inserted tracheostomies.*



Trend analysis in quality improvement metrics

By presenting these data as monthly trends and testing for the significance of changes, it is fairly straightforward to demonstrate an impact of the interventions on target outcomes. This method has advantages of being able to identify early significant trends, perhaps when staff, systems and hospitals are most receptive to change. By feeding back significant changes rapidly, teams are able to demonstrate 'early wins' and use these data to convince any reluctant colleagues that the interventions are worth pursuing.

In order to generate these 'early data' I also employed the strategy of examining historical critical incident reports from sites prior to commencing the GTC QI interventions. This allows me to use the 'before and after' cohorts, as presented in Paper 5, to demonstrate that there are problems at a particular site or ward within a hospital, before the trend data becomes available.

Using trend data to demonstrate changes would appear to hold more weight than aggregating data into before and after groups for pooled analysis. The impact of interventions is likely greatest at the start of a project, especially when considering avoidable harm may be present in around 30% of all hospital tracheostomy patients (Martin et al., 2014). I am currently following patients for up to three years in a separate QI project. One problem that the trend approach may cause is that following an improvement in quality metrics (or not) if the trend line flattens off, then significance may be hard to demonstrate. Of course should the site get to a position of 'perfect care' then a flat line may be possible, but this is unlikely.

Conclusion

The papers presented and appraised in this section have demonstrated improvements in the safety of care of tracheostomy patents, by analysis of the harms resulting from reported critical incidents. These improvements have resulted from advances in the quality of care provided. Whilst quality is difficult to measure and is dependant on many different factors, I have explored varied, measurable and reproducible metrics that I believe can demonstrate genuine improvements in quality for these patients (Hancock, 2015; Braithwaite et al., 2017). Furthermore, by presenting these data as trends, changes over relatively short periods of time can be visually presented to readers and back to participating sites, which can reinforce the impact of interventions and potentially drive engagement during a study.

These papers demonstrate development in my methodologies to incorporate an evaluation of surrogate indicators for the quality of care and can be used as a reference for future quality improvement work in this field.

2.5. Defining the quality of tracheostomy care

2.5.a. Narrative: Defining quality

Defining quality of care is difficult, as discussed above in section 2.4.f. However, because of the central role of correct airway management in the critically ill patient, the potential indicators of quality can be extended beyond reported critical incidents and other surrogates such as length of ICU or hospital stay. The two papers discussed in this section expand on this theme. Paper 7 describes how I have developed a novel system for assessment of tracheostomy tube position that can be used to evaluate a number of elements that constitute effective and safe care. Paper 8 describes my evaluation of existing scoring systems to evaluate Ventilator Associated Pneumonia (VAP) rates, which are proposed as a quality indicator for airway care in ICU.

Positioning of tracheostomy tubes

One of the problems consistently highlighted with tracheostomy care is that tubes may be inadvertently displaced (Thomas and McGrath, 2009; McGrath and Thomas, 2010). Displacement may be complete and therefore visibly obvious or partial and not immediately apparent. Partial displacement can present in many ways from obvious clinical deterioration through to subtle changes in ventilation or other monitoring parameters. One of the recommendations that arose from my earlier work on emergency management of tracheostomy problems was that an early fibreoptic examination of the device was important as this could inform the responder whether the tube was in situ or had become partially displaced. This coincided with technological advances meaning that immediately available and disposable endoscopes were available at the bedside, rather than traditional re-useable and difficult to store fibreoptic bronchoscopes. NICE guidance was released that supported the widespread use of such devices to which I contributed as an expert advisor (NICE, 2015).

However, when viewing the inside of a tracheostomy tube from within the lumen of the tube, this tracheoscopic view is difficult to describe, other than by a narrative description. It became clear that having recommended an inspection, operators needed a common language with which to describe their findings. Furthermore, how this tracheoscopic view agreed with the view from above (trans-laryngeal view) was unknown. I designed this study to address these questions and secured support from industry partners to allow me to conduct the study as Principle Investigator.

Figure 2.10. *The 'T' Trans-laryngeal tube view and the 'L' trans-laryngeal view of a tracheostomy tube in situ. The Right-hand image demonstrates endoscopic assessment via the tube lumen.*

The image of the distal trachea when viewed endoscopically via the tracheostomy tube struck my co-authors and I as representative of the cycles of the moon. The more of the 'black' trachea that was visible, the closer the image represented a 'full moon'. This led to the title of the paper and the study becoming known as 'the Lunar Study'. Further figures demonstrating this comparison are presented in the paper.

The Lunar Study started from the assumption that simple descriptors would best define the tube tip position within the airway, conceptualised as the phases of the moon. However, I developed several related scoring systems using a variety of continuous and discrete variables and tested both their inter-rater agreement (to evaluate ease of use and consistency) and also agreement with the trans-laryngeal view to determine whether one view could predict the other. The findings of this study were surprising; we could not accurately predict these views. This is useful information however with the potential to change practice. This was discussed in a very positive accompanying editorial appearing in the same issue of the *British Journal of Anaesthesia,* presented as an Appendix to this thesis (Lamperti and Caldiroli, 2017).

The second paper presented in this section considers another important surrogate marker for airway and ventilator care, a key element of which is tracheostomy care. Ventilator-associated pneumonia has been proposed as a quality indicator for ICU care by a number of organisations but this is inherently difficult due to differences in diagnosis. In the USA, financial penalties were attached to a patient episode that included a VAP and this led to a rapid reduction in reported VAP rates. This is partly due to the subjective nature of some elements of the existing scoring systems, for example self-reporting of whether an X-ray represented pneumonia or not. Interestingly, refinements to scoring systems led to further reductions in VAP, almost eliminating it as a problem in ICU without necessarily observing a related improvement in techniques or airway devices. Despite this, it is widely accepted that high quality care of the airway device can lead to reductions in hospital-acquired or ventilator-associated pneumonia rates.

In order to better understand the problems with reporting VAP rates and to investigate this as a potential quality indicator for tracheostomy care, I designed a study that I led as Principle Investigator to analyse data from four large teaching hospitals in the North West of England to evaluate the potential for different scoring systems in common use to diagnose VAP. The results were surprising in that a huge variation in rates was apparent, depending on which scoring system was chosen. This made using such systems for future projects flawed and also raised valid questions around the role of these systems as quality indicators for general ICU care.

2.5.b. Paper 7. Scoring systems to assess tracheostomy tube position

BA McGrath, K Lynch, R Templeton, K Webster, W Simpson, P Alexander and MO Columb. Assessment of scoring systems to describe the position of tracheostomy tubes within the airway – the Lunar study. *Br J Anaesth* (2017) 118 (1): 132-138.

Link to article - https://academic.oup.com/bja/article-abstract/118/1/132/2763301/Assessment-of-scoring-systems-to-describe-the?redirectedFrom=fulltext

Citations as of 21st June 2017

- Google Scholar 1
- Web of science 1
- Scopus 1
- Tweeted by 2
- 1 reader on Mendeley
- Altmetric score 2

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Assessment of scoring systems to describe the position of tracheostomy tubes within the airway – the Lunar study.
BA McGrath, K Lynch, R Templeton, K Webster, W Simpson, P Alexander and MO Columb
Br J Anaesth. 2017 Jan;118(1):132-138

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept BAM and PA. Design, protocol and ethics BAM. Data collection BAM 90%. Data analysis BAM 75%, MOC 20%, other authors 5%. Manuscript BAM 75%, MOC/PA 20%, other authors 5%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
W Simpson	[signature]	wsimpson2@doctors.org.uk
P Alexander	[signature]	peter.alexander@uhsm.nhs.uk
MO Columb	[signature]	malachy.columb@uhsm.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

Assessment of scoring systems to describe the position of tracheostomy tubes within the airway – the Lunar study.
BA McGrath, K Lynch, R Templeton, K Webster, W Simpson, P Alexander and MO Columb
Br J Anaesth. 2017 Jan;118(1):132-138

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept BAM and PA. Design, protocol and ethics BAM. Data collection BAM 90%. Data analysis BAM 75%, MOC 20%, other authors 5%. Manuscript BAM 75%, MOC/PA 20%, other authors 5%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

Name	Signature	Current e-mail address
R Templeton	[signature]	richard.templeton@uhsm.nhs.uk
K Lynch	K Lynch	kate.lynch@uhsm.nhs.uk
K Webster	[signature]	drklwebster@icloud.com

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

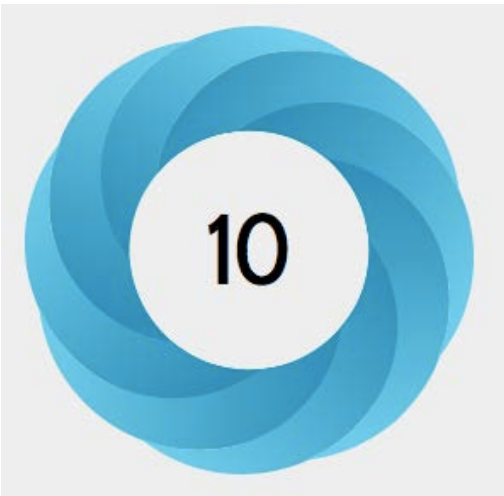
2.5.c. Paper 8. What are the best outcome measures for benchmarking quality for airway device management in ICU: Ventilator associated pneumonia?

Wallace FA, Alexander PD, Spencer C, Naisbitt J, Moore JA, **McGrath BA.** A comparison of ventilator-associated pneumonia rates determined by different scoring systems in four intensive care units in the North West of England. *Anaesthesia*. 2015 Nov;70(11):1274-80.

Link to article - http://onlinelibrary.wiley.com/doi/10.1111/anae.13211/abstract

Citations as of 21st June 2017

- Google Scholar 5
- Web of science 3
- Scopus 3
- Tweeted by 15
- 9 reader on Mendeley
- Altmetric score 10



Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

A comparison of ventilator-associated pneumonia rates determined by different scoring systems in four intensive care units in the North West of England. F. A. Wallace, P. D. G. Alexander, C. Spencer, J. Naisbitt, J. A. Moore and B. A. McGrath. Anaesthesia. 2015 Nov;70(11):1274-80

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept and design BAM. Data collection all authors. Data analysis BAM. Manuscript BAM 75%, other authors 25%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

	Signature	Current e-mail address
C Spencer	C. Spencer	craig.spencer@lthtr.nhs.uk
J Naisbitt	J. Naisbitt	jay.naisbitt@srft.nhs.uk
J A Moore	[signature]	john.moore@cmft.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

Research and Knowledge Exchange

Graduate School

Form **RDPUB (ROUTE 1 AND 2)**

Manchester Metropolitan University

PhD BY PUBLISHED WORK (ROUTE 1/2): CONTRIBUTION TO PUBLICATIONS

This form is to accompany an application for registration for PhD where the PhD is by Published Work. A separate form should be completed for each publication that is submitted with the proposal and should accompany the RD1 form.

1. The Candidate

First Name(s):	Brendan Anthony	Preferred Title:	Dr
Surname:	McGrath		
MMU e-mail address:	brendan.mcgrath@stu.mmu.ac.uk	Contact Number:	0161 291 642
Personal e-mail address:	brendan.mcgrath@manchester.ac.uk	Student ID Number:	16062512

2. Title of PhD Proposal

Advances in multidisciplinary tracheostomy care and their impact on the safety and quality of care in the critically ill.

3. Title of Research Output

A comparison of ventilator-associated pneumonia rates determined by different scoring systems in four intensive care units in the North West of England. F. A. Wallace, P. D. G. Alexander, C. Spencer, J. Naisbitt, J. A. Moore and B. A. McGrath. Anaesthesia. 2015 Nov;70(11):1274-80

4. Candidate's contribution to the research output

(State nature and approximate percentage contribution of each author)

Concept and design BAM. Data collection all authors. Data analysis BAM. Manuscript BAM 75%, other authors 25%.

5. Co author(s):

I confirm that the contribution indicated above is an accurate assessment of the contribution by the candidate to the research output named in section 3.

	Signature	Current e-mail address
F Wallace	FWallace	fiona_wallace@hotmail.com
PDG Alexander	PDG Alexander	peter.alexander@uhsm.nhs.uk

6. Statement by Director of Studies/Advisor

I confirm that I have read the above publication and am satisfied that the extent and nature of the candidate's contribution is as indicated in section 4 above.

Signature: [signature] Date: 22.03.17

(Director of Studies/Advisor)

7. Signature of Faculty Research Degrees Administrator

Signature: Date:

(Faculty Research Degrees Administrator)

2.5.d. Critical appraisal: Defining the quality of tracheostomy care

The papers presented in this section are not just about reducing harm or length of stay, but explore the concept of expanding the envelope of quality tracheostomy care to include systems to manage tube positioning and pneumonia. Both of these areas are linked to the quality of care, and certainly if a poorly positioned tube became displaced or led to aspiration, it is easy to see how this may lead to patient harm, ventilator-associated pneumonia (VAP) or an increased length of stay. However, in exploring metrics that are surrogates for the quality of tracheostomy care, we must be careful to ensure that these links remain valid.

Airway visualization and the quality of care

There is currently no consensus on the definition of a proper tracheostomy tube placement (Lamperti and Caldiroli, 2016). Current approaches include an external visual assessment, direct visualization via an endoscope of the tracheal lumen, end-tidal waveform capnography, ease of ventilation and appropriate oxygenation. Chest X-rays do not provide additional information beyond what a clinical examination can provide (Tobler et al., 2011; Yeo et al., 2014). However, our research has demonstrated that critical incidents with tracheostomies do occur, and the commonest problems encountered are occlusion and displacement. The 'Lunar study' presented here is an attempt to develop a novel system to describe the position of the tube within the airway, as poorly positioned tubes will have an impact on the patient's ability to vocalise, ventilate and swallow and may lead to catastrophic displacement of the tube.

The paper discusses in detail the links between the scoring systems both from the perspectives of assessing their utility, usability and reproducibility. But there is a wider question regarding the use of airway visualization to ensure the quality of care.

One such use of this technique is to ensure that all new tracheostomy tubes are appropriately positioned within the airway. Certainly a poorly positioned tube is more likely to become displaced, with much worse consequences for a patient that is ventilator dependent (Cook, Woodall, Harper, et al., 2011). But this paper has attempted to define what constitutes 'poorly positioned' for the first time. By providing a system to clinicians where there was no system before, this may drive quality of care indirectly by enabling those inserting tracheostomies to communicate with each other in a clear and reproducible manner about the position of the tube. This is likely to be especially useful for a patient who is not at the extremes of tube positioning: if a tube is obviously fine, or obviously not, then nothing (or something) respectively needs to be done. However, if a tube is 'ok' then the clinical staff at the bedside need to know where the tube was at the time of assessment and know if it has moved. Knowledge of a precarious tube may also drive staff to be more careful (on rolling the patient or procedures) or more vigilant (during transfer or movement). In providing a system to describe tube positioning and disseminating this information, quality of care may be indirectly affected.

Future uses of this paper could include assessing 'performance' of an operator by rating the position of a newly inserted tracheostomy tube. Training may be facilitated in airway visualization and relevant equipment provided, which will help with management of emergencies (NICE, 2015). Quality of airway assessment could also be measured by examining how many references there are in a particular patient's records regarding airway visualization, or if a displacement incident occurred, whether the tracheostomy had been inspected since insertion. The paper is praised as a key step forward towards improving the safety of care in an accompanying editorial, presented in the appendix.

Ventilator-associated pneumonia (VAP) and the quality of care

VAP is the most common healthcare-associated infection in ICU and has been reported to occur in up to 30% of critically ill patients requiring invasive mechanical ventilation. As discussed in Paper 8, healthcare-associated infections are increasingly a subject of public and regulatory interest, with ‘VAP rates’ proposed and used as ‘quality indicators’ (F. A. Wallace et al., 2015; Braithwaite et al., 2017). Key to these reported rates are an accurate diagnosis. Not only does this help to treat the patient, but a correct diagnosis would allow appropriate and accurate benchmarking. However, diagnosis of VAP is notoriously difficult. This can be on clinical grounds or by using existing available scoring systems and diagnostic criteria. Central to this difficulty is the lack of a consensus gold standard against which surrogate tests can be assessed. Much of tracheostomy care shares similar problems: there are no ‘gold standards’ for length of stay or for the number of incidents that a tracheostomy patient might be expected to encounter.

Some of these limitations can be addressed by examining improvements from a baseline state. These are the ideas discussed and presented in papers 5 and 6 above. This approach however might advantage a poorly performing site in that relatively small improvements or changes to a poor culture or system might produce impressive results. On the other hand, a high performing site might find it difficult to improve further. Setting individual goals might be a strategy to address this potential problem.

When considering trends and rates, the story with VAP challenges one to consider whether VAP can be eliminated altogether. Is the ultimate aim of quality improvements in this and related areas to achieve a VAP rate of zero? As identified in Paper 8, and by others, data suggest that clinicians continue to routinely diagnose and treat VAP, although their reported VAP rates may be falling, or become zero. The potential discrepancy between surveillance and clinical VAP rates is relevant to not only VAP, but has important relevance to metrics that I have used, or may choose in the future to assess the quality of tracheostomy care.

One of the issues highlighted in this paper is the reliability of the externally reported data. Missing patients are a common problem in analyses of this type, especially when self-reported (Klompas, 2012). External audits are a way to combat this, as is comparison with other mandatory datasets as a way of ensuring high data quality, but these approaches are typically expensive and time consuming.

Another of the issues highlighted in this paper is the distinction between an 'official' VAP (one that counts towards reported statistics) and a clinical impression of VAP (one that results in patients starting a course of antibiotics). There are clear differences in these perceptions presented in this paper, similar to that reported elsewhere (Klompas, 2007; Klompas and Platt, 2007). This may have relevance as a surrogate of tracheostomy care, but also is relevant to classification of more obviously related tracheostomy patient safety incidents for example. One reviewer's impression of the level of harm resulting may be very different to another. One method of reducing this potential bias is to have a limited, independent pool of reviewers that could examine cases, from VAP to tracheostomy incidents. This approach is expensive and time consuming however, although it has worked well for our previous published analyses of incidents (Thomas and McGrath, 2009; McGrath and Thomas, 2010).

To explore this concept further, I undertook a smaller study where we asked clinicians what they considered were the important components of the ideal scoring system for VAP. We conducted three rounds of ranking using a modified Delphi technique (Wallace and McGrath, 2015). We reported significant differences between the criteria identified in our modified Delphi study and those employed by the established scoring systems. VAP scoring systems have been criticised as they may produce different VAP rates depending on the system used. Our data also questioned whether the individual criteria used in VAP scoring systems are perceived as clinically useful in the bedside diagnosis of patients with VAP (Alexander and McGrath, 2015).

Conclusion

These papers explore expanded concepts of quality indicators beyond the basic care of the tracheostomy tube itself. They need to be tested however, and studies examining the link between tube tip position and displacement and whether a trained nursing workforce using appropriate tracheostomy tubes can reduce VAP rates, will ultimately define the utility of these measures.

Section 3 – Future research strategies

3.1 Narrative

3.2 Improving Tracheostomy Care (current grant-funded project)

3.3 Resource use research and cost-of-illness assessment

3.4 Benchmarking and evaluation of emergency algorithms: did they work?

3.5 Evaluating the effect of institution-wide reporting culture on tracheostomy related critical incidents

3.6 Summary: National NHS-wide strategy for tracheostomy QI

3.1. Narrative: Future research strategies

The published works presented in this thesis describe the evolution of my body of work from understanding the problems in tracheostomy care, through to devising and testing innovative resources and methods to improve the quality and safety of care. My work has focussed on the multidisciplinary healthcare team and, mostly, for patients managed in critical care units.

Research limitations

The methodologies and strategies I have employed have some limitations, discussed during the critical appraisals of each relevant section above. Although the principles of my work are likely applicable to the vast majority of hospital in-patients managed with tracheostomies, the diverse environments in which patients are managed may also contribute to limitations in my research to date. In this section, I will attempt to identify these potential limitations and describe strategies that I have considered or employed that show development of my use of research methods in order to produce meaningful and high quality work in the future.

When reflecting on potential limitations in my presented body of work, I have considered:

- Was I able to answer my research questions
- Theoretical and conceptual problems
- Limitations of my strategies
- Problems with research quality

I believe that the works I have presented have fundamentally addressed my research questions, but in demonstrating that my resources have had an impact on the quality and safety of care, one must consider the metrics and methodologies I have chosen. I made the argument in sections 2.4d, e and f that critical incidents and the surrogates for the quality of care I had chosen were rational and effective. However, there may be other metrics worthy of exploration. Through my current work, I have collaborated with qualitative researchers to interview key frontline staff, hospital managers and patients in order to understand what is important to them when it comes to tracheostomy care. I anticipate that from this work, new metrics will emerge that could supplement, enhance or replace some of the metrics that I have presented and used to date.

Unanswered questions include whether the approaches described above will have the same impact on care as they did in a reasonably controlled environment in Greater Manchester. My team and I had fairly close contact with the four sites of the Shine project. Future strategies will be more 'hands off' as geographically diverse sites test whether these interventions can be effectively implemented with more distant support. This is a stepping-stone towards a national Quality Improvement (QI) project around tracheostomy care.

I have also assumed that all sites *want* to improve care. Certainly healthcare professionals wish to avoid harm for patients, but inertia can lead staff and systems to believe that their care is 'fine' and interventions that seem like extra work are not necessary. I have considered various approaches to this problem. Most of the sites I have engaged with to date have been motivated to join and contribute to my interventions and projects, but not all sites, and certainly not all departments and individuals within those sites. There are various concepts and approaches that can be adapted here, broadly speaking divided into 'carrots' and 'sticks'. I have considered methods to feed information back to sites to motivate and encourage change, and attempted to understand specific barriers to healthcare interventions. However, a financial or other penalty for not demonstrating improvement, or financial or other incentives for sites to demonstrate tracheostomy QI is something I have considered in my role as NHS England Tracheostomy Lead Clinician. Developing future research projects to provide robust data to direct these decisions is key to my future work, and will build on the outputs and discussions presented in this thesis.

The context for future research is also interesting as through my collaborations with the GTC, I have the opportunity to develop and test some of the ideas and themes presented in this thesis. It is important to recognise that some of the work presented here as interventions has come from other experts in the field. Similarly, I am certain that others will use some of my work. The GTC has built a collaborative capable of testing, evaluating, refining and re-developing interventions, resources and improvements, and I hope that any future projects will build on the works presented in this thesis.

Healthcare systems such as the US or Australia are broadly similar to the NHS in many ways (and different in others!) For the purposes of testing my work in different contexts, locations or cultures, the principles of basic tracheostomy care, done well, will be valid. Some of the more complex system-wide interventions I have proposed and evaluated may not be as applicable to countries in Asia, South America or Africa for example. A tracheostomy in Africa is often considered as a 'death sentence' as once outside hospital, knowledge and resources to manage the tube safely are almost completely absent. It would be fascinating to test whether the simplest of resources and improvement interventions could change this fact. Addressing these issues and translating my work into different cultures and healthcare systems will require some qualitative work to better understand the needs and potential barriers to implementing a successful QI programme.

Future work

In the sections below, I have highlighted some of my future and current work that attempts to address some of the potential limitations of my publications to date in this field.

3.2. Improving Tracheostomy Care (current grant-funded project)

Introduction

The papers I have presented in this thesis have established the nature and to some extent, frequency of problems experienced by patients with tracheostomies. Through developing multidisciplinary resources, initiatives and approaches, I have built the case for Quality Improvement (QI) programmes that are applicable to all hospitals that manage patients with tracheostomies. In order to test whether the interventions described in this thesis were applicable to the wider NHS, I devised a multi-site mixed methods quality improvement project that could be tested in 20 diverse NHS sites in England, Scotland and Wales. This section describes this project, which was successful in attracting grant funding from the Health Foundation, and is an example of how my published works have led into further research.

Background to the project

As discussed thought this thesis, tracheostomy patients are often complex and dependant on competent, knowledgeable care to keep them safe, as a number of well recognised complications can occur with tracheostomies. (McGrath, Wilkinson, et al., 2015). The importance of meticulous on going care of the tracheostomy patient is recognised, together with the need for multi-disciplinary (MDT) staff to have the competence and confidence to deal with common emergencies.

I have demonstrated that many tracheostomy problems are amenable to prospective QI strategies, leading to the development of groups such as the UK National Tracheostomy Safety Project (NTSP) and the Global

Tracheostomy Collaborative (GTC) in an attempt to provide resources to improve care. The Health Foundation funded *'Improving multidisciplinary tracheostomy care: implementing the Global Tracheostomy Collaborative quality improvement project'* as part of the Shine 2014 innovation programme, presented in Paper 6 of this thesis. This work provided a rich source of qualitative and quantitative data.

Summary of key qualitative results arising from my published works that underpinned this project

Qualitatively, my previous projects provided a basis for emerging learning on the specific improvements chosen and barriers to change from different sites. The biggest changes were seen when high-level institutional support was offered throughout, an effective MDT and oversight committee were established, all relevant patients were seen by a new tracheostomy MDT ward round, and QI initiatives were rapidly implemented.

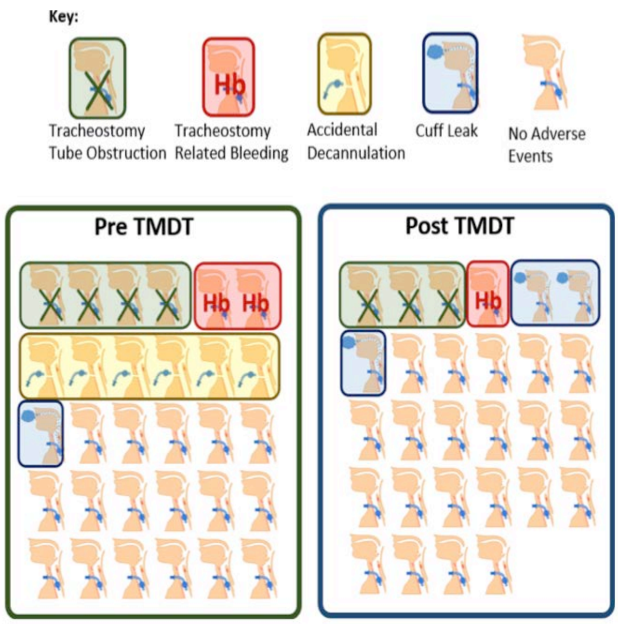


Figure 3.1. Infographic demonstrating the different rates of tracheostomy complications before and after commencing the Tracheostomy Multi-disciplinary Team (TMDT) ward rounds at a single site.

This started to happen at the other sites but took longer than anticipated. One of the key drivers to change was the data and progress reported by the lead site that galvanised others and allowed them to challenge what was possible at their institution. Effective and early presentation of local data proved key and was important learning as I developed future research strategies. An example of the impact of the tracheostomy MDT ward round shared with other sites is shown in the figure 3.1 above.

The Hospital Consumer Assessment of Healthcare Providers and Systems tool was used to collect patient feedback. Key themes included the need for patient-specific communication and information and resources and support for patients and their relatives at key times in their patient journey. Anxiety was high amongst patients and their carers when moving between in-patient locations and especially at discharge, mirrored by staff surveys. One of the Shine sites led an industry collaboration developing '*Trachi-Pass*' patient passports in order to address some of these issues – a key component to be evaluated in the proposed project.

My team and I were able to train nearly 300 staff at one site alone and evaluate different strategies to train staff effectively. Multiple PDSA cycles led to refinement of training with staff reporting significantly increased confidence and competence following training throughout the hospital. Delivering training was resource and time-intensive for the Shine team however, and we have developed a partnership with the Advanced Life Support Group to deliver this training in the future.

Scaling up

The four-site pilot 'Shine' project took important steps towards improving care with the help of the Health Foundation. We made the case in our follow up application to the Foundation that my team and I could effectively and successfully scale our work up as a bridge to improving care on a truly national scale

Key objectives for the *scaling up* programme:

- Partner 20 UK secondary or tertiary care sites who are managing tracheostomy patients
- Establish baseline characteristics, performance, problems and expectations
- Rapidly implement the resources of the NTSP and GTC by creating a change culture
    - High level institutional commitment
    - Commitment to change with on going formative evaluation of local goals, reflection and refining of progress, shared locally and within the collaborative
    - Identifying champions amongst medical, nursing allied health and patient groups
- Create a national collaborative environment for tracheostomy QI, with participant sites, teams and individuals supporting each other. National (and international) support and resources will be provided via the NTSP and GTC.
- To describe and evaluate the experience of patients, clinicians and other key stakeholders evaluating what works, what doesn't work, in what order, and importantly *how* changes were perceived and achieved or not
- Establish a likely 'best recipe' for the nature, scale and order of QI interventions that would guide future adoption, spread and sustainability, based on institutional profiling.

In planning the project, we reflected on the successes and difficulties of the Shine project. We asked ourselves:

- Does it work and will it work in the future?
- Did it work in the way we thought it would?
- Will it work somewhere else?

Logic models

Building on our previous experiences, we proposed a combination of formative and summative assessments with regular feedback to participating sites, including both qualitative and quantitative data.

The logic models below demonstrate the interaction between the resources developed by and available to the project, the activities we plan and the outcomes and output from the work. The first model (Figure 3.2) details the setup phase described above and the second (Figure 3.3) details the data collection, evaluation and reporting phases of the project.

Figure 3.2. *Setup phase logic model*

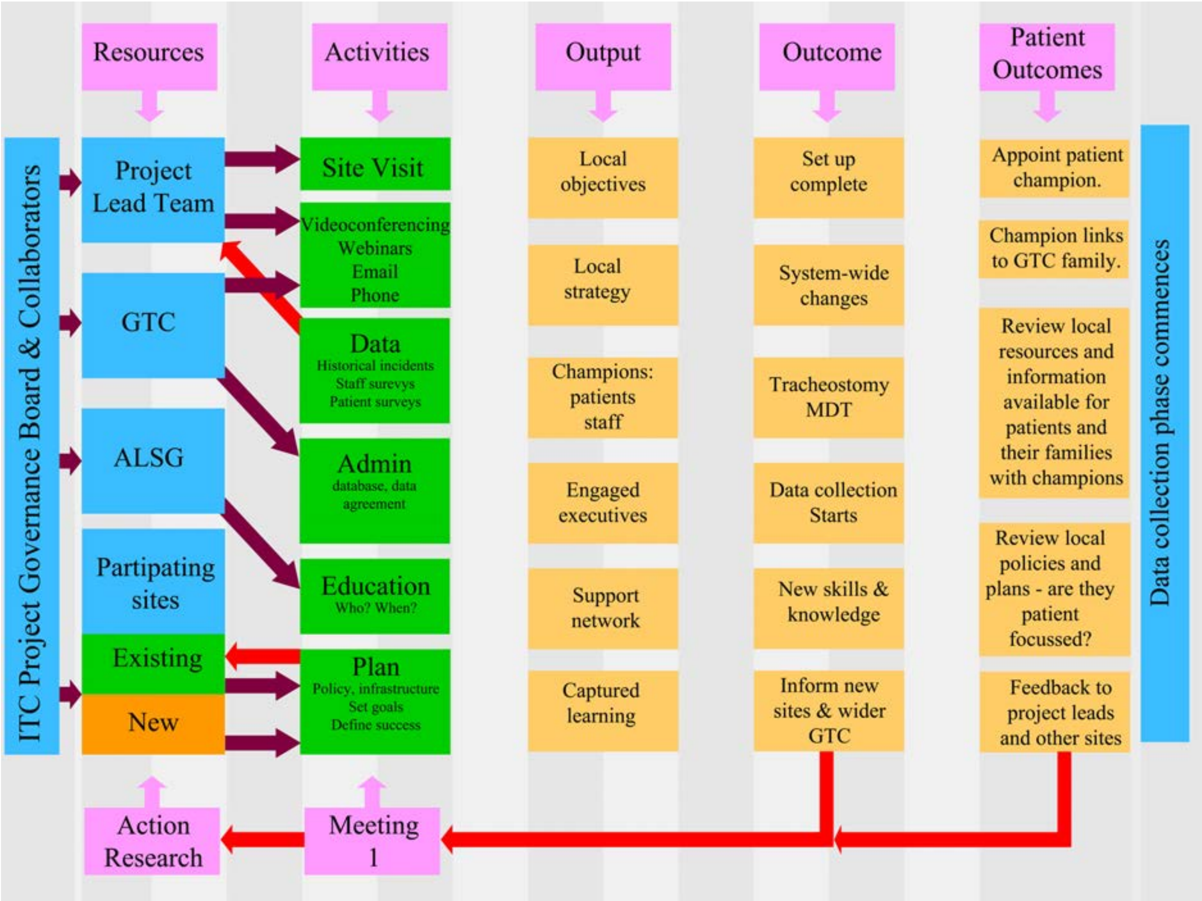
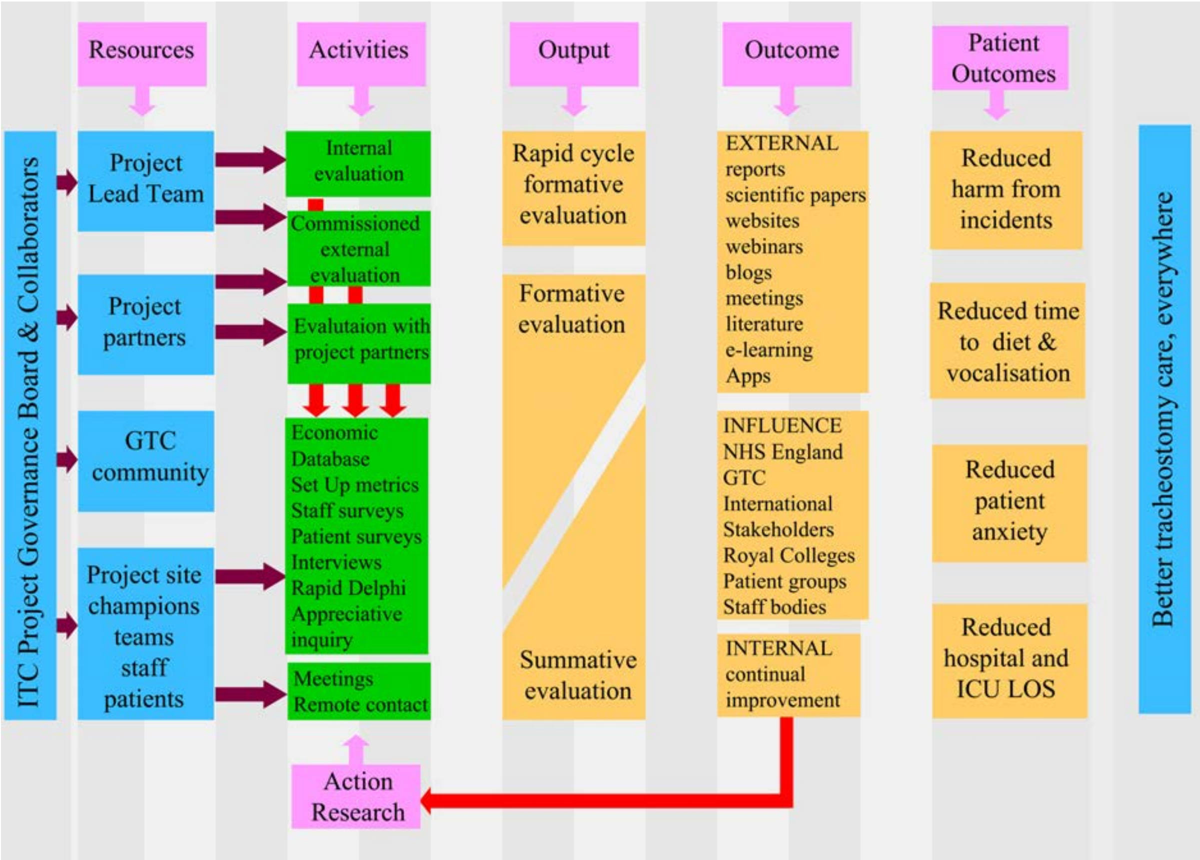


Figure 3.3. *Data collection phase logic model*



Conclusion

This ambitious project builds on my previous work in this field and can be considered as a stepping-stone between the Shine project (Paper 6 presented in this thesis) and a strategy to implement truly national quality improvements for all tracheostomy patients. I plan to present the outputs of this work to NHS England in 2018. The project focused on multidisciplinary improvements in care; and because the majority of patients are managed in critical care units, the themes from this thesis are heavily adopted.

I believe I can make a powerful safety, quality and economic argument to adopt the principles of my work and that of my collaborators, into the wider NHS, and that the qualitative outputs that arise from my work will help understand how best to do this.

3.3 Resource use research and cost-of-illness assessment

My work to date has concentrated on improving the quality and safety of the multidisciplinary care delivered to tracheostomy patients. It is widely accepted that better care saves money, but the mechanisms behind any cost reduction are complex (Fireman et al., 2004). My work to date has produced only crude estimates of potential savings, although based on reduced length of ICU stay alone, these results are significant, owing to the high cost of ICU care. The tracheostomy patient journey includes patients who do not attend ICU, and also patients who may avoid readmission due to higher quality care when they were in hospital. These patients are likely to consume fewer resources from the wider NHS (less frequent GP or follow up appointments, fewer readmissions) and may be able to get back to work earlier and for longer, consuming less and contributing more to the economy. These metrics are difficult to measure, but based on the works presented in this thesis, I have outlined how collaboration with health economists has led to a project to understand better the costs of care and how this might be influenced by quality improvements.

Baseline metrics

Although they account for a relatively small proportion of hospitalisations, the costs and risks associated with patients undergoing tracheotomies are disproportionate (Altman et al., 2015). For example, tracheotomy patients with respiratory failure can impose a high cost on resources and account for the highest cost and hospital reimbursement of any diagnosis related group or 'DRG' (Engoren et al., 2004). US figures estimate that by 2020 tracheostomy care could cost hospitals in the US $10 million in bed stay alone (Zilberberg and Shorr, 2008).

In the UK approximately 15,000 tracheotomies are performed each year. Unplanned or prolonged admission to ICU due to 'failed airway management' costs between £1,500 and £1,800 per day, and poor tracheotomy management has also been implicated. From the National Institute of Clinical Excellence (NICE) cost model, the rate of injury or death due to dislodged tracheotomy was 13%, resulting in an average stay on ICU/HDU of 15.4 days, costing an additional £20,343 per episode. The cost of long-term community care for a patient with a hypoxic brain injury was estimated at £30,000 per year for an average of 9 years survival with additional (unknown) compensation figures due to negligent death (NICE, 2015).

Extrapolating quality improvements into healthcare resources

Currently many health professionals lack the knowledge of risks associated with tracheotomies in addition to the skills to perform relevant technical procedures for the maintenance and emergency management of patients (Choate et al., 2009). Strategies that enhance the knowledge of staff can lead to the avoidance of many early complications such as hypoxia, airway occlusion and tube displacement, as demonstrated in the presented works in this thesis, my wider published works, and by others (Cook, Woodall, Frerk, et al., 2011; McGrath et al., 2013; McGrath, Wilkinson, et al., 2015; McGrath and Wilkinson, 2015b). It has been shown that such approaches reduce length of stay, tracheostomy time and ICU length of stay and can save up to $3million in resources use (Zilberberg and Shorr, 2008). Studies have also shown that better management of patients with tracheotomies in situ have improved delivery of healthcare resulting in resource savings and better outcomes (Cetto et al., 2011).

Whilst the papers presented in this thesis have demonstrated decreases in total and intensive care unit (ICU) length of stay in selected hospitals, further research is necessary to test the strength of the associations between these proposed interventions and surrogates of patient quality and safety, along with wider operational and performance metrics such as length of stay, in other healthcare settings and systems.

Variations in the technique of tracheotomy insertion can lead to variable risks of major complications, possibly with further costs of treatment, with open surgical techniques questioned by some as more cost-effective than percutaneous techniques. Savings of $850.00 per patient ($1753.01 vs $2604.00) have been demonstrated from open vs percutaneous techniques (Bowen et al., 2001).

Costs may also be dependent on stage at which tracheotomies take place. Brook proposed that early tracheotomy had direct associations to reduced length of stay as opposed to late tracheotomy, leading to a reduction in cost in the region of $32,000 (Brook et al., 2000; Altman et al., 2015). In proposed future studies, patients with new or existing tracheotomies admitted to participating sites will be included in the data collection. Based on a previous pilot study, the Health Foundation Improving Tracheostomy Care Project will recruit around 1500 patients per year, over 20 sites. The project will capture data over 2 years and aim to case-find 3000 patients, making it the largest consecutive series of tracheostomy patients to date to be collected and analysed.

From a health economic perspective, the database of these patients can be examined and resource-use by site and patient characteristic (including total length of stay, ICU stay, Emergency Department attendance, outpatient consultations and any readmissions associated with airway occlusion or management) can be studied. It will be possible to examine excess length of stay due to such complications. The project will also look at the feasibility of collecting variable costs associated with intensity of care by monitoring daily charts, including emergency call-outs and medical attendances and emergency test requests during hospital stay. Consideration will also be given to drug and medical device utilisation associated with complications of airway management where these costs can be identified.

Economic estimates from my own work

Separating the cost of specific tracheostomy care, from the costs of providing care for the patient as a whole in hospital is difficult. The 'cost' to an organisation of tracheostomy-related problems can be measured in reputation, service loss and financially; with poor care leading to patient harm, compensation and prolonged LoS. Extreme adverse events leading to death and hypoxic brain injury have well defined, associated costs (NICE, 2015). There was only one tracheostomy-related death during the published Shine project and no hypoxic brain injuries. We have therefore concentrated our cost model around LoS impact.

It is important to note that my analyses of cost-effectiveness do not evaluate the impact of different MDT compositions. For example, it may be possible to achieve similar results with a smaller, focussed team, or there may be potential benefits in expanding the expertise and composition of the team further. Independent detailed economic analyses are required to assess the economic impact of MDT composition.

Length of overall hospital stay also has associated costs. The Institute for Innovation and Improvement used a cost model based on a bed day cost of £225. This coupled with the cost of an average critical care bed day (£1,321) can be used to estimate cost savings across the four project sites during the project. These costs are conservative in comparison to other reports. During the Shine project:

- At least 67.2% of patients were managed on ICU (at some sites this data was only partially disclosed). We achieved a reduction of 1 day median ICU LoS for these patients (conservative figure).

- 32.8% of patients were managed solely on the ward. Crudely, we achieved a median LoS reduction of 9.6 days for these patients.
- Some ICU patients were subsequently managed on the ward, but we were unable to reliably separate this cohort and analyse robustly. Our estimates do not include potential savings in this cohort.

For every 100 patients admitted with a tracheostomy, assuming the reductions in LoS by location above and a similar pattern of care locations (our data is consistent with national patterns):

- 67 ICU admissions would save £ 88,507
  (£1321 x 67 x 1 day LoS reduction)
- 33 ward admissions would save £ 71,280
  (£225 x 33 x 9.6 day LoS reduction)
- 100 patients with tracheostomies would therefore save £159,787
- For the 296 patients in our project, estimated savings £472,969

For a single site to join the GTC and to resource the staff to deliver the improvements, a number of approaches are possible. One is to follow my own site's example (UHSM), with a clinical lead dedicating one day per month (£9,600 pa for a typical consultant pay), a Band 7 project manager, 20 hours per week (18,953 pa) and annual GTC membership (£2,500pa). With £2,000pa for resources and training courses this leads to an annual expenditure of £33,053 (Model A, Table 3.1 below). UHSM demonstrated the largest improvements in LoS data during the Shine project.

At Stockport NHS Trust (the second Shine site) the project was implemented with very little assistance from the Shine project team, owing to a trust-wide drive to improve tracheostomy care. In this instance, staff found the time to collect and analyse data, implementing change from within their current roles. In this instance there would be a £4,500pa spend on GTC membership, training and resources (Model B, Table 3.1).

However, from our experiences during the project, we recommended involving a clinical lead (£9,600) as well as Band 3 (or higher) clerical staff to collect and input data for 10 hours per week (£4,745pa) which results in a

£18,845pa spend (Model C, Table 3.1). This approach will be sustained at UHSM beyond the project, funded by estimated savings.

Using these models and rates of improvement in length of stay that we believe are achievable, we have calculated a crude cost saving model based on patients per annum (Table 3.2). It is important to note that hospital size will play an important part in the size of potential savings as well as potential rates of change. As such the potential saving at several sizes of site (based on tracheostomy patients per annum) are presented in Table 3.2. It is also important to recognise that this project involved data-collection over a 12-month period. Beyond this we are unsure of potential cost benefits.

Table 3.1. *Potential cost saving dependant on adopted Q.I model over 12 months*

Tracheostomy patients per year	**25**	**50**	**100**	**200**
Model A (£33,053pa)	-£8,593	£15,867	£64,787	£162,627
Model B (£4,500pa)	£19,960	£44,420	£92,340	£195,180
Model C (£18,845pa) recommended	£5,615	£30,075	£78,995	£176,835

Table 3.2. *Potential cash release for various sized hospitals*

Tracheostomy patients per year	**25**	**50**	**100**	**200**
Reduction in average length of hospital stay by 2 days (£225 per day).	£11,250	£22,500	£45,000	£90,000
Reduction in average critical care stay by 0.5 days (£1,321 per day, based on 80% tracheostomy patients requiring Critical Care stay).	£13,210	£26,420	£52,840	£105,680
Reduction in average hospital length of stay by 2 days and critical care stay by 0.5 days.	£24,460	£48,920	£97,840	£195,680

To identify the true cost of care, future work will undertake patient-level costing of the resources consumed using standard NHS costings; including Healthcare Resource Groups (HRGs), NHS Reference costs, Personal Social Services Research Unit Costs (London School of Economics) and *ad hoc* cost records. In this way, it will be possible to create one of the first tracheotomy-specific cost databases that could inform a variety of questions, including sub-group analysis by type of intervention; place and personnel performing procedure. Total as well as disaggregated costs will be examined by sub-group, including patients undergoing new or novel approaches to tracheotomy management, such as by age or by co-morbidities.

Conclusion

Establishing the 'cost' of tracheostomy care to the patient, the treating organisation and the wider NHS is complex. However, by building on the works presented, we plan to collaborate with health economists and construct a picture of the costs of care. This will allow us to not only test new methods and costing procedures for building cost-of-illness awareness studies, but also establish the feasibility of conducting future cost-effectiveness studies incorporating this methodology to examine analytical questions such as cost-effectiveness by alternative place of care, procedure/technique, personnel or patient characteristics. These are important questions for the NHS that I believe we can attempt to answer by developing the proposals outlined.

3.4. Benchmarking and evaluation of emergency algorithms: did they work?

Having presented the adult emergency algorithms in Paper 3 of this thesis, it seemed appropriate to review some of my further work that is occurring in this field. This work attempts to address whether the algorithms are fit for purpose and answer the question, 'Do they work?' This is difficult in clinical emergencies, although the NTSP does seek feedback from clinical staff. I have expanded on the use of medical simulation to evaluate, test and refine these emergency algorithms, and discuss this below. Future and on going work around adult and paediatric emergency algorithms is presented separately.

3.4.a. Adult emergency algorithms

In a separate project, I analysed candidate performance metrics between early and final versions of the adult emergency algorithm. Although these observations were uncontrolled, significantly more candidates achieved the intended learning outcomes for the standardized scenarios without pausing or causing prolonged desaturation using the final version. The results are summarised in Table 3.3 below and provided assurance that the revisions to the algorithm were having a positive impact on surrogate metrics for candidate performance.

These data provided reassurance that the algorithms could be followed by diverse multidisciplinary staff and were effective in managing standardised scenarios.

Table 3.3. *Comparison between performance of candidates managing standardized scenarios using early drafts of the algorithm (versions 1-5) vs final drafts (version 11).*

		Prolonged desaturation (SpO_2<90%, >5min)	Significant pause/help	Achieved learning outcomes?
Final Draft N=146	Yes	12 (8.2%)	9 (6.2%)	139 (95.2%)
	No	134 (91.8%)	137 (93.8%)	7 (4.8%)
Early Drafts N=32	Yes	19 (59.4%)	14 (43.8%)	18 (56.3%)
	No	13 (40.6%)	18 (56.3%)	14 (43.8%)
Fishers exact two-tailed p		P<0.0001	P<0.0001	P<0.0001

3.4.b. Further work using the principles described in this paper: Adapting this approach to develop paediatric emergency guidelines

Replicating the adult work, I set up a paediatric patient safety initiative on behalf of the Paediatric Working Group of The National Tracheostomy Safety Project. Local review of 54 tracheostomy clinical incidents in 2012 at a tertiary paediatric hospital demonstrated moderate patient harm in 25% major harm (including death) in 16%. Contributing factors included lack of access to information or emergency algorithms, loss of situational awareness, inadequate training and poor communication, all of which are suitable for simulation-based quality improvement initiatives. National guidelines include standardization of resuscitation algorithms, training, bedhead signs, equipment and care competencies (Cook, Woodall, Frerk, et al., 2011; McGrath, Bates, et al., 2012). We developed and adapted these for paediatric populations and used high-fidelity medical simulation to test the effectiveness of the guidance and the impact of responders following it, prior to formally launching the guidelines.

I led a multi-disciplinary team that created a paediatric tracheostomy emergency draft algorithm with paired bedhead sign and developed a training package, partly delivered using high fidelity simulation. Video feedback and in-depth debriefing principles also highlighted the non-technical skills required to manage the emergency situation. Pre and post-training scenarios were used in over 450 volunteer healthcare professionals encounters at national meetings. As with the adult work, scenarios were subtlety different but had identical clinical courses and learning objectives.

Our analysis included detailed complete performance data from 141 consenting candidates; 37 Anaesthetic trainees, 32 nurses, 52 ENT consultants and 19 ENT trainees. There were significant improvements in performance metrics following training, as detailed in Table 3.5 below. There was a significant increase in the numbers of candidates who called for help following training, from 122/141 (86.5%) to 134/141 (95.0%), χ^2 (1)=6.10, Fisher's exact p=0.01.

Table 3.4. *Time (in seconds) measured during candidate performance of scenarios. Paired sample T tests were used to calculate differences between groups.*

	Pre-training Mean (SD)	Post training Mean (SD)	Mean difference (95% CI)	2 tailed p
Total scenario time	541 (±73)	402 (±62)	139 (129-150)	<0.005
Time SpO_2<88%	474 (±101)	270 (±70)	204 (190-218)	<0.005
Time to call help	342 (±181)	227 (±105)	116 (89-142)	<0.005

These results demonstrated that high-fidelity simulation can improve surrogate metrics of performance following targeted teaching of new resources to manage paediatric tracheostomy emergencies using our draft algorithms. Improvements in performance when responders were following our draft algorithms were clinically significant, likely overcoming bias associated with the repeated measures associated with the observational nature of this small study.

Conclusion

I have continued to expand on the work presented in this thesis to test the validity of my published outputs and also to extend these principles and methodologies into related areas such as paediatric tracheostomy emergency guidelines. This evolution is further explored in the next section.

3.5. Evaluating the effect of institution-wide reporting culture on tracheostomy related critical incidents

Recognising the potential for fluctuations in reporting rates within an organisation to influence my target outcome measures, I developed and refined my methodology in later studies in order to account for potential fluctuations in Trust-wide incident reporting. I led a team who implemented changes at the Royal Manchester Children's Hospital. We reported harm from tracheostomy-related incidents in the paediatric population after implementation of the Paediatric National Tracheostomy Safety Project in this single tertiary paediatric centre, as yet unpublished work.

Similar patient safety concerns also exist in the paediatric population as with adults. Paediatric patients with tracheostomies have significant overall mortality with rates varying from 2.2% to 58.8% (Holscher et al., 2014). Mortality that is directly attributable to the tracheostomy is likely to be considerably lower with studies over the last three decades reporting rates from 0.8% to 5.9% (de Trey et al., 2013; Dal'Astra et al., 2016). Tracheostomy complications occur surprisingly frequently and influence morbidity and mortality. One recent North American paediatric tertiary centre study reported early complications in 11% and late complications in 68.8% of all tracheostomies inserted (Colman et al., 2010).

In response, the Paediatric Working Party of National Tracheostomy Safety Project (NTSP) was established in 2014, made up of health care professionals from multidisciplinary specialties including Paediatric

Otolaryngology, Paediatric Anaesthesia, Paediatric Intensive Care, Speech and Language Therapists, Tracheostomy Nurse Specialists, Physiotherapists and resuscitation practitioners from across the UK and Ireland. The aims of this working party are to reduce mortality and morbidity in children living with a tracheostomy and reflects the NTSP adult work streams and standards developed in 2007 (McGrath, Bates, et al., 2012).

The aims of this paediatric project were firstly to develop algorithms for the management of paediatric tracheostomy emergencies (Doherty et al., 2015). Subsequently, emergency guidance was supported by other interventions such as standardisation of emergency equipment, training and education, cohorting patients to fewer wards, bedhead information detailing the child's tracheostomy clearly displayed at every child's bed space, and identification of all tracheostomy admissions and insertions. Finally, we evaluated the impact of implementing these resources by examining the impact on reported tracheostomy-related patient safety incidents over a 6-year period from 2010 to 2015. We related tracheostomy-specific incident trends to all others incidents reported in the Trust.

A number of interventions were applied over the study period that we thought could and would influence outcome, summarised in Figure 3.4 below.

The search strategy retrieved a total of 252 incidents. Following exclusions, 128 incidents were included in the analysis of severity of harm and incident frequency. We chose to present these data by year, demonstrating the various harm categories, but also compared annual totals against the total number of incidents reported in the Trust (see Figures 3.5 and 3.6 below).

Figure 3.4. Interventions applied at a single tertiary paediatric centre to improve tracheostomy care.

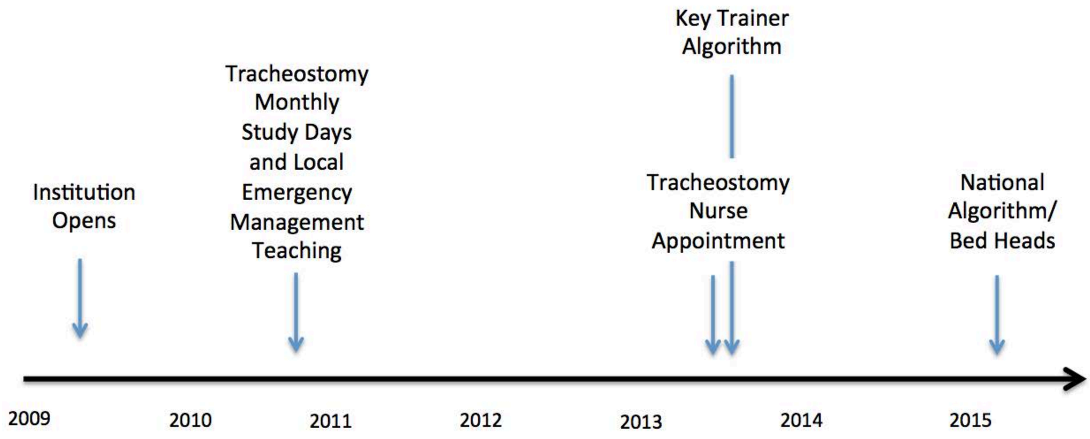


***Figure 3.5**. Incidents per year, divided into primary cause group.*

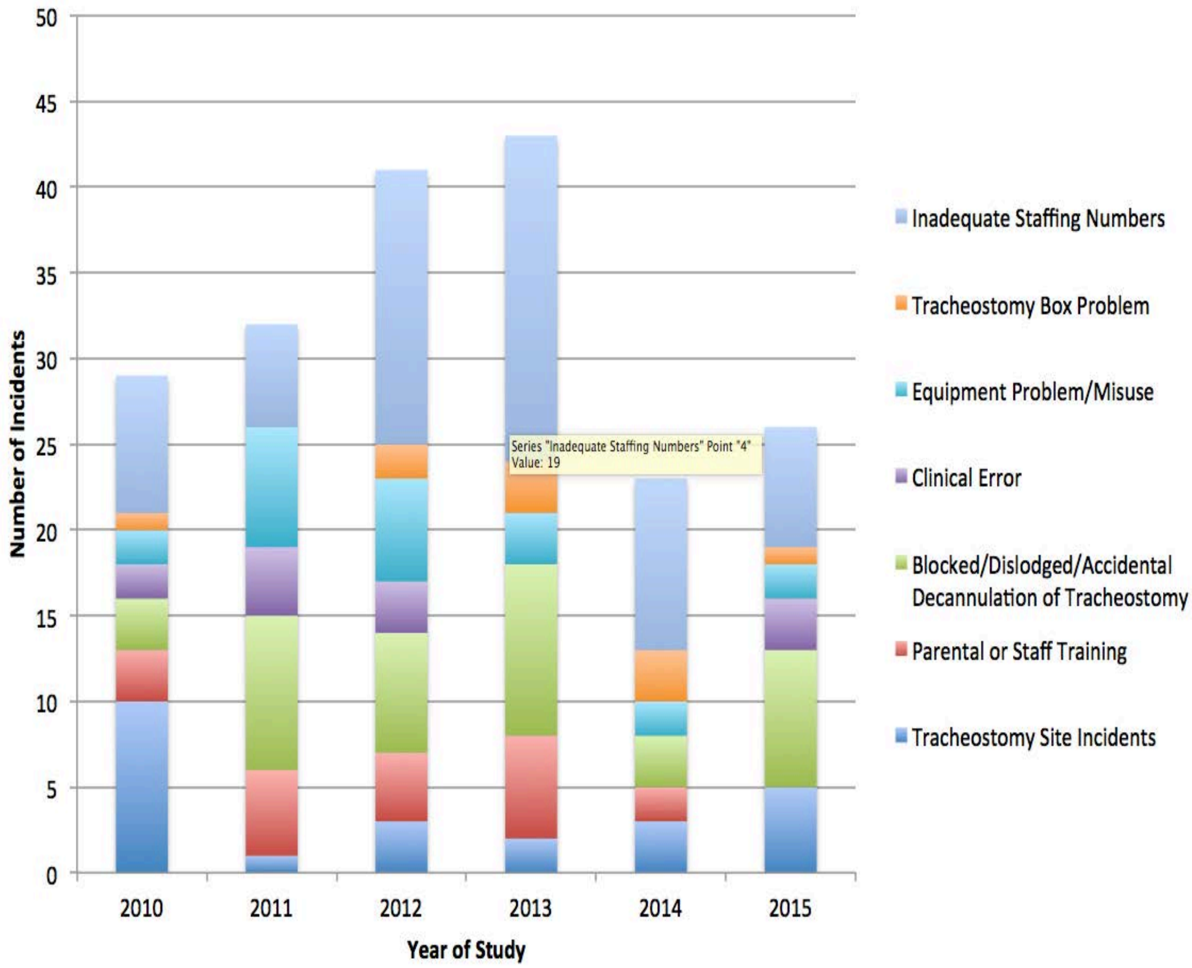
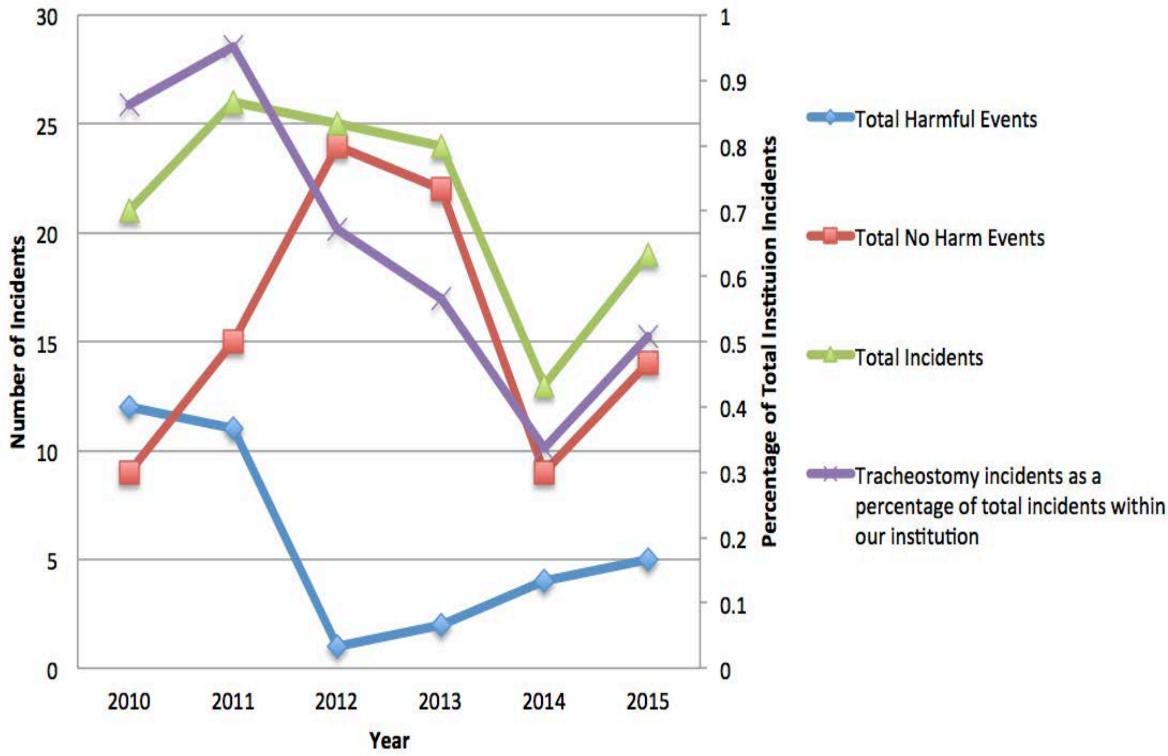


Figure 3.6. *Number of incidents, percentage of all incidents and harmful and non-harmful events per year (excluding inadequate staffing numbers).*



I was able to demonstrate a significant trend towards reduction in the proportion of incidents judged to have resulted in harm, from baseline through progressive years of the project (χ^2 trend p=0.013). Following the implementation of key interventions, the proportion of incidents resulting in harm fell within one year and remained at a level around half that of the baseline period. Whilst the total number of incidents rose initially, this was followed by a gradual reduction over the project. When this is considered as a percentage of all incidents reported across our institution per year, this shows a gradual reduction from 0.9% to 0.5%. Between 2014 and 2015 there is a small percentage rise from 0.3% to 0.5%, but remaining below the 2010 pre-intervention rate of 0.9%.

My team and I also collected data on the number of new tracheostomies performed at the Children's hospital theatres. This remained relatively constant, ranging between 20 and 29 per year. We have moved to collecting data on all new *and existing* tracheostomy admissions through participation in the Global Tracheostomy (Quality Improvement) Collaborative, which should provide further assurance that the denominator patient population has remained relatively constant.(Hettige et al., 2013)

We considered the possibility that general trends in all incident reporting across the institution may have reflected campaigns by the clinical effectiveness department to increase overall incident reporting and safety culture. This may be partly responsible for increased overall numbers of total incidents reported across the trust over time, something that has been noted nationally (Hutchinson et al., 2009). When we considered the tracheostomy incidents as a percentage of all these reported incidents, the percentage decrease was more marked.

Conclusion

In conclusion, by developing the methodology used when considering critical incidents as an outcome measure, I have been able to develop strategies that make my conclusions increasingly robust. This study demonstrated a significant reduction in harm from tracheostomy related incidents over six years following the implementation of a number of interventions, including Paediatric NTSP emergency management guidelines. We concluded that these reproducible interventions were targeted at problems highlighted by local and national incident reviews and are likely to be easily implemented by other sites.

Section 4
Conclusion

4.1. Summary: National NHS-wide strategy for tracheostomy care

4.1. Summary: National NHS-wide strategy for tracheostomy care

As I hope the publications presented in this thesis have demonstrated, improving the quality of care for patients with tracheostomies is achievable. This has been made possible by understanding the nature and scale of the problems, targeting and evaluating quality improvements around key themes and then extrapolating local and regional work into a representative national multi-site project. My work has captured detail on not just *what* to do, but *how* to do it.

Whilst my work initially focused on the multidisciplinary care provided by ICU teams, I have been able to demonstrate that improvements are possible across organisations. I am currently evaluating whether this hospital-wide approach is effective in 20 geographically, politically and culturally diverse sites. This *Improving Tracheostomy Care* project has attracted significant funding and the support of the relevant stakeholder Royal Colleges and Professional bodies. The project will detail safety metrics as well as surrogates for the quality of care. For the first time in tracheostomy care, a project of this scale will also include robust, independent economic evaluation as described throughout section 4 of this thesis.

4.2. Summary of section conclusions

This section brings together the summaries from each of the relevant critical appraisal sections from this thesis are presented below. In so doing, it provides a final summary of the development of my work, with others, that represents a continuing contribution to the knowledge and practice of multidisciplinary tracheostomy care.

2.1 Background: Why do we need to improve care? How do we measure the safety and quality of care provided?

2.1.d. Although imperfect, analysis of reported critical incidents is an appropriate methodology for informing healthcare quality improvements. Evolution of my research through local, regional and national work reinforced recurrent themes around a lack of staff education, equipment provision, inadequate locations and support infrastructure. This led to later development of resources to address these recurrent deficiencies in care.

2.1.e. Further detailed analysis investigating locations in which patients come to harm allowed a deeper understanding of the effect of incident location on the nature and severity of tracheostomy patient safety incidents. Unrelated prospective observational studies by other authors confirmed and validated my initial findings.

2.2 Defining the problem: Why is airway care such a problem in ICU?

2.2.c. The caseload, physiology, environment, staffing, airway devices and airway pathologies in the critically ill are significantly different to those encountered in routine anaesthetic practice. Patients with tracheostomies are at a particular risk of developing complications, with the vast majority of incidents occurring post placement. The focus of guidelines for airway management for tracheostomy care are not historically readily applicable to the critically ill and did not take into account the needs and complexities of the multidisciplinary ICU team. My background work defining these problems sets the scene for the necessary resources that were required to improve routine and emergency multidisciplinary airway management in the ICU, especially that of patients with tracheostomies. This work also highlights the need for further quality improvements to stop emergencies happening in the first place – the focus of my later work.

2.2.d. An important step in building the case for developing actionable resources to improve multidisciplinary tracheostomy care (such as e-learning resources, courses and developing emergency management algorithms) was to devise novel strategies to estimate the likely scale of the problem. The denominator figures which I believed were key to understanding the scale of the problems with tracheostomy care were estimated using a variety of methodologies from the best data available at the time. Subsequent prospective national studies found these figures to be accurate, and further validated my chosen methodologies for understanding the scale of the problems.

2.2.e. The NCEPOD study was unique in documenting outcomes of over two and a half thousand patients undergoing tracheostomy insertion and reports upon a consecutive snapshot of 'real world' care for NHS patients. The report reinforces some of what was known already from my earlier work. Importantly the NCEPOD report adds information on the education and composition of teams and systems that care for patients in ICUs and wards within the NHS. Similar healthcare systems outside of the NHS can learn from the findings of this report and look to implement prospective quality improvement strategies, discussed throughout this thesis, that have the capacity to improve the safety and quality of care for our tracheostomy patients.

2.3 Designing resources and solutions

2.3.c. Through the novel use of simulation to develop guidelines, I have attempted to 'close the loop' on tracheostomy-related emergencies by investigating recurrent themes leading to patient harm and by developing and evaluating resources designed to reduce harm in this vulnerable patient group. The role of high-fidelity medical simulation in recreating reported patient safety incidents and analysing key steps, missed opportunities and potential interventions was key in developing universal emergency management algorithms. Repeating standardised scenarios whilst following subtly different response algorithms allowed refinement of guided responses and this approach led to significantly more changes than those returned by expert peer review. Medical simulation has an important role to play in the initial development and subsequent refinement of airway management algorithms and this methodology can compliment or challenge the established methodologies for development or revision of similar guidelines.

2.4 Evaluating the impact of healthcare improvements

2.4.d. When considering critical incidents as a measure of the effectiveness of healthcare interventions, no significant relationships between overall incident reporting rates and hospital structure, interventions and outcomes were found in my presented works. This was also the case for other authors who evaluated large NRLS datasets. The measurement of critical incidents is considered to be a reasonable outcome measure for the papers presented in this thesis.

2.4.e. Crude reporting of critical incidents does not appear to be significantly influenced by hospital characteristics. Studies have demonstrated no relationships between size of hospital, numbers of staff, mortality outcomes or patient satisfaction outcomes and reporting rates. Whilst reporting rates alone should not be used to assess hospital safety, focusing on different types of safety incident and examining both prospective and retrospective trends is a useful method of determining the impact of interventions. This is especially the case if those interventions have been designed to address the concerns raised by the incident reporting themselves.

2.4.f. Initially, my work demonstrated improvements in the safety of care of tracheostomy patents, by analysis of the harms resulting from reported critical incidents. These improvements have resulted from advances in the quality of care provided. Whilst quality is difficult to measure and is dependant on many different factors, I have explored varied, measurable and reproducible metrics that I believe can demonstrate genuine improvements in quality for these patients. Furthermore, by presenting these data as trends, changes over relatively short periods of time can be visually presented to readers and back to participating sites, which can reinforce the impact of interventions and potentially drive engagement during a study. The later papers presented in this thesis demonstrate development in my methodologies to incorporate an evaluation of surrogate indicators for the quality of care and can be used as a reference for future quality improvement work in this field.

2.5.d. Defining the quality of tracheostomy care can include utilisation of expanded concepts of quality indicators, beyond the basic care of the tracheostomy tube itself. I have presented the rationale for endoscopic evaluation of tracheostomy tube tip position and also system-wide measures of Ventilator-Associated Pneumonia (VAP) as surrogate indicators of quality of care. These approaches need to be tested however, and studies examining the link between tube tip position and displacement and whether a trained nursing workforce using appropriate tracheostomy tubes can reduce VAP rates will ultimately define the utility of these measures.

Section 3 – Future research strategies

3.2. Improving Tracheostomy Care is an ambitious national project that builds on my previous work in this field and can be considered as a stepping-stone between the Shine project (Paper 6 presented in this thesis) and a strategy to implement truly national quality improvements for all tracheostomy patients. I plan to present the outputs of this work to NHS England in 2018. The project focuses on multidisciplinary improvements in care and because the majority of patients are managed in critical care units, the themes from this thesis are heavily adopted. I believe that we can make a powerful safety, quality and economic argument to adopt the principles of my work and that of my collaborators, into the wider NHS, and that the qualitative outputs that arise from my work will help understand how best to do this.

3.3. Establishing the 'cost' of tracheostomy care to the patient, the treating organisation and the wider NHS is complex. However, by building on the works presented, we plan to collaborate with health economists and construct a picture of the costs of care. This will allow me not only test new methods and costing procedures for building cost-of-illness awareness studies, but also establish the feasibility of conducting future cost-effectiveness studies incorporating this methodology to examine analytical questions such as cost-effectiveness by alternative place of care, procedure/technique, personnel or patient characteristics. These are important questions for the NHS that I believe we can attempt to answer by developing the proposals outlined in this thesis as future research strategies.

3.4. I have continued to expand on the work presented in this thesis to test the validity of my published outputs and also to extend these principles and methodologies into related areas such as paediatric tracheostomy emergency guidelines. Our data suggests that following our emergency algorithms and engaging in our tracheostomy teaching resources can improve the emergency management of tracheostomy patients.

3.5. By developing the methodology used when considering critical incidents as an outcome measure, I have been able to develop strategies that make my conclusions increasingly robust. An unpublished follow on study demonstrated a significant reduction in harm from tracheostomy related incidents over six years following the implementation of a number of interventions, including Paediatric NTSP emergency management guidelines. We concluded that these reproducible interventions were targeted at problems highlighted by local and national incident reviews and are likely to be easily implemented by other sites.

Thesis key points

The thesis summary presented overleaf in Figure 4.1 summarises the key points arising from each themed section, both from the narrative and from the related critical appraisal. This figure is reproduced from the introduction.

4.2.1. **Figure 4.1.** *Thesis key points.*

Theme	Linking narrative	Critical appraisal
Background Paper 1 & Paper 2	Retrospective analysis of national critical incident database of reported tracheostomy problems in the NHS	Although imperfect, incident analysis can identify themes and compare locations. Suitable for relatively rare events.
Defining the problem Paper 3	Invited editorial offering expert opinion on the problems that tracheostomy care poses for the multidisciplinary ICU team.	The caseload, physiology, environment, staffing, airway pathology & devices in ICU are different, but effective teamwork can improve care.
Designing resources & solutions Paper 4	Multidisciplinary emergency guidelines	Medical simulation has an important role in development, evaluation and refinement of airway management algorithms.
Evaluating the impact Paper 5 & Paper 6	Exploring different methods to measure the impact of multidisciplinary resources to improve care	Critical incident analysis is a reasonable outcome measure. Trends and system-wide process measures are useful.
Defining quality Paper 7 & Paper 8	Developing and evaluating systems to define and measure quality of tracheostomy care in the ICU	Quality indicators beyond the basic care of the tracheostomy tube itself can demonstrate effective bedside, multidisciplinary and system-wide care.

4.2.2. Conclusion

The goal of my work beyond that presented in this thesis is to establish reliable research data that offers patients, families, hospitals and the wider NHS reassurance that we can work together to improve care for tracheostomy patients.

Patients and their families have told us that they want to have patient-focused information, eat earlier, vocalise earlier and more effectively, and be discharged from hospital sooner. Bedside clinical staff want support, training and resources to help them deliver care. Hospitals want data and direction to reassure them that improvements are having an impact and the NHS wants to improve care, reduce length of stay and of course, save money. I believe that future work building on the projects and papers presented and discussed in this thesis can achieve these goals.

My future aims are aligned to those of the GTC in that I want to improve tracheostomy care, quite simply, everywhere. Challenges remain, the biggest of which will be in understanding and addressing issues in the community for tracheostomy patients. However, I believe that the works presented in this thesis form a solid foundation for addressing these barriers and developing my future research strategies and quality improvement programs to address the needs of this vulnerable group of patients.

References

References

Al-Zahrāwī, Khalaf, A.al-Q,K and von Grunebaum, G. E. (1973) *Albucasis on surgery and instruments.* California. University of California Press.

Alexander, P. D. G. and McGrath, B. A. (2015) 'Ventilator-associated pneumonia: a comparison of rates using different diagnostic scoring systems and across different intensive care units.' *British Journal of Anaesthesia*, 113(2) p. 323P.

Altman, K. W., Banoff, K. M. and Tong, C. C. L. (2015) 'Medical economic impact of tracheotomy patients on a hospital system'. *Journal of Medical Economics*, 18(4) pp. 258–262.

Amathieu, R., Combes, X., Abdi, W., Housseini, L. E., Rezzoug, A., Dinca, A., Slavov, V., Bloc, S. and Dhonneur, G. (2011) 'An algorithm for difficult airway management, modified for modern optical devices (Airtraq laryngoscope; LMA CTrach™): a 2-year prospective validation in patients for elective abdominal, gynecologic, and thyroid surgery'. *Anesthesiology*, 114(1) pp. 25–33.

American Society of Anesthesiologists Task Force on Management of the Difficult Airway' (2003) 'Practice Guidelines for Management of the Difficult Airway: An Updated Report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway'. *Anesthesiology*, 98(5) pp. 1269–1277.

Apfelbaum, J. L., Hagberg, C. A., Caplan, R. A., Nickinovich, D. G., Benumof, J. L., Berry, F. A., Blitt, C. D., Bode, R. H., Cheney, F. W., Connis, R. T., Guidry, O. F. and Ovassapian, A. (2013) 'Practice Guidelines for Management of the Difficult Airway'. *Anesthesiology*, 118(2) pp. 251–270.

Astin, J., King, E. C., Bradley, T., Bellchambers, E. and Cook, T. M. (2012) 'Survey of airway management strategies and experience of non-consultant doctors in intensive care units in the UK'. *British Journal of Anaesthesia*, 109(5) pp. 821–825.

Blair, E. J., Mihai, R. and Cook, T. M. (2007) 'Tracheal intubation via the Classic™ and Proseal™ laryngeal mask airways: a manikin study using the Aintree Intubating Catheter'. *Anaesthesia*, 62(4) pp. 385–387.

Blot, F., Melot, C. (2005) 'Indications, timing, and techniques of tracheostomy in 152 French ICUs.'. *Chest*, 127(4) pp. 1347–1352.

Bowen, C. P., Whitney, L. R., Truwit, J. D., Durbin, C. G. and Moore, M. M. (2001) 'Comparison of safety and cost of percutaneous versus surgical tracheostomy.'*The American Surgeon*, 67(1) pp. 54–60.

Braithwaite, J., Hibbert, P., Blakely, B., Plumb, J., Hannaford, N., Long, J. C. and Marks, D. (2017) 'Health system frameworks and performance indicators in eight countries: A comparative international analysis.' *SAGE Open Medicine*, 2017(5) p. 2050312116686516e.

Braun, U., Goldmann, K., Hempel, V.Krie (2004) 'Airway management. Guidelines of the German Society of Anesthesiology and Intensive Care.'*Anasthesiologie, Intensivmedizin, Notfallmedizin, Schmerztherapie*, 45, July, pp. 302–306.

Brickell, J. (1903) 'Observations on the Medical Treatment of General Washington in His Illness'. *Transactions of the College of Physicians*, 25 pp. 90–93.

Brook, A. D., Sherman, G., Malen, J. and Kollef, M. H. (2000) 'Early versus late tracheostomy in patients who require prolonged mechanical ventilation.'. *American Journal of Critical Care : an official publication, American Association of Critical-Care Nurses*, 9(5) pp. 352–359.

Cameron, T. S., McKinstry, A., Burt, S. K., Howard, M. E., Bellomo, R., Brown, D. J., Ross, J. M., Sweeney, J. M. and O'Donoghue, F. J. (2009) 'Outcomes of patients with spinal cord injury before and after introduction of an interdisciplinary tracheostomy team.' *Critical care and resuscitation : Journal of the Australasian Academy of Critical Care Medicine*, 11(1) pp. 14–19.

Caplan, R. A., Posner, K. L., Ward, R. J. and Cheney, F. W. (1990) 'Adverse respiratory events in anesthesia: a closed claims analysis'. *Anesthesiology*, 72(5) pp. 828–833.

Cetto, R., Arora, A., Hettige, R., Nel, M., Benjamin, L., Gomez, C. M. H., Oldfield, W. L. G. and Narula, A. A. (2011) 'Improving tracheostomy care: a prospective study of the multidisciplinary approach.'. *Clinical Otolaryngology,* 36(5) pp. 482–488.

Choate, K., Barbetti, J. and Currey, J. (2009) 'Tracheostomy decannulation failure rate following critical illness: a prospective descriptive study.'. *Australian Critical Care*, 22(1) pp. 8–15.

Chopra, V., Gesink, B. J., Jong, J. D., Bovill, J. G., Spierdijk, J. And Brand, R. (1994) 'Does training on an anaesthesia simulator lead to improvement in performance?'. *British Journal of Anaesthesia, Sep;73(3):293-7.*

Clark, R. and Sugrue, B. (2010) 'Research on instructional media, 1978-1988 (Chapter 30). In Anglin, G.J,. *Instructional technology: past, present, and future*.' 2010. Englewood, Colorado, pp. 327–343.

Colman, K. L., Mandell, D. L. and Simons, J. P. (2010) 'Impact of stoma maturation on pediatric tracheostomy-related complications.'. *Archives of Otolaryngology-Head & Neck Surgery*, 136(5) pp. 471–474.

Cook, T. M., Woodall, N. and Frerk, C. (2016) 'A national survey of the impact of NAP4 on airway management practice in United Kingdom hospitals: closing the safety gap in anaesthesia, intensive care and the emergency department.'. Myles, P. S. (ed.) *British Journal of Anaesthesia*, 117(2) pp. 182–190.

Cook, T. M., Woodall, N., Frerk, C. On behalf of the Fourth National Audit Project (2011) 'Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: Anaesthesia'. *British Journal of Anaesthesia*, 106(5) pp. 617–631.

Cook, T. M., Woodall, N., Harper, J., Benger, J.Fourth National Audit Project (2011) 'Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 2: Intensive Care and Emergency Departments.'*British Journal of Anaesthesia*, 106(5) pp. 632–642.

Cook, T., Behringer, E. C. and Benger, J. (2012) 'Airway management outside the operating room: hazardous and incompletely studied.'. *Current Opinion in Anaesthesiology*, 25(4) pp. 461–469.

Crosby, E. T. (2011) 'An evidence-based approach to airway management: is there a role for clinical practice guidelines?'. *Anaesthesia*, 66, November, pp. 112–118.

Crosby, E. T., Cooper, R. M., Douglas, M. J., Doyle, D. J., Hung, O. R., Labrecque, P., Muir, H., Murphy, M. F., Preston, R. P., Rose, D. K. and Roy, L. (1998) 'The unanticipated difficult airway with recommendations for management'. *Canadian Journal of Anaesthesia*, 45(8) pp. 757–776.

Dal'Astra, A. P. L., Quirino, A. V., Caixêta, J. A. de S. and Avelino, M. A. G. (2016) 'Tracheostomy in childhood: review of the literature on complications and mortality over the last three decades.' *Brazilian Journal of Otorhinolaryngology*, 83(2) pp. 207-214.

De Jong, A., Molinari, N., Pouzeratte, Y., Verzilli, D., Chanques, G., Jung, B., Futier, E., Perrigault, P.-F., Colson, P., Capdevila, X. and Jaber, S. (2015) 'Difficult intubation in obese patients: incidence, risk factors, and complications in the operating theatre and in intensive care units.'. *British Journal of Anaesthesia*, 114(2) pp. 297–306.

de Trey, L., Niedermann, E., Ghelfi, D., Gerber, A. and Gysin, C. (2013) 'Pediatric tracheotomy: A 30-year experience'. *Journal of Pediatric Surgery*, 48(7) pp. 1470–1475.

Difficult Airway Society Extubation Guidelines Group, Popat, M., Mitchell, V., Dravid, R., Patel, A., Swampillai, C. and Higgs, A. (2012) 'Difficult Airway Society Guidelines for the management of tracheal extubation.' *Anaesthesia, 67(3)* pp. 318–340.

Doherty, C. and McGrath, B. A. (2016) '*Quality of tracheostomy care is probably as important as timing* '. *British Journal of Anaesthesia*, 116(2) p. 300.

Doherty, C., Atkinson, D., Bruce, I., Bateman, N., Cooke, J., Wyatt, M., Neal, R., Perkins, R. and McGrath, B. A. (2015) 'Targeted training using paediatric tracheostomy emergency algorithm improves performance in simulated scenarios.' *British Journal of Anaesthesia*, 114(6) pp. 1015–1024.

Donaldson, L. (2000) 'An organisation with a memory.' [Online] [Accessed 16th January 2017]http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065086.pdf

Eibling, D. E. and Roberson, D. W. (2012) 'Managing tracheotomy risk: time to look beyond hospital discharge.'. *The Laryngoscope*, 122(1) pp. 23–24.

Engoren, M., Arslanian-Engoren, C. and Fenn-Buderer, N. (2004) 'Hospital and long-term outcome after tracheostomy for respiratory failure.' *Chest*, 125(1) pp. 220–227.

Fireman, B., Bartlett, J. and Selby, J. (2004) 'Can disease management reduce health care costs by improving quality?' *Health Affairs*, 23(6) pp. 63–75.

Fischler, L., Erhart, S., Kleger, G. R. and Frutiger, A. (2000) 'Prevalence of tracheostomy in ICU patients. A nation-wide survey in Switzerland.'. *Intensive Care Medicine*, 26(10) pp. 1428–1433.

Flanagan, J. C. (1954) 'The critical incident technique.' *Psychological Bulletin*, 51(4) pp. 327–358.

Fletcher, G. C. L., McGeorge, P., Flin, R. H., Glavin, R. J. and Maran, N. J. (2002) 'The role of non-technical skills in anaesthesia: a review of current literature.' *British Journal of Anaesthesia*, 88(3) pp. 418–429.

Frank, U., Mäder, M. and Sticher, H. (2007) 'Dysphagic patients with tracheotomies: a multidisciplinary approach to treatment and decannulation management.' *Dysphagia*, 22(1) pp. 20–29.

Franklin, B. D., Panesar, S. S., Vincent, C. and Donaldson, L. J. (2014) 'Identifying systems failures in the pathway to a catastrophic event: an analysis of national incident report data relating to vinca alkaloids.'. *BMJ*

Quality & Safety, 23(9) pp. 765–772.

Frerk, C., Mitchell, V. S., McNarry, A. F., Mendonca, C., Bhagrath, R., Patel, A., O'Sullivan, E. P., Woodall, N. M., Ahmad, I. Difficult Airway Society intubation guidelines working group (2015) 'Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults'. *British Journal of Aanaesthesia*, 115(6) pp. 827–848.

Frost, E. A. (1976) 'Tracing the tracheostomy.' *The Annals of Otology, Rhinology, and Laryngology*, 85 pp. 618–624.

Frova, G. and Sorbello, M. (2009) 'Algorithms for difficult airway management: a review.' *Minerva Anestesiologica*, 75(4) pp. 201–209.

Gilbert, RW, McIlwain, JC, Bryce DP, Ross, IR. (1987) 'Management of patients with long-term tracheostomies and aspiration. ' *The Annals of Otology, Rhinology, and Laryngology*, 96 pp. 561–564.

Gomes Silva, B.N., Andriolo, R.B., Saconato ,H., Atallah, A.N., Valente, O. (2012) 'Early versus late tracheostomy for critically ill patients (Review)', *Cochrane Database Syst Rev.* 14(3) pp. 1–69.

Goodall, E. W. (1973) 'The story of tracheostomy'. *British Journal of Children's Diseases*, 31 pp. 167–176.

Grober, E. D., Hamstra, S. J., Wanzel, K. R., Reznick, R. K., Matsumoto, E. D., Sidhu, R. S. and Jarvi, K. A. (2004) 'The Educational Impact of Bench Model Fidelity on the Acquisition of Technical Skill.' *Annals of Surgery*. Lippincott, Williams, and Wilkins, 240(2) pp. 374–381.

Gruenberg, D. A., Shelton, W., Rose, S. L., Rutter, A. E., Socaris, S. and McGee, G. (2006) 'Factors influencing length of stay in the Intensive Care Unit.' *American Journal of Critical Care*, 15(5) pp. 502–509.

Guidance: National Institute for Clinical Excellence (NICE): Medical Technologies Guidance (2013) *Ambu aScope2 for use in unexpected difficult airways*. [On line] [Accessed 21st January 2017]. https://www.nice.org.uk/guidance/mtg14

Halum, S. L., Ting, J. Y., Plowman, E. K., Belafsky, P. C., Harbarger, C. F., Postma, G. N., Pitman, M. J., LaMonica, D., Moscatello, A., Khosla, S., Cauley, C. E., Maronian, N. C., Melki, S., Wick, C., Sinacori, J. T., White, Z., Younes, A., Ekbom, D. C., Sardesai, M. G. and Merati, A. L. (2012) 'A multi-institutional analysis of tracheotomy complications.' *The Laryngoscope*, 122(1) pp. 38–45.

Hancock, C. (2015) 'A national quality improvement initiative for reducing harm and death from sepsis in Wales.' *Intensive & Critical Care Nursing*, 31(2) pp. 100–105.

Harkin, H. (1998) 'Tracheostomy management.' *Nursing Times*, 94 pp. 56–58.

Harris, C. B., Krauss, M. J., Coopersmith, C. M., Avidan, M., Nast, P. A., Kollef, M. H., Dunagan, W. C. and Fraser, V. J. (2007) 'Patient safety event reporting in critical care: a study of three intensive care units.' *Critical Care Medicine*, 35(4) pp. 1068–1076.

Heffner, J. E. (1993) 'Timing of tracheotomy in mechanically ventilated patients.'. *The American Review of Respiratory Disease*, 147(3) pp. 768–771.

Henderson, J. J., Popat, M. T., Latto, I. P. and Pearce, A. C. (2004) 'Difficult Airway Society guidelines for management of the unanticipated difficult intubation.' *Anaesthesia*, 59(7), pp. 675-94.

Hettige, R., Arora, A., Ifeacho, S. and Narula, A. (2008) 'Improving tracheostomy management through design, implementation and prospective audit of a care bundle: how we do it.' *Clinical Otolaryngology*, 33 (5) pp. 488–491.

Hettige, R., Arora, A., Roberson, D. W. and Narula, A. A. (2013) 'Recent developments to improve the standards of tracheostomy care'. *British Journal of Intensive Care*, (Autumn) October, pp. 89–92.

Higgs, A., Cook, T. M. and McGrath, B. A. (2016) 'Airway management in the critically ill: the same, but different'. *British Journal of Anaesthesia*, 117(suppl 1) pp. i5–i9.

Holscher, C. M., Stewart, C. L., Peltz, E. D., Burlew, C. C., Moulton, S. L., Haenel, J. B. and Bensard, D. D. (2014) 'Early tracheostomy improves outcomes in severely injured children and adolescents.'. *Journal of Pediatric Surgery*, 49(4) pp. 590–592.

Hopkins, P., Patel, S. (2017). 'Beware the Trojan Horse - a timely reality check about re-using single-use devices.' *Anaesthesia*, 72(1), pp. 8-12.

Hospital Episode Statistics. (2013) *HESonline*. hesonline.nhs.uk. 26 February. [Online] [Accessed on 26 February 2013] http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937.

Howell, A.-M., Burns, E. M., Bouras, G., Donaldson, L. J., Athanasiou, T. and Darzi, A. (2015) 'Can Patient Safety Incident Reports Be Used to Compare Hospital Safety? Results from a Quantitative Analysis of the English National Reporting and Learning System Data'. Schmidt, R. L. (ed.) *PloS one*. *Public Library of Science*, 10(12) pp. e0144107–15.

Howell, A.-M., Burns, E. M., Hull, L., Mayer, E., Sevdalis, N. and Darzi, A. (2016) 'Incident reporting: rare incidents may benefit from national problem solving.'. *BMJ Quality & Safety*, 26 pp. 517.

Howes, B. W., Wharton, N. M., Gibbison, B. and Cook, T. M. (2010) 'LMA SupremeTM insertion by novices in manikins and patients.' *Anaesthesia*, 65(4), pp. 343-7.

Hunt, K. and McGowan, S. (2005) 'Tracheostomy management in the neurosciences: a systematic, multidisciplinary approach.' *British Journal of Neuroscience Nursing*, 1(3) pp. 122–125.

Hutchinson, A., Young, T. A., Cooper, K. L., McIntosh, A., Karnon, J. D., Scobie, S. and Thomson, R. G. (2009) 'Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System.' *Quality & Safety in Healthcare*, 18(1) pp. 5–10.

Jaber, S., Amraoui, J., Lefrant, J.-Y., Arich, C., Cohendy, R., Landreau, L., Calvet, Y., Capdevila, X., Mahamat, A. and Eledjam, J.-J. (2006) 'Clinical practice and risk factors for immediate complications of endotracheal intubation in the intensive care unit: A prospective, multiple-center study.' *Critical Care Medicine*, 34(9) pp. 2355–2361.

Jackson, K. M. and Cook, T. M. (2007) 'Evaluation of four airway training manikins as patient simulators for the insertion of eight types of supraglottic airway devices'. *Anaesthesia*, 62(4) pp. 388–393.

Jordan, G. M., Silsby, J., Bayley, G. and Cook, T. M. (2007) 'Evaluation of four manikins as simulators for teaching airway management procedures specified in the Difficult Airway Society guidelines, and other advanced airway skills'. *Anaesthesia*, 62(7) pp. 708–712.

Kemppainen, J. K. (2000) 'The critical incident technique and nursing care quality research.'. *Journal of Advanced Nursing*, 32(5) pp. 1264–1271.

King's Fund (2017, May 24th). 'Quality of care.' [On line] [Accessed 22nd May 2017]. https://www.kingsfund.org.uk/topics/quality-care.

Klompas, M. (2007) 'Does this patient have ventilator-associated pneumonia?'. *JAMA : the Journal of the American Medical Association*, 297(14) pp. 1583–1593.

Klompas, M. (2012) 'Is a ventilator-associated pneumonia rate of zero really possible?' *Current Opinion in Infectious Diseases,* 25(2) pp. 176–182.

Klompas, M. and Platt, R. (2007) 'Ventilator-associated pneumonia--the wrong quality measure for benchmarking.'. *Annals of Internal Medicine*, 147(11) pp. 803–805.

Kohli, E., Ptak, J., Smith, R., Taylor, E., Talbot, E. A. and Kirkland, K. B. (2009) 'Variability in the Hawthorne effect with regard to hand hygiene performance in high- and low-performing inpatient care units.'. *Infection control and hospital epidemiology : the official journal of the Society of Hospital Epidemiologists of America*, 30(3) pp. 222–225.

Kory, P. D., Eisen, L. A., Adachi, M., Ribaudo, V. A., Rosenthal, M. E. and Mayo, P. H. (2007) 'Initial Airway Management Skills of Senior Residents: Simulation Training Compared With Traditional Training'. *Chest*, 132(6) pp. 1927–1931.

Ladyshewsky, A. and Gousseau, A. (1996) 'Successful Tracheal Weaning.' *The Canadian Nurse* pp. 3535–3538.

Lamperti, M. and Caldiroli, D. (2016) 'Tracheal visualization during tracheostomy: the dark side of the moon or just the moon and mars'. *British Journal of Anaesthesia*, 118(1) pp. 8–10.

Lamperti, M. and Caldiroli, D. (2017) 'Tracheal visualization during tracheostomy: the dark side of the moon or just the moon and Mars.'. *British Journal of Anaesthesia*, 118(1) pp. 8–10.

Landsberger, H. (1961) *Hawthorne Revisited: Management and the Worker, Its Critics, and Developments in Human Relations in Industry.* Cornell University Press.

Leibowitz, A. B. (2009) 'Persistent preoxygenation efforts before tracheal intubation in the intensive care unit are of no use: who would have guessed?' *Critical Care Medicine*, 37(1) pp. 335–336.

Lucisano, K. E. and Talbot, L. A. (2012) 'Simulation training for advanced airway management for anesthesia and other healthcare providers: a systematic review.' Journal of the *American Association of Nurse Anesthetists*, 80(1) pp. 25–31.

Lynch, J., Wallace, S., Bonvento, B., Sharpe, G., Pieri-Davies, S. and McGrath, B. A. (2015) 'Rapid improvements in quality and safety following introductions of tracheostomy multi-disciplinary team ward rounds at a tertiary hospital.' *In* Intensive Care Society State of the Art, Excel Conference Centre, London, December 2015. Available Online from : https://www.researchgate.net/publication/286404005_Rapid_improvements_in_quality_and_safety_following_introductions_of_tracheostomy_multi-disciplinary_team_ward_rounds_at_a_tertiary_hospital

Mallick, A. and Bodenham, A. R. (2010) 'Tracheostomy in critically ill patients'. *European Journal of Anaesthesiology*, 27(8), pp. 676–682

Martin, I. C., Freeth, H., Kelly, K. and Mason, M. (2014) *NCEPOD: On the right Trach?* [Online] [Accessed on 20 October 2014] www.ncepod.org.uk/./01tc.htm.

Martin, L. D., Mhyre, J. M., Shanks, A. M., Tremper, K. K. and Kheterpal, S. (2011) '3,423 emergency tracheal intubations at a university hospital: airway outcomes and complications.'. *Anesthesiology*, 114(1) pp. 42–48.

Mayo, P. H., Hackney, J. E., Mueck, J. T., Ribaudo, V. and Schneider, R. F. (2004) 'Achieving house staff competence in emergency airway management: Results of a teaching program using a computerized patient simulator'. *Critical Care Medicine*, 32(12) pp. 2422–2427.

McCarney, R., Warner, J., Liffe, S., van Haselen, R., Griffin, M. and Fisher, P. (2007) 'The Hawthorne Effect: a randomised, controlled trial'. *BMC Medical Research Methodology*, July, p. 30.

McComb, S. and Hebdon, M. (2013) 'Enhancing Patient Outcomes in Healthcare Systems Through Multidisciplinary Teamwork'. *Clinical Journal of Oncology Nursing*, 17(6) pp. 669–672.

McGrath, B.A., Calder, N. (2013) 'Tracheostomy and laryngectomy emergency management – implications for critical care.' *British Journal of Intensive Care*. 2013; Autumn, pp. 77-80.

McGrath, B. A. and Calder, N. (2013) 'Tracheostomy and laryngectomy emergency management.' *Clinical Otolaryngology*, 38(6) pp. 541–545.

McGrath, B. A., Ramsaran, R., Columb, M. O., (2012) 'Estimating the number of tracheostomies performed in critical care in England.' *British Journal of Anaesthesia*, 109 pp. 662P.

McGrath, B. A. and Saha, B. (2006) 'Provision of difficult airway equipment & trainees' experience in its use in the theatre suites & ICUs of the Northwest rotation'. *Journal of the Intensive Care Society*, 7(3) pp. 23–25.

McGrath, B. A. and Templeton, R. (2012) 'Estimated total and advanced respiratory support bed days for patients with tracheostomies ln critical care units in England'. *Intensive Care Medicine*, 38(S1) p. S178.

McGrath, B. A. and Thomas, A. N. (2010) 'Patient safety incidents associated with tracheostomies occurring in hospital wards: a review of reports to the UK National Patient Safety Agency.' *Postgraduate Medical Journal*, 86(1019) pp. 522–525.

McGrath, B. A. and Thomas, A. N. (2011) 'Patient safety incidents associated with tracheostomies: a comparison of levels of harm between critical care and ward environments '. *British Journal of Anaesthesia*, 106(3) p. 439P.

McGrath, B. A. and Wallace, S. (2014a) 'The UK National Tracheostomy Safety Project and the role of speech and language therapists.' *Current Opinion in Otolaryngology & Head and Neck Surgery*, 22(3) pp. 181–187.

McGrath, B. A. and Wallace, S. (2014b) 'The UK National Tracheostomy Safety Project and the role of speech and language therapists.' *Current Opinion in Otolaryngology & Head and Neck Surgery*, 22(3) pp. 181–187.

McGrath, B. A. and Wilkinson, K. A. (2015) 'The NCEPOD study: on the right trach? lessons for the anaesthetist.'. *British Journal of Anaesthesia*, 115(2) pp. 155–158.

McGrath, B. A., Bates, L., Atkinson, D. and Moore, J. A. (2012) 'Multidisciplinary guidelines for the management of tracheostomy and laryngectomy airway emergencies'. *Anaesthesia*, 67(9) pp. 1025–1041.

McGrath, B. A., Calder, N., Laha, S., Perks, A., Chaudry, I., Bates, L., Moore, J. A. and Atkinson, D. (2013) 'Reduction in harm from tracheostomy-related patient safety incidents following introduction of the National Tracheostomy Safety Project: our experience from two hundred and eighty-seven incidents.' *Clinical Otolaryngology*, 38(6) pp. 541–545.

McGrath, B.A., Lynch, J., Bonvento, B., Wallace, S., Poole, V., Farrell, A., Diaz. C., Khwaja, S., Roberson, D.W. 'Evaluating the quality improvement impact of the Global Tracheostomy Collaborative in four diverse NHS hospitals.' *BMJ Quality Improvement Reports,* 6(1), pp. bmjqir. u220636. w7996 [Online] [Accessed 19th June 2017] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5457966.

McGrath, B. A., Lynch, J., Wilson, M., Nicholson, L. and Wallace, S. (2015) 'Above cuff vocalisation: A novel technique for communication in the ventilator-dependent tracheostomy patient'. *Journal of the Intensive Care Society*, October, pp. 1–8.

McGrath, B. A., Lynch, K., Templeton, R., Webster, K., Simpson, W., Alexander, P. and Columb, M. O. (2016) 'Assessment of scoring systems to describe the position of tracheostomy tubes within the airway – the lunar study'. *British Journal of Anaesthesia*, 118(1) pp. 132–138.

McGrath, B. A., O'Donohoe, E. A. and Waldmann, C. (2012) 'Airway management in critical care - new guidelines, old problems'. *Journal of the Intensive Care Society*, 13(2) pp. 100–101.

McGrath, B. A., Ramsaran, R. and Columb, M. O. (2012) 'Estimating the number of tracheostomies performed in critical care in England'. *British Journal of Anaesthesia*, 109(4) p. 662P.

McGrath, B. A., Wee, L. and Atkinson, D. (2014) 'Candidate performance on tracheostomy safety courses is influenced by pre-course e-learning modules.' *British Journal of Anaesthesia*, 113(2) p. 320P.

McGrath, B. A., Wilkinson, K. and Shah, R. K. (2015) 'Notes from a Small Island: Lessons from the UK NCEPOD Tracheotomy Report.' *Otolaryngology - Head and Neck Surgery*, 153(2) pp. 167–169.

Mitchell, R. B., Hussey, H. M., Setzen, G., Jacobs, I. N., Nussenbaum, B., Dawson, C., Brown, C. A., Brandt, C., Deakins, K., Hartnick, C. and Merati, A. (2013) 'Clinical consensus statement: tracheostomy care.' *Otolaryngology - Head and Neck Surgery*, 148(1) pp. 6–20.

Mitchell, R., Parker, V. and Giles, M. (2012) 'An interprofessional team approach to tracheostomy care: A mixed-method investigation into the mechanisms explaining tracheostomy team effectiveness.' *International Journal of Nursing Studies*, 50(4), pp. 536-42.

Mohrman, S. A., Cohen, S. G. and Mohrman, A. M. (1995) *Designing Team-Based Organisations.* San Francisco: Jossey-Bass.

Mort, T. C. (2004a) 'Emergency Tracheal Intubation: Complications Associated with Repeated Laryngoscopic Attempts.' *Anesthesia & Analgesia,* 99(2), pp. 607-13.

Mort, T. C. (2004b) 'The incidence and risk factors for cardiac arrest during emergency tracheal intubation: A justification for incorporating the ASA Guidelines in the remote location.' *Journal of Clinical Anesthesia*, 16(7) pp. 508–516.

Mort, T. C., Waberski, B. H. and Clive, J. (2009) 'Extending the preoxygenation period from 4 to 8 mins in critically ill patients undergoing emergency intubation.' *Critical Care Medicine*, 37(1) pp. 68–71.

Nathens, A. B., Rivara, F. P., Mack, C. D., Rubenfeld, G. D., Wang, J., Jurkovich, G. J. and Maier, R. V. (2006) 'Variations in rates of tracheostomy in the critically ill trauma patient.' *Critical Care Medicine*, 34(12) pp. 2919–2924.

Needham, D. M., Thompson, D. A., Holzmueller, C. G., Dorman, T., Lubomski, L. H., Wu, A. W., Morlock, L. L. and Pronovost, P. J. (2004) 'A system factors analysis of airway events from the Intensive Care Unit Safety Reporting System (ICUSRS).' *Critical Care Medicine*, 32(11) pp. 2227–2233.

NHS (2000) The NHS Plan: A plan for investment, a plan for reform. *National Health Service.* [Online] [Accessed 1st January 2017]. http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4002960

Nishisaki, A., Keren, R. and Nadkarni, V. (2007) 'Does simulation improve patient safety? Self-efficacy, competence, operational performance, and patient safety.' *Anesthesiology Clinics*, 25(2) pp. 225–236.

Norwood, M. G. A., Spiers, P., Bailiss, J. and Sayers, R. D. (2004) 'Evaluation of the role of a specialist tracheostomy service. From critical care to outreach and beyond.' *Postgraduate Medical Journal*, 80(946) pp. 478–480.

NPSA (2005) Protecting patients who are neck breathers (Patient safety information leaflet 0149). *National Patient Safety Agency.* [Online] [Accessed 22nd January 2017]. http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59793

NPSA (2016) 'Quarterly Data Summaries'. *National Patient Safety Agency.* [Online] [Accessed 21st January 2017]. www.nrls.npsa.nhs.uk.

Okuda, Y., Bryson, E. O., DeMaria, S., Jacobson, L., Quinones, J., Shen, B. and Levine, A. I. (2009) 'The utility of simulation in medical education: what is the evidence?'*The Mount Sinai Journal of Medicine, New York*, 76(4) pp. 330–343.

Olszewski, J. and Miłoński, J. (2007) '[History of tracheotomy].'*Otolaryngologia polska [The Polish Otolaryngology]*, 61(3) pp. 349–352.

Pandian, V., Miller, C. R., Mirski, M. A., Schiavi, A. J., Morad, A. H., Vaswani, R. S., Kalmar, C. L., Feller-Kopman, D. J., Haut, E. R., Yarmus, L. B. and Bhatti, N. I. (2012) 'Multidisciplinary Team Approach in the Management of Tracheostomy Patients'. *Otolaryngology - Head and Neck Surgery*, 147(4) pp. 684–691.

Parry, K. and Owen, H. (2004) 'Small simulators for teaching procedural skills in a difficult airway algorithm.' *Anaesthesia and Intensive Care*, 32(3) pp. 401–409.

Parsons, H. M. (1974) 'What Happened at Hawthorne?: New evidence suggests the Hawthorne effect resulted from operant reinforcement contingencies.' *Science (American Association for the Advancement of Science),* 183(4128) pp. 922–932.

Peterson, G. N., Domino, K. B., Caplan, R. A., Posner, K. L., Lee, L. A. and Cheney, F. W. (2005) 'Management of the Difficult Airway: A Closed Claims Analysis.' *Anesthesiology*, 103(1) p. 33.

Plummer, J. L. and Owen, H. (2001) 'Learning Endotracheal Intubation in a Clinical Skills Learning Center: A Quantitative Study.' *Anesthesia and Analgesia*, 93(3), pp. 656-62

Rabøl, L. I., Gaardboe, O. and Hellebek, A. (2016) 'Incident reporting must result in local action'. *BMJ Quality & Safety*, August, pp. bmjqs–2016–005971–1.

Rajesh, O. and Meher, R. (2017) 'Historical Review Of Tracheostomy'. *The Internet Journal of Otorhinolaryngology*, 5(2) pp. 1–4. [Online] [Accessed 22nd December 2016]. http://ispub.com/IJORL/4/2/7498

Reibel, J. F. (1999) 'Decannulation: How and where.' *Respiratory Care*, 44 pp. 856-60

Reisner-Sénélar L. (2011) The birth of intensive care medicine: Björn Ibsen's records. *Intensive Care Medicine* Jul;37(7):1084-6.

Roehr, B. (2012) 'US hospital incident reporting systems do not capture most adverse events.' *BMJ (Clinical Eesearch Ed.)*. [Online] 13 January, pp. e386–e386.

Rosenthal, E. and Owen, H. (2004) 'An assessment of small simulators used to teach basic airway management.' *Anaesthesia and Intensive Care*, 32(1) pp. 87–92.

Rosenthal, M. E. (2006) 'Achieving Housestaff Competence in Emergency Airway Management Using Scenario Based Simulation Training: Comparison of Attending vs Housestaff Trainers.' *Chest*, 129(6) pp. 1 453– 1458.

Rowe, R. and Cohen, R. A. (2002) 'An Evaluation of a Virtual Reality Airway Simulator'. *Anesthesia and Analgesia*, 95(1), pp. 62-6.

Rumbak, M. J., Newton, M., Truncale, T., Schwartz, S. W., Adams, J. W. and Hazard, P. B. (2004) 'A prospective, randomized, study comparing early percutaneous dilational tracheotomy to prolonged translaryngeal intubation (delayed tracheotomy) in critically ill medical patients.'. *Critical Care Medicine*, 32(8) pp. 1689–1694.

Runciman, W.B., Sellen, A., Webb R.K., Williamson, J.A., Currie, M., Morgan, C. and Russell, W.J. (1993) The Australian Incident Monitoring Study. Errors, incidents and accidents in anaesthetic practice. *Anaesthesia & Intensive Care,* 21(5) pp. 506-19.

Sari, A. B. A., Sheldon, T. A., Cracknell, A. and Turnbull, A. (2007) 'Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review.' *BMJ (Clinical Research Ed.)*, 334(7584) pp. 79–79.

Schwartz, D. E., Matthay, M. A. and Cohen, N. H. (1995) 'Death and other complications of emergency airway management in critically ill adults. A prospective investigation of 297 tracheal intubations.' *Anesthesiology*, 82(2) pp. 367–376.

Shaw, R., Drever, F., Hughes, H., Osborn, S. and Williams, S. (2005) 'Adverse events and near miss reporting in the NHS.' *Quality & Safety in Healthcare*. BMJ Publishing Group Ltd, 14(4) pp. 279–283.

Susanto, I. (2002) 'Comparing percutaneous tracheostomy with open surgical tracheostomy.' *British Medical Journal*, 324, November, pp. 3–4.

Szmuk, P., Ezri, T., Evron, S., Roth, Y. and Katz, J. (2007) 'A brief history of tracheostomy and tracheal intubation, from the Bronze Age to the Space Age'. *Intensive Care Medicine*, 34(2) pp. 222–228.

Templeton, R., Webster, K. and McGrath, B. A. (2011) 'Patient safety incidents associated with displaced or obstructed tracheostomies: comparison of levels of harm between critical care and ward environments'. *British Journal of Anaesthesia*, 107(5) pp. 834–835.

Thomas, A. N. and Galvin, I. (2008) 'Patient safety incidents associated with equipment in critical care: a review of reports to the UK National Patient Safety Agency.' *Anaesthesia*, 63(11) pp. 1193–1197.

Thomas, A. N. and MacDonald, J. J. (2016) 'A review of patient safety incidents reported as 'severe' or 'death' from critical care units in England and Wales between 2004 and 2014.' *Anaesthesia*, 71(9) pp. 1013–1023.

Thomas, A. N. and McGrath, B. A. (2009) 'Patient safety incidents associated with airway devices in critical care: a review of reports to the UK National Patient Safety Agency.' *Anaesthesia*, 64(4) pp. 358–365.

Thomas, A. N. and Panchagnula, U. (2008) 'Medication-related patient safety incidents in critical care: a review of reports to the UK National Patient Safety Agency.' *Anaesthesia*, 63(7) pp. 726–733.

Thomas, A. N. and Taylor, R. J. (2012) 'Review of patient safety incidents reported from critical care units in North-West England in 2009 and 2010'. *Anaesthesia*, 67(7) pp. 706–713.

Thomas, A. N. and Taylor, R. J. (2014) 'An analysis of patient safety incidents associated with medications reported from critical care units in the North West of England between 2009 and 2012.' *Anaesthesia*, 69(7) pp. 735–745.

Thomas, A. N., Panchagnula, U. and Taylor, R. J. (2009) 'Review of patient safety incidents submitted from Critical Care Units in England & Wales to the UK National Patient Safety Agency.' *Anaesthesia*, 64(11) pp. 1178–1185.

Tobin, A. E. and Santamaria, J. D. (2008) 'An intensivist-led tracheostomy review team is associated with shorter decannulation time and length of stay: a prospective cohort study.' *Critical Care (London, England)*, 12(2) p. R48.

Tobler, W. D., Mella, J. R., Ng, J., Selvam, A., Burke, P. A. and Agarwal, S. (2011) 'Chest X-ray after Tracheostomy Is Not Necessary Unless Clinically Indicated'. *World Journal of Surgery*, 36(2) pp. 266–269.

Tracheotomy (no date). The history of tracheotomy. [Online] [Accessed on 10 January 2017] http://www.tracheotomy.info.

Valentin, A., Capuzzo, M., Guidet, B., Moreno, R. P., Dolanski, L., Bauer, P., Metnitz, P. G. H., Research Group on Quality Improvement of European Society of Intensive Care Medicine Sentinel Events Evaluation Study Investigators (2006) 'Patient safety in intensive care: results from the multinational Sentinel Events Evaluation (SEE) study.' *Intensive Care Medicine*, 32(10) pp. 1591–1598.

Van Heurn, L. W. and Brink, P. R. (1996) 'The history of percutaneous tracheotomy.' *The Journal of Laryngology & Otology*, 110 pp. 723–726.

van Hoof, J., Zwerts-Verhelst, E. L. M., Nieboer, M. E. and Wouters, E. J. M. (2015) 'Innovations in multidisciplinary education in healthcare and technology.' *Perspectives on Medical Education*, 4(3) pp. 146–148.

Veenith, T., Ganeshamoorthy, S., Standley, T., Carter, J. and Young, P. (2008) 'Intensive care unit tracheostomy: a snapshot of UK practice.' *International Archives of Medicine*, 1(1) p. 21.

Vincent, C., Stanhope, N. and Crowley-Murphy, M. (1999) 'Reasons for not reporting adverse incidents: an empirical study.' *Journal of Evaluation in Clinical Practice*, 5(1) pp. 13–21.

Wallace, F. A., Alexander, P. D. G., Spencer, C., Naisbitt, J., Moore, J. A. and McGrath, B. A. (2015) 'A comparison of ventilator-associated pneumonia rates determined by different scoring systems in four intensive care units in the North West of England.' *Anaesthesia*, 70(11) pp. 1274–1280.

Wallace, F. and McGrath, B. A. (2015) 'Criteria for diagnosing ventilator-associated pneumonia: a modified Delphi study.' *British Journal of Anaesthesia*, 113(2) p. 322P.

Wayne, D. B., Siddall, V. J., Butter, J., Fudala, M. J., Wade, L. D., Feinglass, J. and Mcgaghie, W. C. (2006) 'A Longitudinal Study of Internal Medicine Residents' Retention of Advanced Cardiac Life Support Skills.' *Academic Medicine*, 81(10) p. S9.

Wikipedia contributors. Hawthorne effect. Wikipedia, The Free Encyclopaedia. [Online] [Accessed on 14 March 2017] https://en.wikipedia.org/w/index.php?title=Hawthorne_effect&oldid=827571045

Yeo, W. X., Phua, C. Q. and Lo, S. (2014) 'Is routine chest X-ray after surgical and percutaneous tracheostomy necessary in adults: a systemic review of the current literature.' *Clinical Otolaryngology*, 39(2) pp. 79–88.

Young, D., Harrison, D. A., Cuthbertson, B. H., Rowan, K. and TracMan Collaborators, F. T. (2013) 'Effect of Early vs Late Tracheostomy Placement on Survival in Patients Receiving Mechanical Ventilation.' *JAMA : the Journal of the American Medical Association*, 309(20) p. 2121.

Zilberberg, M. D. and Shorr, A. F. (2008) 'Prolonged acute mechanical ventilation and hospital bed utilization in 2020 in the United States: implications for budgets, plant and personnel planning.' *BMC Health Services Research*, 8(1) p. 242.

Summary of figures and tables

Figure	Page	Legend	Source / Permission
1.1	25	A tracheostomy tube in situ.	Author's own material.
1.2	25	Sagittal section through the neck and shows a cuffed tracheostomy tube passing through the anterior neck into the trachea.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.3	26	Antonio Musa Brasalova.	US Library of Medicine, with permission.
1.4	27	Chevalier Jackson demonstrating a tracheostomy on a rag doll in his car.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.5	28	A patient from the Copenhagen polio epidemic being ventilated via a tracheostomy.	Lassen 1953, Reproduced with permission from Elsevier.
1.6	30	A cuffed oral endotracheal tube in situ.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.7	33	Anatomy relevant to tracheostomy.	Author's own material.
1.8	34	Tracheostomy position in the obese neck.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.9	35	The differing anatomy of a tracheostomy (shown on the left) and laryngectomy (shown on the right).	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.10	36	Percutaneous tracheostomy insertion into a model via the Seldinger technique.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.11	37	If a percutaneously inserted tracheostomy tube becomes displaced, the recently dilated tissues can 'spring' into their original positions, making re-insertion difficult.	Author's own material.

1.12	43	Cuffed tubes have a soft balloon around the distal end of the tube that inflates to seal the airway.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.13	44	Un-cuffed tubes do not have a cuff that can be inflated inside the trachea.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.14	45	Fenestrated tubes can be cuffed or un-cuffed; the various inner tubes are shown.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.15	45	Different airflow patterns with different tubes inserted. Left cuffed (no airflow via upper airways), centre uncuffed (some airflow), right uncuffed and fenestrated (most airflow).	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.16	46	Sub-glottic suction may reduce the incidence of a ventilator associated pneumonia.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
1.17	47	Adjustable flange tracheostomy tubes.	Comprehensive Tracheostomy Care, McGrath BA (Ed), with permission.
2.1	84	Interaction of incident and location. Adapted from Templeton et al.	Author's own material.
2.2	116	Timeline detailing the key steps in developing the Emergency algorithms.	Author's own material.
2.3	139	Pooled incident rates per 1,000 tracheostomy bed days, by level of harm, during the 12-month data collection period.	Author's own material.

2.4	149	Pooled hospital Length of Stay (LoS) data for all sites over the 12-month data collection period (n=296).	Author's own material.
2.5	149	ICU Length of Stay (LoS) per month for hospital (n=196)	Author's own material.
2.6	152	Monthly percentage of patients with newly inserted tracheostomies who used a speaking valve.	Author's own material
2.7	153	Box-Whisker plot of monthly days to first use of speaking valve for patients with newly inserted percutaneous tracheostomy.	Author's own material.
2.8	153	Box-Whisker plot of monthly days between first cuff deflation and first oral diet for patients with newly inserted percutaneous tracheostomy.	Author's own material.
2.9	154	Monthly trend in median days between first cuff deflation and full oral diet for patients with newly inserted tracheostomies.	Author's own material.
2.10	158	The 'T' Trans-laryngeal tube view and the 'L' trans-laryngeal view of a tracheostomy tube in situ. The right-hand image demonstrates endoscopic assessment via the tube lumen.	Author's own material.

3.1	182	Infographic demonstrating the different rates of tracheostomy complications before and after commencing the Tracheostomy Multi-disciplinary Team (TMDT) ward rounds at a single site.	Author's own material.
3.2	186	Setup phase logic model.	Author's own material.
3.3	187	Data collection phase logic model.	Author's own material.
3.4	203	Interventions applied at a single tertiary paediatric centre to improve tracheostomy care.	Author's own material.
3.5	203	Incidents per year, divided into primary cause group.	Author's own material.
3.6	204	Number of incidents, percentage of all incidents and harmful and non-harmful events per year (excluding inadequate staffing numbers).	Author's own material.

Table	Page	Legend	Source / Permission
2.1	82	Tracheostomy patient safety incidents stratified for incident and by location. Adapted from McGrath & Thomas, 2011.	Author's own material
2.2	98	Expected tracheostomy patients and rates, based on extrapolating MIDAS data from the North West of England ICUs. 'Tracheostomy' refers to all surgical and percutaneous procedures. Adapted from McGrath, Ramsaran et al 2012.	Author's own material
2.3	142	Comparison of rates of harm between the Shine (4 site) data and rates from the NW 2008-12 dataset for reported critical incidents. TH – Temporary Harm, LoS – Length of Stay.	Author's own material
2.4	143	Number of patients in each of the papers presented in this section for which a patient safety incident was recorded. Comparison is made with the NCEPOD dataset. See text for details.	Author's own material
2.5	143	Number of patient safety incidents occurring per patient in Paper 6, compared with NCEPOD (UK) and GTC (International) pooled data.	Author's own material
2.6	145	Incident rates per 1,000 Tracheostomy Bed Days (TBDs) in the Shine sites (paper 6) vs the international GTC dataset.	Author's own material

3.1	194	Potential cost saving dependant on adopted QI model over 12 months.	Author’s own material
3.2	195	Potential cash release for various sized hospitals.	Author’s own material
3.3	198	Comparison between performance of candidates managing standardised scenarios using early drafts of the algorithm (versions 1-5) vs final drafts (version 11).	Author’s own material
3.4	199	Time (in seconds) measured during candidate performance of scenarios. Paired sample T tests were used to calculate differences between groups.	Author’s own material

Appendix

Appendix

The following recent Editorials were commissioned by Journals that accepted my published work and describe the potential impact that my work could have in my field.

Editorial 1

Lamperti, M., Caldiroli, D., 'Tracheal visualization during tracheostomy: the dark side of the moon or just the moon and mars.' (2017) *British Journal of Anaesthesia*, 118(1), pp. 8-10.

Accompanies McGrath et al. (2016) Paper 7.

Editorial 2

Hopkins, P., Patel, S. (2017). 'Beware the Trojan Horse - a timely reality check about re-using single-use devices.' Anaesthesia, 72(1), pp. 8-12.

This editorial discusses a paper that I published that is a follow on article to Papers 7 and 8:

McGrath BA, Ruane S, McKenna J, Thomas S. Contamination of single-use bronchoscopes in critically ill patients. *Anaesthesia.* 2017 Jan;72(1):36-41.

The paper describes a small study evaluating the potential infection control impact of re-using bronchoscopes. This is relevant to the body of work presented as the immediate availability and use of single-use bronchoscopes is one of the recommendations arising from my work. The abstract is presented below. The manuscript generated an accompanying editorial that the reader may find of interest as it discusses the wider issues around bronchoscopes, the potential for contamination and artificial airway devices.

Abstract in McGrath BA, et al., Contamination of single-use bronchoscopes in critically ill patients. *Anaesthesia.* 2017 Jan;72(1):36-41.

Disposable bronchoscopes such as the Ambu aScopeTM 3 are marketed as 'single use.' The risks of contamination from prolonged device storage before possible re-use are unknown. Following clinical bronchoscopy in patients whose lungs were mechanically ventilated, 20 aScopeTM 3's bronchoscopes received a standard 'social clean' and were then stored. Subsequent paired saline flush and swab samples were taken at time zero, and at 24 h and 48 h. Positive microbiological cultures were obtained from at least one time point from 16 of the 20 bronchoscopes. Pathogens considered at high risk of causing pneumonia were isolated from seven bronchoscopes, with significant quantities from six of them. Our study demonstrates that aScopeTM 3's should not be re-used on the same patient, as clinically significant growth of micro-organisms occurs frequently, despite adequate social cleaning. Culture of bronchoscopes themselves may be a potentially useful diagnostic tool in the context of pulmonary infection. Our data make it clear that these devices are single use and not single patient use.