Choosing the right tracheostomy tube for adults in intensive care: size matters

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Index

Declaration

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

Abstract

Introduction: Tracheostomy tubes (TTs) are artificial airways commonly used in ICU. The size of TT is important. Inner and outer diameters should be balanced to allow breathing both through and around the TT. Undersizing can cause difficulties in delivering mechanical ventilation. Oversizing can prevent patients speaking and risks tracheal trauma. There are no clear guidelines on choosing size of TT for adults in ICU.

Aim: To develop evidence-based guidance on factors to consider when selecting the size of TT for adults in ICU. Secondary aim: to identify barriers and facilitators to changing practice.

Methods: This mixed methods project used qualitative evidence synthesis; an observational study of theoretical sizing outcomes using current methods; a benchtop investigation of the effect of size of TT on work of breathing; and focus groups of ICU clinicians to generate knowledge on a range of factors involved in TT size decision-making.

Results: The key findings were that current sizing practices are not patient-centred and are likely to result in poor fit of TTs within the trachea, more so in females. The impact of TT size on function depends on tracheal size and respiratory parameters. Decision-makers underestimate problems caused by sizing decisions and the importance to patients of voice. Gaps in the evidence are a major barrier to improvement. Joint MDT learning and redesign of TTs could facilitate change and improve patient outcomes.

Conclusion: Good practice should tailor decisions to the individual. Size should be based on anatomical and physiological parameters and aim to allow one-way valve use to restore laryngeal functions, particularly voice. The wider MDT should be involved in sizing decisions and policy to ensure holistic care for patients. Re-design of TTs may make decisions easier for clinicians and help achieve humanisation of care for patients.

Impact Statement

This mixed methods project could meaningfully change practice around tracheostomy tube sizing decisions in ICU and, for the first time, place the patient and person-centred outcomes at the centre of decision making. Moreover, it could help prevent inequality in outcomes between males and females, particularly females with a high body mass index. Through quantitative and qualitative workstreams, new knowledge has been generated on patient priorities; the outcomes of current sizing practices; the impact of sizing decisions on WOB and one-way valve use; and clinician perspectives. Outputs include immediately implementable changes to practice as well as identification of areas for further research and innovation. Importantly, target areas have been identified for implementation strategies to encourage adoption of new guidance by tracheostomy teams.

The first workstream showed that having one's own voice was core to feeling and being treated as a human for patients in ICU with a tracheostomy, and not of secondary importance. Clinical implications that can immediately be factored in to clinical decision making were identified and have been presented in national and international forums. The published findings have been cited 17 times, indicating an impact in the field already.

Workstreams two and three identified that current practices and equipment are biased towards male anatomy and may be putting females at higher risk of physical and psychological harm. Current sizing methods are likely to frequently recommend tracheostomy tubes that are too large in females, leading to higher likelihood of tracheal trauma and of not being able to speak. Conversely, males are more likely to receive tracheostomy tubes that are smaller relative to their trachea. In those with average size tracheas and larger tidal lung volumes this may negatively impact breathing if the cuff is inflated but make breathing (and talking) easier with a one-way valve in place. For patients with a large trachea, the project findings indicate resistance to breathing could be kept low with one size of tracheostomy tube regardless of cuff or one-way valve use. Focus groups highlighted the multiple perspectives of the different professionals within the tracheostomy team and the challenges and benefits this brought to tracheostomy tube size decision-making. Find-

ings support the inclusion of the whole MDT in decision-making and highlight the need for adequate training and funding for therapy posts.

Integrating findings helped generate a conceptual model of tracheostomy tube sizing that serves both as a description of the challenges involved in size decisions and a tool to guide current practice at the bedside, local staffing and organisational policy, and future research and innovation.

In summary, this project has real potential to change international practice and improve quality of care for adults with a tracheostomy in ICU. Through highlighting the impact of sizing decisions on things that matter to patients and the importance of considering the individual anatomy and physiology of patients, it could help make tailored decision-making the norm in this field. Further, it recommends clinician-researcher and industry collaborations to overhaul tracheostomy tube design to help deliver truly person-centred outcomes for all patients.

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Helen Newman: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Writing – original draft, Writing – review & editing. Gemma Clunie: Data curation, Writing – review & editing.

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In which chapter(s) of your thesis can this material be found?

Chapter 2

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Table 1.: List of abbreviations

Abbreviation	Meaning
ACCP	advanced critical care practioner
ACV	above cuff vocalisation
AHP	allied health professional
AMI	air-mucosa interface
BMI	body mass index
CASP	critical skills appraisal programme
COM-B	model of behaviour change influences relating to capability, opportunity and motivation
DSH	data safe haven
ETT	endotracheal tube
FG	focus group
HVF	humanisation value framework
ICU	intensive care unit
NCEPOD	National Confidential Enquiry into Patient Outcome and Death
M-BMI	method of selecting tracheostomy tube size based on patient's body mass index
M-BP-Max	best practice method of selecting size of tracheostomy tube
M-height	method of selecting tracheostomy tube size based on patient's height
M-sex	method of selecting tracheostomy tube size based on patient's sex
M-shoulder	method of selecting tracheostomy tube size based on shoulder width
MDT	multidisciplinary team
MV	mechanical ventilation

Abbreviation	Meaning
OWV	one-way valve
PEEP	positive end expiratory pressure
PT	physiotherapist
POCUS	point of care ultrasound
PRISMA	preferred reporting items for systematic reviews and meta-analysis
RR	respiratory rate
SLT	speech and language therapist/speech and language therapy
TT	tracheostomy tube
TV	tidal lung volume
WOB	work of breathing

1. Introduction

This chapter starts with an explanation of the tracheostomy procedure, tracheostomy tubes (TTs), and key issues in tracheostomy management for adults in the intensive care unit (ICU). It presents the current guidelines and evidence around tracheostomy management and highlights gaps in the evidence to support decision making relating to TT size. These gaps are presented in the context of person-centred care. The final section of this chapter defines the research questions and describes the project methodology and thesis structure.

1.1. Tracheostomy insertion and indications

Tracheostomy is a common surgical procedure performed on patients in ICU. It involves the insertion of an artificial airway through the front of the neck and into the trachea. Around 15000 tracheostomies are performed annually within the UK and most are performed in ICU [1–3]. Within the ICU, the most common indications for tracheostomy insertion are to facilitate prolonged mechanical ventilation (MV) or weaning from MV [4–6]. They are also used to secure a patent airway in cases of airway obstruction, to facilitate clearance of pulmonary secretions via suction catheter and to reduce the risk and/or quantity of aspiration of secretions or refluxed stomach contents into the lungs.

The two main insertion techniques are surgical and percutaneous dilatation techniques [6]. Surgical tracheostomies are usually performed by ENT and head and neck surgeons in the operating theatre and involve dissecting the anterior neck tissues and surgically creating a window in the trachea through which to insert the TT. Within ICU, most tracheostomies are performed percutaneously by intensivists [1]. Contra-indications to percutaneous insertion include the presence of blood vessels over the insertion site, altered anatomy, or high body mass index (BMI). Bronchoscopy and ultrasound are routinely used for placement confirmation of the guide wire and TT in the trachea and for screening for vessels in the anterior neck, respectively [4]. Extensive research has been conducted including a

Cochrane review around which technique is better and this remains a controversial topic. There are indications that percutaneous insertion has benefits in certain areas such as cost, prodecure duration and location, but no consensus on the impact on early and late complications [7–10].

The best timing for tracheostomy also remains debated. A well cited study investigating the effect of early versus late tracheostomy found no benefit of early insertion [11]. Other studies have mirrored these findings whilst some suggest a potential benefit of early tracheostomy within specific patient populations, on ICU and hospital length of stay, duration of MV, reduction in sedation and earlier commencement of rehabilitation [12–14]. Limitations in the evidence include definitions of early versus late insertion, primary outcome measures used, and failure to meet the target sample size.

1.2. Anatomy and physiology

TTs are inserted in the upper trachea, below the laryngeal cartilages. In ICU nearly all TTs have an inflatable balloon (cuff) that bridges the gap between TT and tracheal wall. The cuff primarily serves to aid MV through preventing breaths from the ventilator leaking upwards through the upper airway, which would reduce the pressure/volume delivered to the lungs. Immediately post-insertion the cuff serves to reduce the risk of aspiration of blood and secretions into the lungs. While the cuff is inflated, no air passes through the larynx. Since airflow is required for the production of voice, a patient is unable to talk while the cuff is inflated, unless another source of airflow is provided (see Section 1.5.2.3 below for details of above-cuff vocalisation and its limitations). Other physiological processes dependent on laryngeal function are also affected, for example coughing, swallowing and physiological positive end expiratory pressure (PEEP) (see Section 1.5). When the cuff is deflated, airflow through the upper airway (supra-glottic airflow) should be restored, provided there are no airway obstructions and the TT is small enough to allow air to pass between the tracheal walls and the TT.

1.3. Complications

Peri-insertion complications of tracheostomy include bleeding, false tract (where the TT is inserted into para-tracheal tissues), subcutaneous emphysema, tissue trauma to the neck and loss of airway. Post-insertion complications include bleeding, dislodgement,

blockage, damage to the skin around the stoma and infection. Long-term complications include the growth of granulation tissue, tracheal stenosis, tracheomalacia, failure of the stoma to heal, and infection [3, 4, 15]. Laryngeal complications in patients with a tracheostomy are increasingly recognised and may be due to tracheostomy or prior intubation [16]. Tracheal stenosis is a narrowing of the airway that can be caused by tissue trauma and subsequent scarring at the site of the TT cuff or tracheal stoma [17, 18]. Patients with mild stenosis may remain asymptomatic whereas those with severe stenosis may require surgical reconstruction or permanent tracheostomy [17, 19, 20]. Since TTs provide patients an airway, the consequences of complications can be severe and sometimes fatal [21].

1.4. Tracheostomy tube types

TTs vary in diameter, length, profile and special features. In UK ICUs the use of inner cannulae is standard practice. These are small tubes that fit inside the main TT and can be removed for cleaning, reducing the risk of secretion build-up and tube occlusion [1, 3]. Other optional features include sub-glottic suction ports, which can be used to aspirate secretions accumulated above the cuff or provide a port through which to pass air to support above cuff vocalisation (ACV) [22, 23] (see Section 1.5.2.2 below). Outside ICU cuffless TTs are sometimes used for non-ventilated patients with low risk of aspiration but in ICU cuffless TTs are rare due to the potential future need for ventilatory support. Fenestrated TTs exist that contain one or more holes (fenestrations) in the wall of the TT to allow passage of airflow through the upper airway, with potential benefits for voice and other laryngeal functions. Due to the risk of fenestrations rubbing against tracheal mucosa and causing granulation, these are less commonly used in UK ICUs now [3, 24].

Sizing usually refers to the inner diameter of a TT but is not standardised across manufacturers in terms of units of measurement or whether size refers to the inner diameter with or without the inner cannula in situ [25]. Length of TT generally increases with increasing diameter [25]. Extra-length TTs and adjustable flanges that allow greater or lesser insertion of a longer proximal portion of the TT also exist and are increasingly used for patients with high BMI to reduce risk of accidental dislodgement [1, 4]. Tube options available to clinicians may be influenced by local policy, financial considerations, and national availability [26, 27].

1.5. Tracheostomy management and weaning

1.5.1. Daily care

Management of TTs for patients in ICU entails a number of daily care tasks aimed primarily at reducing the risk of complications described in Section 1.3 above. For example, changing stoma dressings daily (or more frequently if visibly soiled), reduces infection risk and subsequent risk of poor stoma healing or tracheal stenosis; regularly cleaning inner cannulae, suctioning pulmonary secretions and ensuring adequate humidification of inhaled air reduces risk of TT occlusion; checking tracheal ties reduces the risk of accidental TT dislodgement; and monitoring cuff pressures reduces risk of damage to tracheal mucosa caused by over-inflation [3, 28].

1.5.2. Weaning and decannulation

'Weaning' in relation to tracheostomy management is the term broadly used to describe the process and steps taken to get a patient ready for removal of the TT (decannulation). There is no consensus use of the term, however, and 'respiratory wean' is sometimes used to capture the whole process of weaning from MV and tracheostomy, whereas 'tracheostomy wean' is sometimes used to specifically describe tracheostomy-related steps towards readiness for decannulation [3]. This can cause confusion since 'weaning' is also commonly used to describe the process of liberation from the ventilator [29]. Likewise 'decannulation' might refer to the physical removal of a TT or the whole weaning process.

Unlike timing and technique of tracheostomy insertion, there is relatively little evidence to guide this process [30]. Checklists exist to determine readiness for decannulation and usually include some or all of the following: resolution of primary indication for tracheostomy; confirmation of patent upper airway, absence of respiratory infection; independence from MV for more than 24 hours; ability to manage own pulmonary secretions and a functional swallow. A systematic scoping review found wide variation in practice, however, and that decision making was subjective and potentially caused discomfort and harm to patients [31]. The authors concluded an algorithmic approach to decannulation that was tailored to individuals was preferable to a protocolised one and in keeping with the heterogeneity of this patient group. A small body of literature exists on the processes and interventions used to meet checklist criteria for decannulation. Again, there is wide variation in practice, with or without protocolisation, though typically this starts with cuff deflation trials and may include any of the following: trials of a one-way valve (OWV); swallow assessment;

swallow rehabilitation; downsizing or changing to a different type of TT; and capping [32–35].

1.5.2.1. Laryngeal rehabilitation

More recently, an approach of 'laryngeal rehabilitation' has emerged, led by Sarah Wallace and other leading critical care Speech and Language Therapists (SLTs) in the UK [36, 37]. This approach recognises the multiple critically important roles of the larynx. The most salient of these is voice production, but laryngeal function is also essential in airway protection, swallowing, coughing and auto generation of PEEP [38], all important in tracheostomy weaning. It also recognises the prevalence of laryngeal impairment associated with artificial airways, such as intubation trauma, damage caused by endotracheal tubes (ETTs) rubbing against the vocal folds, changes in laryngeal sensation due to the absence of continuous airflow in and out of the larynx, and disuse atrophy related to lack of swallowing whilst patients are sedated or nil by mouth [16].

1.5.2.2. One-way valves

A key element of laryngeal rehabilitation is restoration of airflow through the glottis. This is usually achieved through cuff deflation and use of an OWV, though in cases where the cuff cannot be deflated, ACV may be an option. This is the practice of entraining air through the sub-glottic suction port ('above cuff'), to generate a translaryngeal airflow that can stimulate the larynx and be modulated by the vocal folds to create voice [23, 39]. There are limitations of this approach such as the requirement for a specialist tube with a sub-glottic suction port; naturalness of voice; lack of patient control of airflow; drying of mucosa and consequent limitations on duration of use; and risks relating to surgical emphysema [39, 40]. A lack of evidence and staff knowledge and skills also impact standardisation in the use of ACV [40, 41]. The best option is use of OWVs since they divert all exhaled airflow through the larynx, restoring physiological airflow and natural voice [36]. However, they are dependent on size of TT and adequate space around the TT to allow airflow through the larynx on deflation of the TT cuff. Use of OWVs without adequate space around the TT would cause inability to exhale, with subsequent inability to inhale, leading to respiratory failure and death if left unmanaged.

1.5.2.3. Voice restoration

A key benefit of OWVs is the restoration of voice. OWVs were previously known as 'speaking valves' for this reason, though a move away from this reflects recognition of the other benefits they confer. Voice restoration allows patients to communicate with family and staff in a natural way, without the need for alternative means of communication [36]. Some patients may not be able to talk with an OWV, for example if they have damaged vocal folds or neurological impairment affecting speech or language. OWV use may previously have been discounted for these patients, however, they are becoming increasingly used with these patients due to increased recognition of their other benefits as outlined below.

1.5.2.4. Respiratory wean

Research in patients following cardiac surgery showed OWV use improved lung recruitment during and for a period after OWV use in patients weaning from MV [38]. Closure of the TT and restoration of airflow through the larynx that occurs during exhalation with an OWV also re-enables patients to generate the intra-thoracic pressure needed to produce a cough [42]. This is achieved by the patient closing the laryngeal vestibule (adducting the true and false vocal folds and folding over the arytenoids and epiglottis), whilst simultaneously using expiratory muscle strength to raise intra-thoracic pressure followed by a rapid release of airflow [43, 44]. Ability to cough means patients are better able to clear pulmonary secretions without the need for suction and helps protect against aspiration [44].

1.5.2.5. Swallowing

There is mixed evidence on the impact of tracheostomy on swallowing. Proposed effects have included laryngeal tethering due to inflated cuffs, bulky tubes or the weight of ventilator tubing, impaired oesophageal motility due to indentation of the trachealis muscle by cuffs and tubes, and disruption of pharyngeal pressures generated in the normal closed-system upper airway [45–47], while some authors have concluded no effect of tracheostomy on swallowing [48, 49]. Heterogeneity and small size of study samples makes it difficult to draw conclusions on this or the impact of TT interventions on swallowing (such as cuff deflation or tube occlusion) [50, 51]. In the absence of clear evidence, expert consensus is that OWVs can help eating and drinking through restoration of olfactory senses, increased supra-glottic airflow, improved laryngeal sensation, and improved

cough strength to clear penetrated or aspirated material [52–55] . Restoration of voice can also allow perceptual evaluation of vocal fold function and potentially flag penetration of food and drink into the larynx [56].

1.5.3. Multidisciplinary team working

There is widespread agreement that good multidisciplinary team (MDT), working is required for quality of care for tracheostomy patients [3, 4, 30] though high-quality evidence is lacking. There are contradictory findings on the impact of MDTs on time to decannulation and length of stay, which may reflect sample sizes, patient groups, chosen outcome measures, and baseline level of care in authors' local institution [57–60], however there is support for MDT working leading to a reduction in adverse events and an improvement in time to OWV use and communication [57, 58, 61, 62]. Core members have been identified as intensivists, surgeons, SLTs, respiratory physiotherapists and specialist tracheostomy nurses and specific roles and competencies have been described [37, 63, 64].

1.6. Tracheostomy guidelines

Fifteen years ago guidelines on tracheostomy management were mostly limited to local organisational guidelines. Since then, more comprehensive guidelines have been produced by the National Tracheostomy Safety Project [65], and jointly by the Intensive Care Society and the Faculty of Intensive Care Medicine [4]. These drew on findings from the National Patient Safety Association, coroners' reports, a national audit of major complications of airway management [21] and a National Patient Enquiry into Patient Outcome and Death (NCEPOD) audit of national practice in tracheostomy management [1]. The latter showed that care had room for improvement in 60% of cases reviewed and that failings in the care for patients with a tracheostomy was a major cause of airway related injury and death [1]. The report authors made recommendations for the organisation of care, TT insertion and equipment, management, and MDT working, and highlighted areas for further research. The Global Tracheostomy Collaborative was also launched as an international initiative to improve the safety and quality of care for patients with a tracheostomy, with an emphasis on patient-level data collection and involvement of patients and their families in order to ensure meaningful improvement in patient-centred outcomes [66, 67].

While existing guidelines have helped improve the care of patients with a tracheostomy, gaps and weaknesses in the evidence mean many aspects of care remain based on

expert consensus. There are no clear guidelines, for example, on how to choose the right size TT for patients. The 2014 Intensive Care Society Standards for the management of adults with a TT [68] recommended that outer diameters of TTs should be no larger than three-quarters the diameter of the trachea. However, clinicians were not told to measure the trachea or how to do this. Moreover, this recommendation was removed in the latest version due to a lack of supporting evidence. The revised document acknowledges the reliance on clinical experience in decision making in the absence of scientific evidence:

> '..tube size often comes down to experience and the multidisciplinary team can be invaluable. There may be a role for pre-procedural ultrasound or imaging in tube selection, although at present, there are no clear guidelines for tube selection.'

Given the potential impact on patient function while the TT is in situ and longer-term impacts as outlined above, this is an important area to address.

1.7. Patient experience of tracheostomy in ICU

1.7.1. ICU experience

There is a large amount of evidence on patient experience of ICU, including around pain, MV, sleep, delirium and family contact [73]. ICU admission is known to be enormously distressing for many patients and their families, especially for those with prolonged stays [74–76]. Particular stressors include fear of death, pain, not being able to communicate, being nil by mouth, having tubes inserted and the associated restrictions in movement, and not feeling in control [77–79]. Much of this literature is based on intubated patients, however, and less is known about the specific experiences of patients with a tracheostomy.

1.7.2. Post-ICU experience

As technology and medical interventions evolve, increasing numbers of patients are surviving ICU admission and with this comes increased prevalence and recognition of the wide-ranging longer-term impacts on patients, from weakness to post-traumatic stress disorder (PTSD) [80–82]. The term Post Intensive Care Syndrome (PICS) was coined in 2010 by consensus of the attendees of the Society of Critical Care Medicine conference and refers to lasting physical, mental health or cognitive effects of critical care illness and

interventions [83–85]. It is now understood that survival does not equal recovery, and current goals of ICU research and innovation include reducing the risk of long-term negative sequelae of ICU admission, which includes improving patient experience of ICU [86].

1.8. Gaps in the evidence

Selecting a TT that suits breathing through the TT and around the TT (i.e. with an inflated cuff or a deflated cuff and OWV), requires an understanding of the fluid dynamic properties of airway tubes within the trachea and knowledge of tracheal dimensions in relation to TT size. There is little evidence on these issues. Studies of artificial-airway related fluid dynamics have primarily focused on airflow through tubes and may over-emphasise the need for large inner-diameters, increasing the risk of damage to the trachea [87]. Oversizing also risks failure to tolerate an OWV.

Tracheostomy tubes that are too large prevent patients from being able to breathe around a TT with a deflated cuff and therefore from speaking (see Section 1.5.2.2). Not being able to speak is very stressful for patients in ICU [76, 77, 79]. It can lead to treatment decisions being delayed or made by others on behalf of the patient, and has been linked with increased levels of anxiety and depression and the development of post-traumatic stress disorder [79, 88, 89]. Though the importance to patients of being able to speak is understood, it has not been sufficiently addressed in the context of other tracheostomy related outcomes and TT size decision-making.

There is little evidence on size of the trachea in relation to TT sizing decisions. A few observational cohort studies have looked at normal tracheal dimensions. Some have investigated associations with other patient anthropometrics [90–93]. Evidence from a paediatric study supports a correlation between height and tracheal dimensions in children [90]. The literature on adults is inconclusive, however, and data collection methods such as x-ray imaging, taking measurements in cadavers, and maximal breath holding in live subjects may have distorted tracheal anatomy [91, 93, 94]. One study used CT scans of the thorax and pulmonary angiograms to aid TT size decisions during the COVID-19 pandemic, however, these imaging techniques are not routine in ICU. They also involve exposure to ionising radiation and transport of patients out of ICU and so may not be indicated solely for TT sizing decisions. In contrast, ultrasound is portable, non-invasive, and increasingly used to assess the airway (including during TT insertion in ICU) [95]. A number of studies have reported strong correlation between ultrasound measurements of

the trachea and measurements taken from CT and MRI imaging [96–98], suggesting this would be a better method of obtaining tracheal measurements.

A number of benchtop laboratory studies have looked at airflow resistance of TTs [99–103]. One demonstrated that poor positioning of a tube, which may happen due to poor sizing, increases airflow resistance [101]. Others have mostly focussed on the aim of reducing airway resistance through the tube in order to facilitate mechanical ventilation, generally concluding that 'big is best', citing Poiseuille's equation that shows resistance is proportional to r^4 where r is the radius of the tube [99, 100, 102]. However, there are important limitations in some of these studies. Some look only at airflow through tubes in isolation, not in the context of the trachea [100, 102]. This could exaggerate the relative effect on total airway resistance and work of breathing. One study suggested that the inner diameter of a TT should not be narrower than 8 mm [100]. This is significantly larger than many TTs used in practice in the UK. None of the bench top studies paired tracheostomy size with expected airflow rates for a patient with a tube of that size. This may be important if those who require a smaller TTs are assumed to have lower tidal volumes, since resistance is proportional to flow. There was minimal acknowledgment also of the ability to compensate for increased resistance by adjusting ventilator settings, known as tube compensation [104]. While bench top studies may have overplayed the significance of airway resistance of smaller tubes, they have largely ignored the need to limit the outer diameter of the tube to allow speech or to facilitate weaning from a tracheostomy.

I found no evidence in the peer-reviewed literature on the perspectives of ICU clinicians on TT sizing. A local service evaluation and anecdotal evidence suggests differences in perspectives across professions. Understanding these differences could aid the development of successful implementation strategies through identification of barriers and facilitators to changing practice at the clinician level.

Finally, and perhaps most importantly, no previously published studies or reviews have focused on what matters most to patients with a tracheostomy in ICU. Nakarada-Kordic et al's [105] systematic review of patient experience of tracheostomy provided important insights on the experiences of patients living with a tracheostomy. However, it focussed on community experience and the majority of ICU patients are decannulated prior to hospital discharge. The experiences of those in ICU could therefore be different to Nakarada et al's cohort due to differences in the patient sample and setting. Understanding patients' experiences of tracheostomy in ICU is key to ensuring ICU tracheostomy practices are aligned with patient-centred goals.

The evidence described above supports the need for this research by demonstrating the potential harmful consequences of poor selection of TT size on clinical outcomes that are important to patients, and highlighting gaps in knowledge relating to physical factors to consider in the selection of TT size.

1.9. Patient-centred care

Clinicians need to understand patient experience and know what matters to patients in order to provide care that leads to meaningful health outcomes. The concept of patient-centred care (PCC), has steadily become more prominent as a guiding concept in research, policy and quality improvement [106–109]. There is no consensus on a definition of PCC, but the International Alliance of Patients' Organizations (IPAO), and published concept analyses highlight the essential principles of respect; patient choice and empowerment; patient involvement in policy; fair access to services; and the provision of information [110–112]. PCC is consistent with biopsychosocial models and 'whole person' approaches to health care that recognise the physical, cognitive, emotional and social impacts of illness and treatment [111–115]. It contrasts with biomedical models of care that prioritise diagnosis and treatment of disease processes, with 'expert clinicians' deciding treatment for passive patients. PCC relies on clinicians seeking to understand and incorporate patient wishes in decision making about care in order to make the most meaningful difference to patients and their families [116]. It also requires an understanding of how treatments affect patients' lives.

Intensive care medicine faces particular challenges in delivering PCC [117, 118]. The patients are, by admission criteria, critically ill. Doctors make life and death decisions on a daily basis and care may necessitate a focus on physiological signs to guide life-supportive treatment. Many patients are unable to enter into discussion around their care due to sedation, delirium or low levels of consciousness [117]. However, as described in Section 1.7.1, there is a body of literature which shows ICU admission can be frightening, confusing and traumatic. The evidence base on tracheostomy in ICU mostly focuses on timing, technique and epidemiology, and the outcomes used by researchers are usually mortality or hospital metrics [119]. More needs to be done to ensure the holistic needs of patients are at the centre of care decisions and academic inquiry.

1.10. Patient and public involvement

A patient and public involvement (PPI) group was convened during the development of the research proposal to help ensure that it was grounded in what mattered to patients. PPI members had all experienced tracheostomy on ICU and had either responded to a request for support via ICUSteps (patient support charity https://icusteps.org), been a patient of the first author or were recruited via word of mouth. Their personal experience leant weight to the project proposal. One explained how she had been in severe pain, but due to her TT could not explain what was wrong to the nurse. The nurse mistook frustration and pain for agitation and sedated her. A lack of voice meant this patient's physical symptoms were not addressed and she was given medication that is a known causal factor for delirium, which in turn is a risk factor for adverse outcomes. Another said that being unable to speak due to the TT was "the most frustrating thing I've experienced in all my 46 years on the planet". Further details of patient and public involvement in the project can be found in Appendix A.

1.11. Summary

Tracheostomy is a common procedure in adult ICUs. Whilst potentially lifesaving, there are inherent risks associated with artificial airways. Complications are common. The results can be serious, long-lasting and/or fatal. A growing body of evidence has led to improvements and standardisation of care. However, important gaps in the evidence remain. There remains no clear guidance for clinicians on how to select the right size TT. This is important because TT size impacts patient function and experience, as outlined above. A patient-centred approach is largely lacking in the tracheostomy literature. This project seeks to develop guidance that is tailored to patients in terms of individual anatomy, physiology and patient priorities.

1.12. Research questions and aims

The overarching research question was 'what factors should be considered when choosing the size of TT for adults in ICU?'

The primary aim of the project was to develop evidence-based guidance on factors to consider when selecting the size of TT for adult patients in ICU, taking into account anatomy,

physiology, airway-related fluid dynamics, and patient centred outcomes.

A secondary aim was to propose strategies to support implementation of guidance by the multidisciplinary tracheostomy team.

An outline of methodological approach used in the project is provided below, followed by a description of the study design and specific aims and questions addressed in each part of the project.

1.13. Mixed methods

The project questions and aims around TT sizing required understanding of

1. physical factors that were measurable and best addressed with quantitative methods, and
2. patient experience and clinician perspectives, that were best investigated through qualitative methods.

A mixed methods methodology was therefore chosen for this project. Mixed methods has been used as an overt approach in scientific inquiry since the 1950s and in practice, for much longer [120–122]. It has been used extensively in health and social care due its ability to address complex problems involving human behaviour [121, 123, 124].

1.13.1. Research paradigm

Criticisms of mixed methods methodology have been made by researchers who argue that quantitative and qualitative research cannot be mixed on the basis of the incompatibility of the ontologies, epistemologies and methods (or paradigms), that underpin quantitative and qualitative inquiry [125]. An ontology refers to a set of beliefs around the nature of existence. Epistemology refers to beliefs around how knowledge can be acquired. In quantitative methods, traditional positivist philosophy holds that reality exists independent of the observer and knowledge can be gained through controlling external influences on the entity under investigation, allowing unbiased measurement and analysis to reveal truths about that entity. In contrast, in qualitative methods, a constructivist philosophy holds that reality is co-constructed by the observer and their environment, that knowledge is a social construct subject to the observer's senses, prior perspectives and interactions with their environment [126]. However, alternative research paradigms have evolved that

accommodate both quantitative and qualitative methods and value the ability of mixed methods approaches to expand knowledge through complimentarity of findings. For this project, a pragmatist approach was adopted. Pragmatism goes beyond a mixed method's goal of providing a more comprehensive view of complex topics; it specifically values the practical applicability of research outputs, using the most appropriate methods for specific objectives and contexts to deliver actionable findings [120, 124, 127]. A pragmatist mixed methods approach is therefore useful in addressing complex, real world problems where policy and practice change are project goals. Such issues are common in health and social care, where problems may involve facets that are amenable to quantitative methods such as measurement and statistical analysis, and require deeper knowledge of social phenomena and experience that are better explored through qualitative methods. Decisions around TT sizing involve measurable factors such as size of TT, tracheal dimensions and airflow resistance that can be analysed using statistics, and factors that require word-based methods and analysis such as rich understanding of patient priorities and staff perspectives.

1.13.2. Reflexivity

Reflexivity is valued within most qualitative research methodologies. This is the practice of self-reflection to understand how the researcher themselves might influence the process and outcomes of a piece of research. Points of reflection may include their ontological and epistemological viewpoints, background and life experiences, and prior knowledge and beliefs on the research topic [128–130]. Hertz [131], quoted in Finlay [128] argues researchers should be aware that they are

> 'imposed at all stages of the research process - from the questions they ask to those they ignore, from who they study to who they ignore, from problem formulation to analysis, representation and writing - in order to produce less distorted accounts of the social world'.

Various approaches to reflexivity have been described, from expansive and continuous self-reflection throughout the research process, to acknowledgement and acceptance that researchers' beliefs and values affect research decisions, implementation and findings [132–134].

Whilst reflexivity is seen as a strength that enhances research rigor, challenges exist in determining how much is enough, how to report it, and how to appraise it in within primary studies and reviews [134–136]. The pragmatist approach of this research project focuses

on using the most appropriate methods for investigating the research questions at hand, with less emphasis on philosophical congruity of beliefs and methods or reporting of this. It is relevant, however, to report my experience as a speech and language therapist working with adults with a tracheostomy as this was what motivated me to undertake this project. I am aware that this background might predispose me to certain assumptions and biases around how tracheostomy sizing decisions are and should be made in ICU. To evaluate the influence on the research process I kept research journals for each workstream and for the project as a whole which provided an audit trail of critical thinking and decision making. I sought supervision from researchers with medical and nursing ICU backgrounds and from subject experts with non-clinical backgrounds. I invited non-speech and language therapists to assist in the analysis of qualitative data. Additionally, though my professional experience may introduce bias, it has given be beneficial insights into patient experience of tracheostomy and the impacts of sizing decisions, the perspectives of different members of the ICU MDT, and the practicalities and organisational factors affecting TT sizing decisions.

1.14. Mixed methods study design

The choice of mixed methods study design should be led by the project aims, questions, and methods [120, 124]. This project sought to develop a more complete picture of TT size decision-making for adults in ICU through generating knowledge on quantitative and qualitative factors to consider, using diverse methods such as benchtop experiment and focus groups. The project therefore consisted of separate but related components with a parallel convergent mixed methods design [120]. Data for each workstream were collected and analysed separately and weighted as of equal importance. Though parallel in design, due to the work being mostly undertaken by one PhD student, in practice the workstreams were undertaken in series. There was also an element of nested sequential design since some integration of quantitative and qualitative data occurred within the focus group study: participants were shown a brief video summary of workstreams 1-3 halfway through each focus group, hence earlier workstreams influenced the latter half of focus group discussions and data. Figure 1.1 shows a diagram of the project structure.

1.14.1. Project structure

Four workstreams were developed to address four aspects of TT sizing. The questions, aims and methods for each workstream were as follows:

1.14.2. Workstream 1

Question: what matters most to adults with a tracheostomy in ICU?

Aim: to explore what matters most to adults with a tracheostomy in ICU and interpret the clinical implications

Methods: Systematic review and metasynthesis of qualitative data on patient experience of tracheostomy in ICU

1.14.3. Workstream 2

Questions: 1) how well do TT sizing methods used in practice agree with sizing by tracheal dimensions; 2) what is the strength of correlation between tracheal width and other biometrics

Aims: 1) to determine concordance between sizing methods used in practice and sizing by tracheal dimensions 2) to determine the strength of correlation between tracheal width and other biometrics

Methods: observational study

1.14.4. Workstream 3

Questions: how does size of TT affect work of breathing (with an inflated cuff or with a deflated cuff and OWV)

Aim: to compare WOB across different size TTs

Methods: benchtop study

1.14.5. Workstream 4

Questions: 1) what are the perspectives of ICU tracheostomy team members on TT sizing methods; 2) what are the barriers and facilitators to changing practice around TT sizing?

Aim: 1) to describe the perspectives of ICU tracheostomy team members on TT sizing methods; 2) to identify barriers and facilitators to changing practice

Methods: focus group study

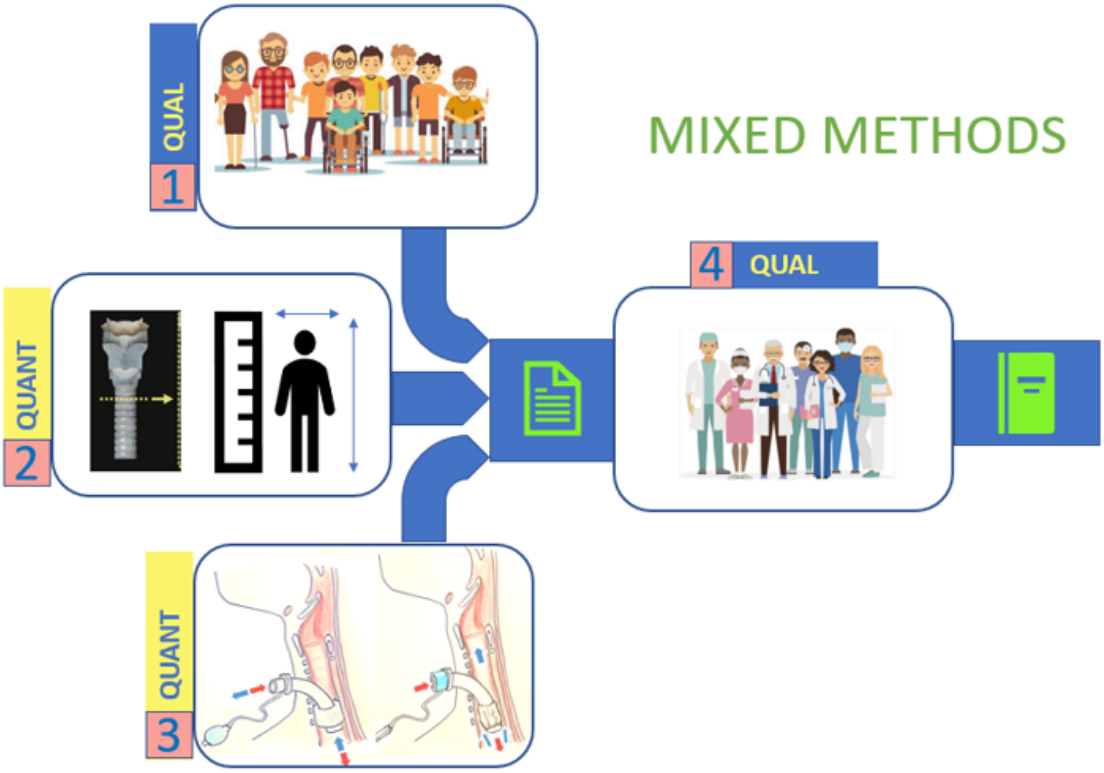


Figure 1.1.: Outline of project structure showing quantitative and qualitative workstreams and points of integration

An extra piece of work was added to workstream 2 in response to questions arising through data collection and re-appraisal of the existing literature. This work investigated the validity and reliability of tracheal measurement techniques used in workstream 2. Specific objectives were around discriminating anatomical landmarks from artefact on tracheal ultrasound images and assessing reliability of ultrasound measurements against direct measurement. This work is presented in Chapter 3.

1.14.6. Integration

An *a priori* integration plan was developed to integrate quantitative and qualitative data after the results of individual workstreams had been analysed and interpreted. As described

above, there was also an element of data integration within the focus group study. The integration process is presented in full detail in Chapter 7.

1.15. Clinical steering group

A clinical steering group (CSG) was convened during the development of the observational study protocol to advise on clinical aspects of the study design. Input was also sought on clinical parameters to use in the benchtop experiment. CSG feedback was invited on the moderator guide for the focus group study and CSG members aided recruitment to the focus group study through the circulation of recruitment documents among clinical networks. Members of the group were identified by contacting leading clinicians in and authors of articles relating to tracheostomy policy and management. Membership included my NIHR fellowship clinical supervisors, and members of the National Tracheostomy Safety Project (including the NHS lead for tracheostomy), and Global Tracheostomy Collaborative.

1.16. Thesis structure

The structure of this thesis is organised around the project's mixed methods design. In addressing the central topic of TT sizing methods, the project incorporated four independent but related components. There is therefore no separate methods chapter. Rather, workstreams are reported individually in full. Each workstream chapter presents the evidence base and rationale specific to that piece of work, as well as the methods, analysis, results and interpretation of findings. A discussion including the strengths and limitations is presented within each workstream.

The first workstream presented is the qualitative systematic literature review of what matters most to patients. This chapter underscores the importance of the project as a whole as it highlights the impact of TT sizing decisions on functions that matter to patients. The following chapter presents a cadaver study validation of ultrasound measurement of the trachea. This was undertaken after data collection for the observational study presented in Chapter 4. However, it has been presented first as it underpins the methods used to measure participants' tracheas.

The observational study presents findings on the 'fit' of TTs in the trachea according to different TT sizing methods used in practice and a method based on individual partici-

pants' tracheal dimensions. This chapter also reports on the correlation between tracheal width and other anatomical measurements, highlighting the dangers of using surrogate measures for tracheal width in TT sizing.

Chapter 5 presents the findings of a benchtop study investigating the effect of size of TT on resistance to airflow (i.e. the impact on work of breathing, WOB), both with an inflated cuff and with a deflated cuff and OWV. This workstream identifies potential systemic disadvantages for patients with smaller tracheas, who will predominantly be female.

Chapter 6 presents ICU MDT perspectives on TT sizing practices, showing that current practice is subjective, uni-professional and that differences in perspectives exist across professions. It identifies barriers and facilitators to changing practice, including a lack of recognition of the problem among many making sizing decisions, a lack of evidence to guide clinicians, and organisational and manufacturing factors. This chapter concludes with measures that can be immediately implemented in practice and suggestions for future research and innovation.

A separate integration chapter follows the workstream chapters; here, the main project findings derived from integration of quantitative and qualitative workstream data are presented. Finally, a discussion chapter summarises the main project findings and compares them to the existing literature.

2. Qualitative systematic review and metasynthesis

2.1. Introduction

Chapter 1 highlighted the importance of understanding patient experience and perspectives when making treatment decisions. This chapter addresses what matters most to adults with a TT on ICU and considers the implications for clinical practice. Findings were published in a peer-reviewed journal [137] and can be found via this link. Copyright was retained by the authors and some of the manuscript content has been reproduced in this chapter.

As described in Chapter 1, it is now widely accepted that high quality healthcare must be patient-centred, and that this requires understanding of patient experience and perspectives, including within ICU. However, much of the evidence guiding tracheostomy management focuses on incidence, timing and technique of insertion, risk factors and associated complications. A number of quantitative, measurement-focused studies have addressed quality of life (QOL) and mental health outcomes in patients with a tracheostomy [138–140]. While these studies capture prevalence and patterns of symptoms, they are not designed to present accounts of patient experience, which could help to shape future care. Qualitative methods have been used to provide insights into ICU patient experience of delirium [141] and mechanical ventilation [73, 78, 142]. Nakarada-Kordic et al's [105] mixed-methods systematic review described challenges facing patients with a tracheostomy and their caregivers such as poor basic care, speech and communication difficulties, altered body image and reduced social interaction in the community. However, their review was not ICU specific. A qualitative scoping review by Tolotti et al [143] addressed nurse-patient communication experiences in patients with a tracheostomy and/or on mechanical ventilation, and Whitmore et al's [30]'s mixed-methods scoping review of post-insertion ICU tracheostomy management concluded that more research was needed into patient experience of events relating to or impacted by tracheostomy. Further robust

evidence and conceptual understanding of the global experience and priorities of ICU patients with a tracheostomy could help clinicians to make better decisions to meet the holistic needs of this group of people and improve patient-centred outcomes.

The aim of this systematic review and metasynthesis was to develop a deep understanding of what matters most to patients with a tracheostomy in ICU and consider the implications for clinical practice. The research questions were:

- What are the outcomes and experiences that matter most to patients with a tracheostomy in ICU?
- What are the implications for clinical practice?

2.2. Methods

2.2.1. Qualitative systematic review and metasynthesis

A qualitative approach to enquiry allowed the collection of in-depth and realistic views, opinions and experiences from the perspective of those with lived experience of the research topic in a way that would be unachievable through quantitative methods [144–146]. Qualitative research may use inductive or deductive methods. Inductive methods work 'bottom up', using data to develop themes and theories, whereas deductive methods apply *a priori* frameworks or theory to analyse data [147]. In the absence of robust evidence on the research topic, inductive methods were used to encourage the emergence of descriptive themes from the data rather than reviewers' prior knowledge and beliefs [144].

Systematic review and evidence synthesis was used to develop a core understanding of the key concepts associated with lived experience of tracheostomy in ICU, capturing a large number of patient voices from different settings. The strength of qualitative evidence synthesis in creating generalisable findings to guide healthcare improvement is now well recognised [148–152]. A metasynthesis was included with the aim of going beyond an aggregative synthesis of primary studies and to generate a more abstract, theoretical understanding of patient experience, developing new concepts and insights and identifying actionable clinical implications [152–156].

The stages involved in this review included: a systematic, comprehensive literature search; title and abstract screening and full text screening of search returns; data abstraction; critical appraisal of selected articles; and thematic synthesis of data following a published method [156]. Consideration of findings in the context of a theoretical

framework of humanised healthcare [157] and a sensitivity analysis to determine impact of lower quality data strengthened the trustworthiness of findings [158].

2.2.2. Search strategy

The literature search of a systematic review (SR) is fundamentally important due to its inherent influence on the quantity and relevance of the data identified for inclusion, and hence its impact on the review findings [159]. Different approaches to searching have been proposed as suitable for different purposes. Traditionally, authors of SRs have employed comprehensive searches to ensure capture of the widest selection of primary research on the basis that larger sample sizes increase statistical power, reduce bias and improve validity of findings [160–162]. However, this contradicts qualitative approaches routed in constructivist epistemologies that value richness of data and usefulness in theory generation or conceptual understanding over numbers of cases [163, 164]. Grounded theory proposes 'data saturation' is an indicator of adequate sample size in qualitative research, i.e. where data is collected until no new information is uncovered [165, 166]. However some argue that this approach is incongruent with a qualitative project's aims, and does not aid work planning or take into account richness of data from individual cases [163, 167]. Malterud et al [163] write instead of sample size being guided by the 'information power' required by the research question. An alternative to comprehensive searches are iterative search strategies which allow reviewers to follow leads and identify useful data on which to build knowledge and theory [164, 168, 169]. The search strategy in this review was developed to meet the project aims of developing knowledge that could be generalised to the wider patient population and guide clinical decision-making. A comprehensive search strategy was therefore developed to maximise information power, aided by an expert librarian. The *a priori* search strategy combined an expansive search of four major bibliographic health databases (Medline, Embase, CINAHL and Web of Science), with grey literature searches, citation searches and requests for recommendations from a multi-professional group of experts. The review protocol was registered with PROSPERO (reg. CRD42020227554) prior to commencing data selection.

A preliminary scoping search was conducted in PubMed to determine the range and depth of relevant evidence and to identify keywords and medical subject heading terms for use in the final search strategy. The research question was analysed using a modified population, intervention, context, outcome (PICO) framework to identify the key search concepts of interest and increase specificity of search returns. These were 'patients with a tracheostomy', 'intensive care' and 'views/experiences/clinical outcomes'. Clusters of

keywords were used to describe and define these three key concepts. Keywords were identified from my clinical experience, keywords in published articles and the advice from expert clinicians from a range of professions working with patients with a tracheostomy. Individual searches were completed for these concepts using relevant subject headings, keyword searches, synonyms and thesaurus terms. Different spellings and truncation and wildcard symbols were used with the aim of capturing as many relevant returns as possible and maximising sensitivity of the search.

The search strategy was first applied in Medline via the OvidSP interface. Here, problems with the third key concept above became apparent. It encompassed a wide range of aspects of tracheostomy care and patient experience and yielded high numbers of irrelevant articles. There was also a concern that the results could be biased by specifying particular clinical topics in the search terms (‘suctioning’, ‘communication’), and missing others. Following discussion with the expert librarian it was agreed that the search should be reduced to two key concepts: ‘tracheostomy’ and ‘the patient perspective’, to locate the most data on patients’ experience of tracheostomy, capturing all anticipated and unanticipated patient views. To avoid retrieval of articles with little relevant information or that were not focussed on tracheostomy, the ‘tracheostomy’ keyword search was restricted to titles and keywords. This reduced the number of articles where tracheostomy was mentioned only as an outcome associated with a particular condition or intervention.

The ‘patient perspective’ search term was more difficult to define. There were no corresponding subject headings so terms such as ‘priority’, ‘need’, ‘wish’, ‘voice’, ‘perspective’ and ‘experience’ were combined with ‘patient’ to create a ‘patient-perspective’ set of search terms. This was used in keyword searches of abstracts, titles and author keyword heading words and combined with keyword searches for ‘lived experience’ and ‘phenomenology’ in all fields to form the final ‘patients perspective’ construct. The ‘tracheostomy’ and ‘patient perspective’ search constructs were then combined using the Boolean operator ‘AND’ to further refine and reduce the number of returns. The search was developed iteratively with amendments to truncation, wildcards and adjacency operators to refine or expand results. Table 2.1 shows the final Medline search strategy which was then translated in the following bibliographic databases: EMBASE; CINAHL; and Web of Science (WOS) (see Appendix B for each search strategy). No filters were used in the bibliographic database searches.

Table 2.1.: Ovid MEDLINE search terms

Line	Search term
1	exp Tracheostomy/
2	(tracheost* or tracheot*).kf,ti.
3	1 or 2
4	(lived adj4 experience*).mp.
5	Phenomenol*.mp.
6	(quality adj3 life).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7	(patient* adj3 (perspective* or attitude* or opinion* or experience* or perception* or view* or feeling* or thought* or priorit* or choice* of decision* or outcome* or satisfaction*)).mp.
8	4 or 5 or 6 or 7
9	3 and 8

A search for grey literature research reports included keyword searching in OpenGrey, sources identified through OpenDOAR, and Grey Matters, and on websites of relevant organisations, e.g. the Intensive Care Society. Expert clinicians (nurses, doctors, speech and language therapists and physiotherapists), in critical care were approached for suggestions of peer-reviewed academic papers. Grey literature and keyword searching was also completed in relevant full text online journals. Finally, forward and backward citation searching was completed for the initial set of selected articles and articles that were only ineligible due to lack of qualitative data. Search results were uploaded to EPPI-Reviewer software for systematic reviews [170] for de-duplication and screening. The literature searches were first run between 23rd December 2020 and 18th January 2021, and repeated prior to submission of this work for publication in a peer-review journal in 2022. A final re-run of bibliographic database searches was completed in May 2024.

2.2.3. Study selection

2.2.3.1. Inclusion and exclusion criteria

Included articles were those that focussed on adult patients with a tracheostomy tube in a critical care setting and reported qualitative data from the patient's or non-professional carer's perspective. Qualitative or mixed-methods studies were eligible. Wholly quantitative studies were excluded. No restrictions on date of publication were applied. Only English language articles were retrieved due to available resources. It is acknowledged

that this exclusion brings a source of potential bias to the review as there may be differences in content and findings of studies published in non-English languages due to cultural differences of the sample and researchers, and researchers' choices of where to publish may be influenced by their study findings [171].

Table 2.2.: Selection criteria and rationale in EPPI-Reviewer Web screening tool

Criterion	Rationale
Exclude: insufficient focus on tracheostomy	To avoid bias from articles focussing on other ICU related experiences. Articles were included if they included data on experience of tracheostomy even if this was not the primary focus of the study, for example studies focussed on mechanical ventilation. Data from such studies that was clearly related to mechanical ventilation was not coded for use in analysis.
Exclude: no data from patient or non-professional carer's perspective	To ensure selected articles contained data reflecting patients' perspectives
Exclude: no qualitative data	The review relied on textual data to provide rich information on experience of tracheostomy from the patient perspective
Exclude: no adult subjects	The research question related to adult patients
Exclude: full text not available in English	No funding was available for translation of articles published in other languages. Data from studies published in other languages may have altered theme development. Readers should consider the local context when translating findings into practice. Further research is needed to include non-English sources of evidence.
Exclude: not primary academic research	Review articles were excluded to avoid bias due to contribution of same study more than once (e.g. as primary study and as part of a review article). Articles had to be research reports with documented methods and results for the purposes of critical appraisal. Documented personal narratives were not included.
Exclude: no data relating to intensive care	The review question required data from the intensive care setting. Articles were included if they included data on ICU experience, even if this was not the primary focus of the study.
Exclude: 'other' (please explain)	Used e.g. when article found to be unavailable.

2.2.3.2. Screening

I undertook title and abstract screening using a bespoke screening tool developed in EPPI-Reviewer (see Table 2.2). Two reviewers provided a second opinion, each independently reviewing half of the eligible articles. Disagreements between pairs of reviewers were resolved by referring to two further members of the research team. I completed full-text screening of all remaining articles and three reviewers screened a third of this set each. Any disagreements were resolved by the fifth member of the team. To take advantage of the auto-advance function in EPPI Reviewer software, criteria for selecting abstracts or full articles were expressed in terms of exclusions: when a reviewer indicated an article met

an exclusion criterion by checking the box next to it, the article was marked as excluded and the next article was automatically loaded. This meant that where multiple reasons existed for exclusion, only one was noted on the system, with implications for reporting search findings according to the updated PRISMA statement [172] (i.e. reporting number of articles excluded by reason for exclusion).

2.2.4. Data extraction: study characteristics

I developed a data extraction tool within EPPI-Reviewer which I and a second reviewer piloted independently on 4 articles. The two sets of data extracted were very similar and no modifications were deemed necessary. The following data fields were included in the tool:

- Citation details
- Stated aims
- Theoretical/conceptual framework
- Sample size
- Sample strategy
- Sample characteristics
- Inclusion criteria
- Recruitment
- Setting
- Data collection period
- Data collection methods
- Data analysis methods and procedures
- Key findings/major themes
- Author conclusions
- Author limitations

2.2.5. Data extraction: Data items

Whole texts were uploaded to EPPI-Reviewer software [170]. All text from 'Results'/'Findings' onwards was treated as data, including participant quotes, researcher interpretation, statements, assumptions and ideas.

2.2.6. Risk of bias

Quality assessment of qualitative research for inclusion in evidence synthesis has been much debated in the literature, from how to do it to whether it is appropriate or possible [173, 174]. Dixon-Woods et al [175] found there was little agreement between experienced researchers and across different quality appraisal tools on which studies to include or exclude in a review. It is generally accepted now, however, that quality appraisal is necessary to determine the value of a study and the weight of influence it should carry on practice [173, 176, 177], especially in evidence synthesis [178]. Thomas and Harden [156] used a bespoke set of criteria derived from existing sets available at that time, covering reporting of methodological considerations, attempts to confirm reliability and validity, and the appropriateness of study methods to meet the aims of the review. In this systematic review all included studies were critically appraised using the Critical Appraisal Skills Programme (CASP) for qualitative research [179]. The CASP has been endorsed by Cochrane [178] and covers a broad range of criteria that address methodological rigor and transparency of reporting, most of which mirror those collated by Thomas and Harden [156] in their review (including criteria taken from a prior version of the Cochrane Handbook) [180, 181]. It also allows flexibility in appraisal. When addressing analytical methods, for example, the CASP requires appraisors to judge rigor of the analytical process but does not prescribe specific methods or approaches. It was therefore flexible enough to determine trustworthiness of findings from studies using different qualitative methodologies and congruent with the pragmatist approach of this PhD project.

Following the example of a previously published metasynthesis [182], weighting was applied using a 3-point scale to each criterion (0 = not met; 1 = partially met; 2 = fully met) to provide a summary score of quality and aid comparison between primary sources. An additional dimension of 'relevance to the ICU setting' was added during the appraisal process. This aligns with the approach taken by Thomas and Harden [156] whose quality criteria included appropriateness of methods to meet the aims of their review, highlighting the potential for bias in findings when data sources did not closely match the focus of a

study [156]. In this review, some included articles were more focussed on the post-ICU experience of patients with less data on the ICU experience. It is important for researchers to consider how the results of quality appraisal will be used in their research project if the quality appraisal is to add meaningful value [177]. The results of critical appraisal in this study were used to inform a post-hoc sensitivity analysis of findings; no articles were excluded on the basis of critical appraisal, however the sensitivity analysis reviewed the impact of inclusion of lower quality evidence on the research findings. This approach has been recommended as a way to avoid reducing transferability through potentially arbitrary exclusions [173].

2.3. Data synthesis strategy

Thomas and Harden [156] developed thematic synthesis as a method for synthesis of the evidence on topics where little or no direct evidence exists, in their case, barriers and facilitators to healthy eating in children [183]. It was therefore felt to be well suited to synthesising the qualitative evidence on patient experience of tracheostomy on ICU. Thematic synthesis involves an additional step after the derivation of descriptive themes that moves beyond a summative account of the literature to generate a 'fresh interpretation of the phenomena under review' [184]. This third analytical step is similar to the derivation of third order constructs in meta-ethnography [184]. Through this stage, generalisable implications are generated as outputs of the synthesis and this method has been used to inform recommendations for policy and practice in healthcare [151, 153, 184, 185]. The three stages of thematic synthesis are as follows:

1. line-by-line inductive coding of text; development of new codes as each set of findings from studies are coded
2. descriptive themes developed by identifying similarities and differences between the initial codes, then grouped into hierarchical structure.
3. synthesis from each study is reviewed, and newly developed themes applied to the review question (delineated above), resulting in broader, more abstract analytical themes and meta-synthesis.

During the second stage, similarities were noted between the emergent descriptive themes and the dimensions of the Humanisation Value Framework (HVF) [157]. The HVF is a conceptual framework for evaluating how well a healthcare service recognises the patient as a whole and tailors care to suit individual needs. It consists of eight

dimensions of 'humanisation' and provides a reference framework for healthcare workers and researchers (see Table 2.4). In order to explore this further and reveal potential new understandings of the data, descriptive themes and sub-themes from this study were reviewed against the dimensions of the HVF as an extra step to data synthesis: the HVF was used as a lens through which to view and shape emerging analytical themes arising from stage 3 of the thematic synthesis in which the research question was used to interrogate descriptive themes to draw out collective inferences.

2.4. Rigor

Double screening of search returns helped enhance dependability and credibility of search results [186]. To further enhance trustworthiness of research findings, two reviewers followed the three stages of thematic synthesis independently, coming together to review codes and themes and discuss potential new analytical themes, repeating this in an iterative cycle [158]. To enhance the transparency of reporting in this study two tools were used: the ENTREQ [187] checklist for reporting the synthesis of qualitative research was followed to ensure all key details of the study protocol, results and analysis were openly reported in the appropriate sections. The results of search and study selection processes were presented using a PRISMA flow diagram [172]. Feedback on descriptive and analytical themes from the wider PhD supervisory team and PPI group was incorporated into the findings. Together, the measures described above enhanced the trustworthiness, credibility, confirmability, and transferability of findings [146].

2.5. Results

2.5.1. Study selection

A total of 2971 records were identified through the protocolised search (see Figure 2.1) . The breakdown of search returns by source was as follows: database searching – 2887; grey literature searching – 33; citation searching – 28; expert recommendations – 14; journal keyword searching – 5; and author communication – 4. There were 576 identified duplicates leaving 2395 to be screened on title and abstract. One-hundred and twenty-seven items were included in full-text screening and 13 of these were included in the final sample. Reasons for exclusion on full-text screening were as follows: insufficient focus on tracheostomy (e.g. mentioned only as an outcome); no patient experience, views or

opinion presented; no qualitative data; no adult subjects; not available in English; did not include intensive care experience; item was an abstract only or unavailable via UCL interlibrary loan. One article was excluded post selection due to difficulty distinguishing whether quotes and findings were related to orally intubated or tracheostomised patients [188]. A large proportion of new returns found when bibliographic searches were repeated in 2022 and 2024 focussed on technical aspects tracheostomy management. No new primary studies reporting qualitative data on experience of tracheostomy on ICU from the patient perspective were found.

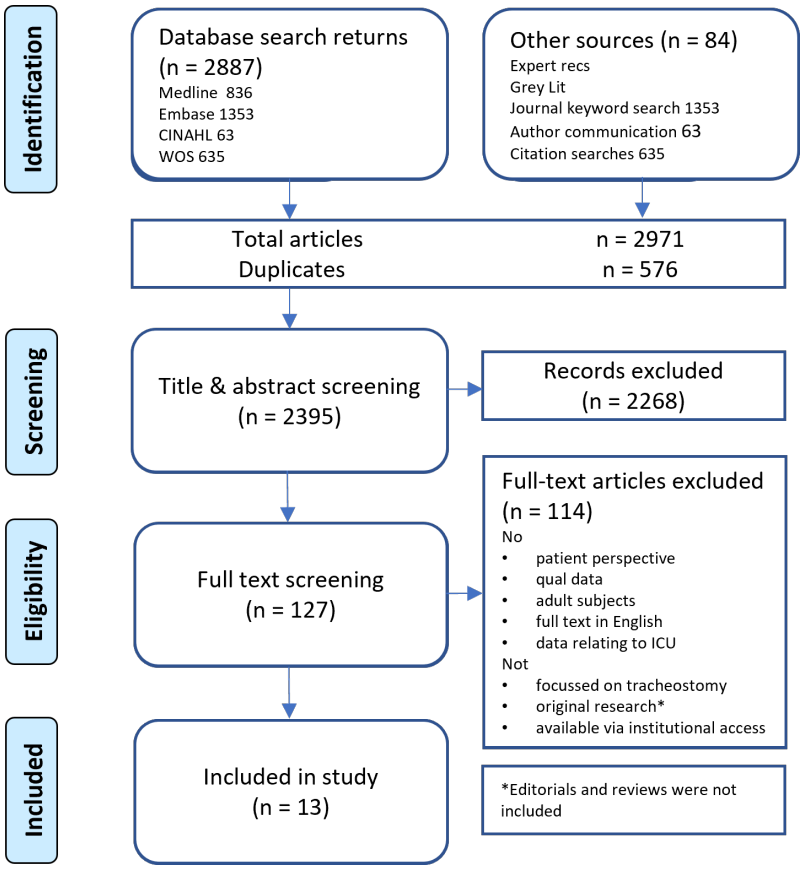


Figure 2.1.: PRISMA flow diagram [189] of article selection process and search results

Within EPPI reviewer there was an 'auto-advance' option that opened the next record as soon as an exclusion criterion box was checked by the reviewer. For this reason, the primary or first exclusion criterion met was usually the only exclusion criterion recorded by reviewers. It was not therefore possible to count how many articles met each exclusion criteria, as required by the revised PRISMA guidance [172]. However, it was possible to reorder the check boxes for convenience of screening, i.e. to move the most frequently checked criteria to the top of the list, and the most frequently checked were 'not focussed on tracheostomy', 'no patient perspective' and 'no qualitative data'.

2.5.2. Study characteristics

The synthesis of findings encompassed data from 203 participants across 7 countries (UK, Australia, Norway, US, Canada, Germany and Italy), published between 2003 and 2019. Table 2.3 shows the characteristics of each study including aims, theoretical framework, sample characteristics, inclusion and exclusion criteria, recruitment strategy, setting, data collection timing, method and recording, data analysis, key findings and author conclusions. Sample sizes ranged from 3 to 81 and age ranged from 19 to 88 in studies where this information was provided. Of the 10 studies (107 participants) who gave details of the sex of the sample, 41% were female. Where ethnicity was described (three studies; 29 participants), the majority were white (n = 26) and all were English speaking. Seven studies included only people who spoke the first language of the country in which the research was conducted. Participants were all patients who had experienced having a tracheostomy, no caregiver data was included. Data was collected via interview in 12 of the 13 studies. At the time of data collection, some patients remained in hospital in intensive care or an acute ward while others were in rehabilitation facilities, their own home or long-term care settings. Research questions related to the lived experience of tracheostomy (n = 8) or mechanical ventilation (n = 4) and eating and drinking (n = 1), all in patients with a tracheostomy. The professional background of the first author by bibliographic indexing was nursing (n = 9), SLT (n = 2), dietetics (n = 1), and medical (n = 1). The collection of qualitative data in the latter study was secondary to the collection of quantitative data on patient anxiety and depression and satisfaction with care.

2.5.3. Risk of bias assessment

Findings of critical appraisal are provided in Appendix D for transparency and to facilitate judgement of transferability of findings to other clinical contexts. All but one article provided a clear statement of the aims of the research. Qualitative methods were deemed appropriate in all cases. Two studies used mixed methods: Freeman-Sandeson et al [190] combined quantitative data obtained through two patient reported outcome tools with qualitative data obtained through structured interviews and McGrath et al [191] used patient questionnaires relating to anxiety and depression and satisfaction with care with answers to a free text response at the end of one of the questionnaires. The qualitative component in the latter study was secondary to the quantitative component, generating a small dataset. Only brief details of the analysis were provided. This and the absence of rich qualitative data and findings was reflected in the low scores on the weighted CASP

critical appraisal tool for qualitative research (15/23, see Appendix D). The amount of detail provided on research design, recruitment and data collection in other studies varied greatly. Some authors described philosophical underpinnings of their research while others provided only brief details of methods. The influence of author choice and journal requirements on what was included in the manuscript may have resulted in aspects of methods being unavailable for critical appraisal and this is acknowledged as a limitation of the critical appraisal process.

Table 2.3.: Characteristics of included studies

Study	Stated aims	Sample characteristics	Setting	Methodology	Author themes	Author conclusions
Arslanian-Engoren (2003)	To describe the experience of patients who survived prolonged mechanical ventilation via tracheostomy and identify factors contributing to liberation	Size: 7, Sex: 6 f, 1 m, Age: 22 - 69, Ethnicity: not given, Other: of 429 eligible patients 227 had died prior to study, 99 uncontactable, 49 declined, 26 no recollection of events, 21 physically unable	University affiliated, urban level I trauma centre. Country: US	Phenomenological study. Data collected via individual, audio-taped, semi-structured interviews.	1. Endures a traumatic experience; 2. Relies on self-determination; 3. Credits family support and devotion; 4. Finds comfort through religion and prayer; 5. Praises health care professionals; 6. Derives reassurance from angelic encounters.	Successful liberation from prolonged mechanical ventilation via tracheostomy was aided by self-determination and the expertise and care of health care professionals. Surviving PMV was frightening and traumatic, but comfort and resolve were derived from family members, religion, prayer and angelic encounters.
Donnelly (2006)	To investigate the lived experience of a tracheostomy tube change	Size: 4, Sex: not given, Age: not given, Ethnicity: not given, Other: 7 approached, 3 declined	Recruited via ICU of a large metropolitan acute care hospital. Country: Australia	Hermeneutic phenomenology study. Data collected via individual, audio-recorded, unstructured interviews	1. Physical sensations; 2. Psychological preparation; 3. Trust and confidence; 4. The essentialness of communication	The experience of a tracheostomy tube change is more complex than that of simply a physical sensation. Patients need to prepare themselves psychologically, trust in nursing staff and be confident in nursing competence. Communication and the ability to speak were at times more significant for participants than the risk of airway complications.

Study	Stated aims	Sample characteristics	Setting	Methodology	Author themes	Author conclusions
Segaran (2006)	To describe what eating and drinking signifies to patients following a critical illness and tracheostomy	Size: 8, Sex: 3 f, 5 m, Age: 32 – 65 years, Ethnicity: not given, Other: diagnoses of GBS, spinal cord injury or disease, TBI, MG	Neuro-critical care unit at the National Hospital for Neurology and Neurosurgery. Country: UK	Phenomenological study. Data collected via individual, audio-taped, in-depth, unstructured, interviews	1. Perceptions of eating; 2. Returning to normality; 3. Eating with a tracheostomy, 4. Eating in critical care.	Eating and drinking are important to the psychological wellbeing of ICU patients and provide a positive milestone to identify that recovery is possible. Eating and drinking signify a to return to normality.
Carroll (2007)	To understand the communication experiences of those who are non-vocal and ventilated	Size: 19, Sex: 9 f, 10 m, Age: 43 – 82, Ethnicity: 18 white; 1 African American, Other: diagnostic groups included respiratory conditions and postoperative complications	Inpatient pulmonary/ventilator units in two acute rehabilitation hospitals. Country: US	Interpretive phenomenological study. Data collected via individual, audio-recorded, semi-structured interviews	Being trapped in a silent world makes me feel frustrated and incomplete; 2. Days pass in slow motion while the rest of the world speeds by; 3. Making and preserving connections is of paramount importance; 4. The powerlessness of being non-vocal was ameliorated by developing coping strategies and by consistent and reliable nursing care. Over-arching theme: Silent, slow life world	Voicelessness leads to a sensation of physical restriction. Lip-reading is valued by patients as it is the closest to natural speech. Time slows for patients who are voiceless. Coping changes over time.
Sherlock (2009)	To explore the experience of patients with a temporary tracheostomy while in hospital, specifically focusing on views of information received	Size: 8, Sex: 3 f, 5 m, Age: 19 – 76, Ethnicity: not given, Other: patient populations included post cardiac surgery; head and neck cancer, neurological condition, respiratory failure	Large teaching hospital, Country: UK	Qualitative study using constant comparative method. Data collected via individual, audio-recorded, semi-structured interviews	1. Physical sensations; 2. Understanding; 3. Information; 4. Experiences after removal of the tracheostomy tube	The experience of tracheostomy is a complex mix of physical sensations and emotions. Tracheostomy may be a relatively routine procedure for clinicians but can be very distressing to patients. Patients need comprehensive information that is tailored to suit individual needs.

Study	Stated aims	Sample characteristics	Setting	Methodology	Author themes	Author conclusions
Briscoe (2010)	To explore the subjective meaning of the experience of transition from spontaneous breathing to reliance on long-term invasive mechanical ventilation	Size: 11, Sex: 9 f, 2 m, Age: 40 – 88, Ethnicity: not given, Duration of ventilation via tracheostomy: 2 to 21 years	Long-term care residence or own home. Country: Canada	Hermeneutic phenomenological study. Data collected via individual audio-recorded, semi-structured, in-depth interviews	1. Tyranny of symptoms; 2. Self in peril; 3. Awakening to a paradox; 4. Struggling for autonomy; 5. Life goes on with a reclaimed self, Over-arching theme: Sustaining Self.	The transition to long-term invasive mechanical ventilation is complex. Individuals need strategies to support sense of self as they transition to dependence on long-term mechanical ventilation. Patient and family education should begin early. Non-vocal patients need an effective means of communication. Transition from hospital to home needs careful planning.
Foster (2010)	To describe the experience of tracheostomy tube in associated with acute or critical illness	Size: 3, Sex: 1 f, 2 m, Age: not given, Ethnicity: white BritishOther: duration of trache cannulation 36 days, 14 days, permanent.	Acute NHS Trust hospital.Country: UK	Phenomenological study. Data collected via individual, audio-taped Semi-structured interviews	1. Necessity of communication 2. Retaining normality 3. Psychosocial discomfort 4. Painful procedures 5. Fear of the unknown 6. Relationships with staff	Care for tracheostomy patients should be holistic. The experience of living with a tracheostomy is complex and dependent on patients' perceptions on the background of their illness and recovery. Communication is essential to ensure patient participation and patient-centred care. Trust in proficiency of staff is also important.

Study	Stated aims	Sample characteristics	Setting	Methodology	Author themes	Author conclusions
Dyrstad (2013)	To describe the lived experience of home mechanical ventilation via tracheostomy and to identify factors associated with user satisfaction.	Size: 6, Sex: 3 f, 3 m, Age: 37 – 78, Ethnicity: not given, Other: range of diagnoses and level of disability, all receiving 24h ventilation.	Participants' own homes. Country: Norway.	Qualitative design using qualitative content analysis. Data collected via individual, audio-recorded, semi-structured interviews.	1. Tailored information; 2. Sensitivity in decision-making; 3; Building trust and confidence. Over-arching theme: Different individual needs require a range of approaches.	Satisfaction with care is improved when patients feel well-informed and involved in decision making from an early stage.
Flinterud (2015)	To describe how tracheostomised patients in intensive care experience acts of communication and to better understand their experiences in the context of the transitions theory	Size: 11, Sex: 3 f, 8 m, Age: 47-72, Ethnicity: not given, Other: duration of tracheostomy ranged from 3 to 27 days. 14 approached, 3 declined.	Patients recruited via 10 bedded ICU. Interviews took place at home, hospital, work. Country: Norway	Qualitative design using inductive content analysis. Data collected via individual, audio-recorded interviews.	1. Emotionally challenging; 2. Experience changes with time; 3. Successful communication, Over-arching theme: Experience of caring and understanding despite having uncomfortable feelings due to troublesome communication.	Caring attitudes and sense of safety communicated by healthcare professionals help patients cope with their situation. Patients place importance on non-verbal communication, such as eye contact and physical contact.
Tolotti (2018)	To describe the experience and sources of comfort and discomfort in tracheostomy patients, when communicating with ICU nurses	Size: 8, Sex: 8 m, Age:36-80. Ethnicity: not given.Other: 1 female recruited but died before interview. Diagnoses of participants included acute medical, surgical, respiratory and neurology	Recruitment via ICU; interviews took place a few days post ICU discharge. Country: Italy	Qualitative study using thematic analysis. Data collected via individual, audio-recorded, semi-structured interviews	1. Feeling powerless and frustrated due to the impossibility to use voice to communicate; 2. Facing continual misunderstanding, resignation and anger during moments of difficulty and/or communication misunderstandings.	Communication is important to patients with a tracheostomy and is intrinsically linked to many aspects of patient experience. Patients struggled with not knowing what was happening, feeling like others had given up on them, living in isolation and feeling invisible. Being with family members, feeling reassured by having a call bell nearby and nurses' presence improved patient comfort.

Study	Stated aims	Sample characteristics	Setting	Methodology	Author themes	Author conclusions
Freeman-Sanderson (2018)	To investigate experience of change in communication function, communication-related self-esteem and quality of life in ICU patients with a tracheostomy	Size: 17, Sex: not given, Age: not given, Ethnicity: not given, Other: recruited from cohort of 30 patients enrolled on earlier RCT. Of patients not recruited 7 had died, 6 not contactable.	Recruited via tertiary ICU, interviewed 6 months post decannulation.Country: Australia	Qualitative study using thematic analysis. Data collected via individual, audio-recorded, structured telephone interviews	1. What is happening to me?; 2. It's hard communicating without a voice; 3. A storm of dark emotions; 4. More than a response…it's participating and recovering	Lack of effective communication reduces patient comfort, emotional wellbeing and participation in care decisions. Strategies to support voiceless patients, including early restoration of voice should be considered early.
Nelissen (2019)	To examine the experiences and life circumstances of people with home mechanical ventilation via a tracheostomy	Size: 20, Sex: 7 f, 13 m, Age: 19 – 86, Ethnicity: not given, Other: duration of ventilation via tracheostomy between 2 months – 24 years	Home/residential ICU/support living. Country: Germany	Grounded theory study. Data collected via individual, audio-recorded, semi-structured interviews.	1. To be seen as a human being; 2. The desire to trust in nurses; 3. To live autonomously again and to regain independence; 4. Seeing HMV as both an aid and an obstacle	Participants living with invasive home mechanical ventilation accepted the associated restrictions since it enabled them to continue living. Adequate information and preparation relating to disease progression and tracheostomy was important to patients. Effective systems of communication were essential.

Study	Stated aims	Sample characteristics	Setting	Methodology	Author themes	Author conclusions
Ng (2019)	To describe the patient experience of tracheostomy	Size: 81, Sex: not given, Age: not given, Ethnicity: not given, Other: sub-set of 120 patients who completed quantitative questionnaire.	Nine UK secondary and tertiary NHS hospitals. Country: UK	Qualitative study design using thematic analysis. Data was collected via three free-text questions from a 33-question written questionnaire.	Positive and negative comments related to 1. Staff care; 2. Clinical management; 3. Communication and information., Other: understanding the necessity of tracheostomy to survive; value of speech restoration; physical discomfort and limitation; fear and anxiety related to tracheostomy	Anxiety, communication impairment and swallowing difficulties are important factors in patient experience of tracheostomy. These could be use as patient-centred indicators of quality of care and used to measure impact of improvement initiatives.

Most studies used convenience sampling strategy (i.e. recruited consecutive patients) or recruited participants from a prior, linked study. Seven studies had fewer than 10 participants, which might be justified where the recruited participants were able to provide sufficient data to meet the given study's aims [164]. As discussed in Section 2.2.2 above, sample size is usually much smaller in qualitative studies than in quantitative since research objectives usually require the capture of rich data on the topic of interest rather than specific data from a large sample that is then amenable to statistical analysis. The smallest sample, however, was three [192]. Despite being described as a purposive sample of patients with lived experience of tracheostomy, this small sample size was felt to limit the transferability of findings and scored accordingly. In keeping with Vasileiou et al's [164]'s review findings on the reporting of sample sizes, reasons given for small samples related to difficulty recruiting due to restricted time or high mortality and morbidity rates associated with intensive care cohorts. In contrast, one study had a large sample of 81 but generated a lower total and per participant volume of data which mostly consisted of short phrases or words, consequently also limiting the value of findings [191].

Data collection was via interview in 12/13 studies. Timing of interviews varied, with some taking place in intensive care units and others a number of years post insertion of tracheostomy. Some authors gave rationales for their approach; earlier interviews could capture experiences and feelings that may be forgotten over time, whereas later interviews allow a period of reflection and processing of thoughts and events. Lowest CASP scores were achieved on author reflection on the researcher-participant relationship, with four studies not addressing this question [191, 193–196]. Most authors reported having obtained appropriate ethical approvals. One study was described as Quality Improvement rather than research, though the authors drew conclusions for the wider target population, which would be considered research under current UK Health Research Authority criteria (https://www.hra-decisiontools.org.uk/research), and therefore require ethical approval. Details of who first approached participants, consent processes and potential impact of participation on participants were lacking from some studies.

All authors named the data analysis approach used but details of analytical processes ranged from naming a specific method and illustrating theme development to providing the general approach. In one article all analysis appeared to be completed by one student researcher with no reference to second reviewers [192], reducing the credibility of findings. Length and number of quotes varied. Some author conclusions were felt not to be strongly supported by participant quotes [193, 195], raising questions of credibility, dependability and confirmability as described by Lincoln and Guba [146]. Finally, variation in clinical

practice was evident across studies. For example, one study writes of voice returning on decannulation, suggesting the research site did not routinely use OWVs. The findings of this study might be different in a facility where OWV use was common, and may reflect geographical variation or change in practice over time.

2.5.4. Descriptive themes

Five major descriptive themes were identified through thematic analysis. These were:

1. Voice and disrupted communication
2. Autonomy and self-identity
3. Cognitive, psychological and emotional needs
4. Physical needs and experiences
5. Facilitators to wellbeing and recovery

The ability of patients to communicate is core to Theme 1 in itself. It was also seen as a common thread in Themes 2-5, forming a foundation upon which successful outcomes in each area depended. A detailed description of each theme is provided below followed by illustrative quotes. Author quotes are shown in plain font and participant quotes are shown in italics for transparency and to aid readers' appraisal of findings. Participant names or identifiers are provided where available.

2.5.4.1. Desriptive theme 1: Voice and disrupted communication

Theme 1 addressed the functional and emotional impacts on patients of not being able to talk, including not being able to express who they were.

(i) How it feels to be voiceless in ICU

Participants in all but one primary study [194] conveyed that being in ICU and unable to speak was a profoundly negative experience, leading to frustration, fear, anger, uncertainty and withdrawal. Some studies reported that being misunderstood and experiencing people mis-guessing a message could be infuriating for patients [190, 192, 197, 198]. The return of speech brought great relief and happiness [190–192]. The depth of feeling as indicated by choice of words was more marked in data from participants with temporary tracheostomies than those with tracheostomies for long-term mechanical ventilation.

"Oh it was horrendous. To not be able to make a sound is the most awful thing, especially when you can't move either. I just felt complete helplessness and frustration. Um … anger at times that nobody could understand." [190]

"Yes, it was a really overwhelming feeling when I couldn't make myself be understood, that they didn't understand me, and that I couldn't tell them anything. That, that was just so distressing.. .it was simply my temper that came, when I realized, I couldn't manage it." [196]

'Not being able to communicate with others was frustrating, hard or difficult, terrible, lousy, depressing, stressful, shocking, horrible, anxiety producing, irritating or aggravating, and "like hell."' [197]

"I tried hard to use my voice but it obviously never came… I could not talk and I naturally tried to speak, I tried to find a way to communicate but I couldn't… I was frustrated.. . Incredible…" [198]

(ii) Non-verbal communication is a poor substitute for speech

When unable to speak, patients used a wide range of means to communicate including mouthing words, shaking/nodding their head, banging on tables, throwing things, gestures, writing, alphabet charts, communication charts and tablets or high-tech communication aids. Whilst some highlighted the benefits of non-verbal communication in the absence of speech [190, 196], most reported dissatisfaction with augmentative and alternative communication (such as alphabet charts, pen and paper), which was described as effortful, slow and often unsuccessful [190, 192, 195–200]. Failure often related to dependence on good limb strength, good cognition, and the skills and patience of the listener. Lip reading was popular with patients, and authors proposed this was due to its closeness to natural speech [196–198], but not all staff were proficient at lip reading [196, 197].

'Many described that they were confident that they would be able to use aids such as an iPad or pen and paper, and they became extremely disappointed when they failed in these efforts.' [196]

"…the frustration of not being able to make myself understood. It was horrible… maybe you want something and gestures are not enough." [198]

(iii) Speech functions: implications of impaired communication

Speech was of fundamental importance to patients. It was the main currency of interpersonal transactions. Without voice, patients could not always ask for the information they

need in order to understand what was happening to them or draw attention to their needs [190, 197, 201]. Not knowing if they would be able to summon help could be terrifying [190, 196, 198, 199, 202]. Non-verbal patients struggled to express their personality and were unable to correct mis-assumptions [190, 196]. This in turn impacted their ability to form or maintain relationships with staff, family and friends [193, 198].

> *''…the call bell reassured me because every time I rang it they came… instead that evening I didn't have it and it was a tragedy… because I thought I would die and instead the nurse saw that I was in a bad condition and she immediately helped me and I asked her to give me a call bell and also my wife can tell you that since then I never let go of the call bell…"* (Agostino) [198]

2.5.4.2. Desriptive theme 2: Autonomy and self-identity

Theme two described the threat to patients' identities whilst they were on ICU with a tracheostomy and patients' ability to take an active role in events, encompassing the freedom to make decisions, determine care, and maintain social roles within and beyond the ICU.

(i) Agency and self-determination

Whilst on ICU, participants with a TT were not always involved in decisions about their care, often due to impaired communication [190, 193–195, 197–199]. Some were acutely aware of their dependency on others, which could lead to a sense of loss of control or influence on what happened to them and a sense of powerlessness. As well as communication barriers, opposing priorities between care teams and patients could restrict the ability of patients to direct or influence care; some spoke of independence and control in care decisions as an important goal but felt staff were more focussed on physical safety [196, 199]. Self-determination was described separately as both having control over care and a mental attitude that drove some patients to fight for control and recovery [194, 200, 202]. One study found that importance of the message determined how hard patients persevered to be understood [197]. In contrast, others found that a sense of futility led patients to give up or withdraw [190, 192, 196, 198]. Families often played vital roles as intermediaries, advocating for patients needs and wishes, and providing motivation to keep going [198, 202].

> 'They struggle not so much with being unable to do anything for themselves, but with having no influence over how anything is carried out' [193]

"..because I couldn't communicate, sometimes I didn't bother. I just felt that well, 'I'll just lay here, I can't really be bothered'…and that's what I done, just switch yourself off with things' ' [192]

(ii) The self and connecting with others

Losing their voice made some participants feel incomplete as a person [192, 197, 199, 200]. Stripped of a voice and ability to convey who they were, patients could become dehumanised with care focussed on the physical body [192, 193, 195, 197, 199]. Some studies reported that creating connections and building relationships was important to patients [193, 197, 198], but without speech this was hard and some participants felt alienated, separated from the rest of the world [192, 197–199]. Families reinforced and sustained a patient's sense of identity and facilitated relationships between staff and patients. Patients praised nurses and other members of staff for their care when they felt well looked after [191–193, 196–198, 200, 202]. Some patients also defended or dismissed examples of perceived poor care such as taking a long time to answer call bells, causing pain on changing a tube, ignoring patients or not making enough effort to communicate with them and some attributed this to staff being over-worked [197, 198, 200]. One study highlighted the importance of preserving the nurse-patient relationship to patients , suggesting a reluctance on the part of the patient to jeopardise this may have led to acceptance of negative behaviours [197]. Patients in one study [198] noted that doctors did not speak directly to patients until their voice returned, whereas nurses, who spent more time with patients and got to know them better, engaged in communication more with them.

"And then the first day I got my voice, it's like a grand opening, you know . . . and I can relate to [others] what went on during the day. Just instead of sitting there like a bump on a log." [197]

"*I was feeling caged, being very smothered and stifled, and that I was losing my own sense of who I am and that, you know. And it was making me hurt inside"* [199]

' '…I felt as if I counted for nothing… I could not say anything… I couldn't interact…" (Lorenzo) [198]

2.5.4.3. Descriptive theme 3: Cognitive, Psychological and emotional needs and experiences

(i) Fear, anxiety, and mental wellbeing

Being in ICU with a tracheostomy was a frightening experience for patients [190–192, 194–202]. Sources of fear were not knowing if they would live or die, having difficulty breathing, not being able to talk, medical interventions, choking or aspirating on food or drink, uncontrolled pain, or simply the unknown. Donnelly et al's [200] study concluded that ICU procedures seen by staff as routine, such as changing a tracheostomy tube were not 'routine' for patients and could cause anxiety. In agreement with this, a patient declined to participate in another study due to the trauma caused by a tube change [201]. Many patients experienced a sense of shock on waking to find they had a tracheostomy tube [195, 196, 201]. However, some with planned admissions described being well informed and prepared in advance [191, 195]. One participant recognised a heightened need for information in response to anxiety [197] whereas others were scared by information provided [201]. These factors and an inability to communicate could cause patients to feel vulnerable and helpless and experience loss of coping [190, 193, 194, 199, 202]. The ability to communicate, provision of information, caring attitudes of staff, and the presence of family were all ways in which anxiety could be lessened [191, 192, 196, 197, 200–202].

> *"I was shaking…"* Interviewer: What did they do to relax you? *"Oh nothing they just calmed me down a bit they just said relax, its nothing major, or anything…its gonna be quick"* (Ada) [200]

> *"It was very scary for me not knowing if I was ever going to be able to get off [the ventilator]. . .all I could think of was is this the way the rest of my life is going to be?"* [202]

(ii) Information needs and situational awareness

Some patients who understood their medical situation could reflect on the necessity of the tracheostomy and appreciated that ICU treatment, including tracheostomy, meant the difference between life and death [191–193, 199, 201]. This helped the acceptance of restrictive treatment but also engendered fear of tube blockage or dislodgement and aspiration or choking on food and drink [192, 194, 197, 198, 200]. In several studies voiceless patients found that staff offered less information or did not talk to them and that they were not always able to ask questions about care [140, 193, 198]. Being well informed helped build a sense of safety for others [196, 201]. One patient recognised that anxiety drove her

heightened need for information and reassurance [197]. In the absence of adequate information, patients sometimes did not know what was happening to them, why they could not talk or if they would ever talk again [190, 195–198]. Some patients acknowledged that confusion or memory impairment made it harder for them to make sense of the situation, or to retain the information they were given [190, 192, 195].

Participants in two studies spoke about watching people and events around them to help them process what was happening [194, 197], and one participant measured their own recovery by comparing themself with other patients. He also reflected on existential questions such as 'why me?' in relation to his progress compared to other patients [194]. Reliance on a tracheostomy for long-term ventilation caused some patients to consider what their situation meant for their life and them as a person, from self-identity to their residential setting and sense of freedom [199].

> 'Despite the frustrations and discomfort that all the participants described, all of them appeared to understand the need for a tracheostomy. They emphasized that they had no choice. They viewed the tracheostomy as a means of survival' [201]

> *"If I knew what to prepare for, it would have been better for me. Not enough knowledge of tracheostomy, did not understand what was happening."* [191]

(iii) The experience of time

Altered perception of time was a major theme in one study [197] and echoed in others whose participants had temporary tracheostomies [[198]; [202]; [201]; [196]. Time seemed to slow and stretch and this was exacerbated by a lack of voice, and the slowness and effortfulness of trying to communicate non-verbally [197]. Some patients feared they may be voiceless forever. A lack of structure in the day or occupation also added to the slowed passage of time [194, 201] and caused boredom [197, 198]. Return of eating and mealtimes gave comfort and normality, bring back routine and helping pass the time [194].

Some studies reported patients' experience changed through the early acute phase to hospital discharge [196, 197]. During this time patients went through a process of adaptation and making sense of their new situation. Developing systems of communication or the return of voice helped this process. Differences were noted in terms of disease stage as well as time since admission to ICU; participants in Briscoe et al's [199] study had chronic respiratory failure and had begun long-term ventilation. These participants spoke of the relief that ventilation provided as well as the restrictions. It was also noted

that anger was predominantly described by participants providing data during or close to the acute phase of their illness, suggesting that this reduced with time.

> 'A participant reflected on the time when she was voiceless and stated that time passed *"very badly. Slowly. And to me, it would never end. Then I was starting to think— I said, 'Oh, my God. This [pointing to tracheostomy, indicating not having voice] could go on and on and on forever."* [197]
>
> "*[time was]…endless, even because you had nothing to do. You just gazed at the people who went back and forth…"* (Giorgio) [198]
>
> *"In ICU there isn't really any routine or pattern, it's just twelve hours of blur. Whereas, with eating, it breaks this up and makes it more like your normal day."* [201]

2.5.4.4. Descriptive theme 4: Physical needs and experiences

(i) Physical sensations related to tracheostomy

Pain directly related to the tracheostomy was reported in four studies and referred to the stoma site, stitches, dressing changes, having a large tube, tube changes and suctioning [191, 192, 200, 201]. Pain was not mentioned in studies where data was collected from patients on long-term mechanical ventilation. Patients spoke of swallowing changes with a tracheostomy, including periods of being unable to eat or drink which they found physically and psychologically challenging [191, 192, 194, 199–201]. Some described cravings for food and intense thirst, with dry mouth meaning desire to drink was strongest [194, 201]. Some were aware of aspirating on food and drink and concerned about possible setbacks to recovery, and some experienced choking episodes [194, 200].

Patients reported difficulties breathing due to their illness, suctioning, a blocked tracheostomy tube, choking or asynchrony with the ventilator and this was frightening [191, 192, 199–201]. Coughing and suctioning were described as tiring and painful [191, 192, 201]. Patients in one study reported variation in staff technique affected discomfort during suctioning [192] but also a sense of relief that secretions had been cleared.

> *"I did want to grab hold of a pint of water and glug it down…it was a bit desperate wanting to have a drink. Food, not so much, but the drinking…You're so thirsty it's unbelievable"* (Pt H) [194]

"The one used was too big and was painful and uncomfortable until it was changed" [191]

'Comments on negative experiences described physical discomfort and limitation (14 responses, 29%), relating to pain and discomfort caused by the stitches or harsh material of the tube, coughing during tube change or suction, and inability to eat' [191]

(ii) Meeting physical needs

Being unable to speak meant patients were not always able to make their needs known [190, 196–199, 202]. This led to enduring pain or discomfort, and fear and uncertainty over whether their needs would be met. Studies focused on communication noted that anticipation of needs improved as staff got to know patients better and as communication improved [196–198]. Some studies found that care was better when staff were competent and teams worked together well, and that patients were upset by conflicting information from team members [191, 195, 200–202]. Patients noted the quality of care they received both in terms of physical care tasks (if they were washed, received suctioning, the inner cannula was changed, suctioning technique), and in the attitudes and behaviours of staff performing them [191, 193, 196–198, 200, 202]. Lack of preparation and information around decannulation meant some patients found the adjustment post decannulation in terms of breathing and stoma healing difficult [192, 201].

"Then it hurt so much I almost screamed my head off. Well, inwardly. But I didn't get out a damn thing. It really hurt. So, it sucks when you can't say anything" [196]

'Participants described impaired communication causing their needs for toileting, pain medication, and suctioning to go unmet..(….). One woman's silent screams were not heard when her oxygen tank ran out. This resulted in extreme anxiety for her because she felt the constant need to ensure that her oxygen tank was full.' [197]

2.5.4.5. Descriptive theme 5: Facilitators to wellbeing and recovery

(i) Improving communication

Finding methods of communication was critical for patients with a tracheostomy in ICU, and no method compared to the return of voice [190–193, 197, 198, 201]. Voice gave patients a sense of freedom, control, ability to join in, request information and ask for

things to be done [190, 193, 197, 198]. In the absence of voice, tailored communication strategies and allowing more time helped patients signal basic needs and have a level of social interaction [190, 196, 197, 201]. Two studies found that familiarity with the patient aided communication, which meant communication with staff improved over time [196, 197]. Family and friends were often able to understand patients the best and acted as advocates and translators [196, 198, 202]. Patients were sensitive to body language, eye contact, touch and staff presence at the bedside, which could communicate a sense of calm, safety and interest in patients [191, 196, 197, 202].

> *''I was very, very pleased! …when you gave me this (speaking valve), one hell of a difference!"* (Colin) [192]

> *"But I recall that she [the nurse] was also very good at holding hands and using touch. And I found that very comforting, so that's really important, you know"* [196]

(ii) Coping strategies and character traits

Different coping strategies were employed by participants to help them get through their intensive care admission [194, 196–198, 202]. Some used humour, some carefully monitored their progress towards rehabilitation goals, while others sought to bring back normality to their daily lives, such as the routine of meals and participation in religious practices. Others focused on staying calm and some used sleep or watching TV as a means of escape. Some referenced spiritual beliefs and deriving strength from these [194, 202], including seeing visions of deceased relatives and angelic beings with messages of strength. Taking control of rehabilitation goals and certain character traits such as self-determination were attributed with coping and encouraging recovery.

> 'Bijal reported that getting rid of tubes was important for psychological and moral reasons. He expressed the need to 'start shedding attachments', which enabled him to 'start believing that the end is in sight'. ' [194]

> 'One participant described conversing with her deceased mother who told her, "*Baby, go back. It's not your time yet. God has something for you to do and you go back.*"' [202]

(iii) Signs that indicate recovery to patients

The removal of the tracheostomy and nasogastric tubes was important and signified recovery to some [194, 197, 201]. One study focussed on patients' desire to return to normality, which meant showering, using the toilet, taking communion, speaking with family and

friends, and going home [194]. In this study eating and drinking brought physical pleasure to patients but also symbolised a return to normality and satisfaction/end to deprivation of basic human needs. However, modified diets or fluids and the ICU environment could make mealtimes feel medicalised. For one patient family presence restored the social aspects of mealtimes. Regaining voice improved patient experience as discussed above; in one study it also contributed to the feeling of getting better [190].

> *"It would appear that often it is less the need for food, than what eating signifies that is important. Eating is part of normal life, it wasn't like I was dying for a plate of fish and chips, but it represented a return to normality and that was so important."* (Fred) [194]

> *' 'It was pleasing to be able to speak again. Mainly you felt as though you were getting better, recovering from the worst of your illness".* (Charles) [194]

(iv) Making sense of the situation

Many patients were reassured and put at ease when staff provided them with adequate information. This was illustrated at different stages of their admission: from understanding why they were admitted, to pre-tracheostomy counselling, to preparation for a tube change [191, 195, 196, 198, 200, 201]. Having a voice helped as it enabled patients to ask for information that they were not given before [201]. Patients with a long-term tracheostomy reflected on their living situation with those living at home expressing more satisfaction [195], and those in residential care or reliant on carers emphasising the importance of autonomy in decisions about care and daily life [195, 199].

> 'Some were satisfied and one HMV [home mechanical ventilation] user stated: "*Yes, I got the information about tracheotomy, we were well prepared".*' [195]

> *"Was well looked after and talked through each part when needed"* [191]

(v) The essentialness of families and relationships with others

Families were a huge source of support to patients. They acted as translators and advocates for patients and their presence brought great comfort [191, 194–196, 198, 202]. For some, they provided patients a reason and motivation to recover [198, 202]. Patients also valued good relationships with staff. Most data referred to nurse-patient relationships and only one study mentioned relationships between patients and therapists [39]. Nurses who were present at the bedside and took time to get to know patients and their needs made patients feel well looked after, and the use of non-verbal communication such as eye contact, holding hands and touch alongside giving patients information provided important

reassurance [191, 192, 196–198, 200–202]. Trust and sense of safety was developed through perception of both competency and caring attitudes of staff and helped mitigate fear and anxiety [191–193, 195–198, 200, 202].

> ‘Several of the participants also highlighted the importance of their relatives being familiar with their usual body language and gestures. This familiarity put them in a good position to understand and relay the participants’ concerns to others.’ [196]

> *’’…I really trusted them, the nurses don’t know how good they are, …they don’t realize how important they are…”’’… they treated me like a baby, they reassured me…”* (Dario) [198]

2.5.5. Analytical themes

The analytical themes and inferred answers to the research question were derived through thematic synthesis as described above (see Section 2.3). Similar to “best fit” framework synthesis [174], this review combined inductive and deductive methods. In contrast, however, the conceptual model used here was selected and incorporated into the analysis process *after* developing and *in response to* the descriptive themes. The ‘human’ aspects of experience and care were noted in the descriptive themes and sub-themes and the Humanisation Value Framework for healthcare [157] helped shape a cohesive conceptual model of the experience of having a tracheostomy in ICU. The eight dimensions of humanisation are shown in Table 2.4 (and Appendix E shows the descriptive themes against these eight dimensions). This step helped reveal the interplay between descriptive themes and move from surface level findings to higher order themes and conceptual understanding of patient experience of tracheostomy in ICU. It also aided interpretation of implications for practice.

Table 2.4.: The Humanisation Value Framework [157]

Forms of humanization	Forms of dehumanization
Insiderness	Objectification
Agency	Passivity
Uniqueness	Homogenization
Togetherness	Isolation
Sense-making	Loss of meaning
Personal journey	Loss of personal journey
Sense of place	Dislocation
Embodiment	Reductionist body

Analytical themes were cross-checked with original texts and descriptive themes to ensure they captured and explained the core concepts identified. Implications for clinical practice were also identified. These are described below and presented in Table 2.5, Table 2.6 and Table 2.7 alongside references of supporting texts.

The three analytical themes identified were: 'Being seen as a whole, unique, autonomous person'; 'Making sense of it, coping, and connections'; and 'Patients' voices as a key currency in humanising care'. Descriptions of themes and the interpretation of 'what matters most' in relation to them are presented below with corresponding implications for practice. The overarching analytical theme was defined as 'To be seen and heard as a whole person'. Patients wanted to be treated as a human, and having a voice made this easier.

2.5.5.1. Analytical theme 1: Being seen as a whole, unique, autonomous person

The evidence suggests that it is greatly important to patients to be seen for who they are as a person, not just for their medical needs. In the studies reviewed, not being able to speak threatened this through changing interactions between patients and staff. It made patients feel invisible [198], not valued as a human being [193, 195, 197, 198, 200], or treated as 'just a "body" on which people act' [198].

> *"they talked as if I weren't there at all. As if I were deaf, or not quite right in the head.. that sort of thing, a bad situation. It was degrading"* [193]

> 'Common to all participants were the communication challenges that occurred while they were in ICU on the ventilator. Their compromised ability to communicate resulted in feelings of frustration, vulnerability, isolation, and a diminished sense of self' [199]

Perceptions of staff not making an effort to communicate with voiceless patients, not attempting to correct misunderstandings, or jumping to conclusions about a message [190, 192, 193, 197, 198, 200, 202] were deeply upsetting to patients, and can be seen as dehumanising. In contrast, Flinterud and Andershed's (2015) [196] study highlighted the value of caring, attentive staff who acknowledged communication difficulties, took time to try to understand, were present at the bedside and communicated through verbal and non-verbal means. Patients wanted to have some control or influence over care and management decisions. This extended from immediate concerns, such as getting basic needs met [196–199, 202], to longer term decisions around rehabilitation or discharge destination [190, 199]. Family was seen to be hugely important to patients [191, 196, 198, 202].

In terms of humanisation, families afforded patients agency through interpreting communication more easily and acting as advocate for patient needs. Functional activities such as eating and drinking were seen to be important to patients for physical and psychological reasons and symbolised not only being human but also milestones in recovery [191, 194, 200, 201].

Table 2.5.: Clinical implications relating to analytical theme 1, with contributing sources

Data generated clinical implications	Source: Primary data	Source: Evidence synthesis
MDT training should cover a) technical and b) compassionate aspects of care, e.g.,		
a) suction technique, inner tube removal and cleaning, stoma care, humidification, pain management	[192, 200, 202]	[191, 193, 195, 197, 198, 201, 202]
b) behaviours such as making eye-contact, touch, being present at the bedside, establishing effective communication, social/non task-focussed communication with patients and getting to know them as a person	[196, 200, 202]	[191–193, 195, 197, 198, 201]
Patients should be screened for tracheostomy related pain		[191, 194, 200]
Treatment goals should be whole-person centred with full MDT input: functional impact must be considered alongside medical/surgical needs and interventions		[192, 194, 202]
Ward rounds should address whole person needs, including communication, return to safe eating and drinking, information, and emotional needs	[191]	[194, 201, 202]
MDT should involve patient in care decisions and activities		[190, 193, 194, 198]
Team members should gather and share relevant person specific information (e.g., religious practices, interests, preferences) with MDT and incorporate in care plans	[202]	[194, 196, 198]

***What matters most*:** Patients need to feel seen as a person as well as a patient. They need to feel they have some control over care and treatment decisions. Treatment plans should take into consideration patients' individual preferences and circumstances. Getting to know patients and their needs and showing kindness and compassion is as important as providing technically competent care and helps patients feel safe.

2.5.5.2. Analytical theme 2: Making sense of it and connections with others

The need to make sense of the situation was a strong theme across studies. Patients wanted to understand what had happened to them, their current situation, and what the future held [192, 199, 202]. Reduced situational awareness due to lack of information, confusion and communication or memory impairment could lead to fear, anxiety, and loss of coping.

Connections and relationships with others were highlighted as important to patients and without them patients felt isolated [191–193, 196–200, 202]. Caring staff-patient relationships were powerful in creating a sense of trust and safety. Connections were made verbally but also non-verbally, through eye contact, presence at the bedside, facial expressions, and touch [196–198, 202]. In this review, connections meant more than simple transfer of information; they meant human contact.

> 'The importance of being well informed, in conjunction with eye and physical contact, was noted by several of the participants. This conveyed calmness and was very important in fostering a sense of security and safety in the participants. One participant emphasised this feeling:
>
> *"But they spoke to me, all of them. I understood that, and it was just fantastic. But I recall that she [the nurse] was also very good at holding hands and using touch. And I found that very comforting so that's really important, you know.""* [196]

Processing and understanding ICU admission is important to patients [190–192, 195–197, 199, 200] as is building and maintaining relationships with those around them [191, 192, 195, 196, 198, 199, 202] 'Making sense of the situation' and 'connections' appear to be interdependent; as staff-patient relationships are established, staff convey more information and provide more social and emotional support [196, 197]. Some studies highlighted the strength of support derived from relationships with family [191, 194, 196, 198, 202].

Table 2.6.: Clinical implications relating to analytical theme 2, with contributing sources

Data generated clinical implications	Source: Primary data	Source: Evidence synthesis
Patients should be given education on tracheostomy: anatomy; function; impact on voice, cough, smell, swallow; weaning plans	[192, 195, 200]	[190, 191, 193, 196, 198, 201]
Patients should be given information on what has happened to them and future treatment plans	[195, 200]	[191, 193, 196, 198, 201]
Quantity, content, and repetition of information should be tailored to needs (e.g., delirium, memory, cognitive, patient preference)		[190, 198, 201]
Patients should be given opportunity to ask questions, with communication facilitated as needed		[193, 198, 200]
ICUs should be aware of and address social and emotional communication needs of patients with a tracheostomy (e.g., wellbeing rounds)	[192]	[190, 197, 198, 202]
Family visits and open visiting policies should be encouraged	[202]	[191, 194, 196, 198]

What matters most: Patients want to know what has happened to them and what the future holds (e.g., prognosis, treatment plans). Not knowing what has happened or is happening can be bewildering and frightening. Feeling connected with others reduces anxiety and the sense of isolation. Family/close friends are the most important social and emotional support to patients. Caring relationships with staff are also important.

2.5.5.3. Analytical theme 3: Patients' voices as a key currency in humanising care

Much of what mattered to patients depended on having a voice, both literal and metaphorical. For staff to see the patient as a whole person; understand their worldview; meet their physical, psychosocial, and emotional needs; and for patients to have a say in care, establishing communication was vital [190, 192, 193, 195–200]. Patients communicated in a range of ways. Voice was valued over augmentative and alternative communication, however, partly due to the efficiency of communication it afforded but also due to its contribution to patients' identities [190–193, 196–198, 200, 201]. Literal voice re-enforced patients' uniqueness as well as facilitating agency.

> *"It was a relief; just so, so good being able to speak…It was so good to be able to communicate normally again instead of trying to mouth words. It was just so much easier."* [190]

> 'When this woman no longer had her tracheostomy tube and therefore was vocal at all times, she said "Look, I'm free! I'm so happy" ' [197]

Table 2.7.: Clinical implications relating to analytical theme 3, with contributing sources

Data generated clinical implications	Source: Primary data	Source: Evidence synthesis
Voice restoration should be given high priority	[190, 191]	[196–198, 200–202]
MDTs should consider the impact on voice of interventions and aim to maintain/restore voice where possible (e.g. early assessment for cuff deflation and speaking valve use, selection of the appropriate type and size of tracheostomy tube, ENT referral, Speech and Language Therapy (SLT) referral)		[190, 191, 196–198, 200–202]
When voice is not possible, personalised alternative methods of communication should be established, with consideration of physical and cognitive ability and referral to SLT if needed	[190, 192, 197, 199]	[190, 193, 196, 198, 202]
Non-verbal communication should be as natural as possible to patient (e.g., lip reading if able to mouth words)	[197]	[193, 201]
MDT training should be given training on supporting verbal and non-verbal communication and when to refer to SLT	[192]	[190, 193, 198]

Data generated clinical implications	Source: Primary data	Source: Evidence synthesis
Family and staff should check they have understood the patient correctly to avoid patient frustration		[190, 195, 198]
All patients with a tracheostomy should be provided a call-bell	[192, 198]	[191]

What matters most: Having a voice is hugely important to patients. Voice contributes to patients' identities and underpins their ability to make needs known, participate in care decisions, seek information, and build essential connections with others. Family/close friends can mitigate the impact of voicelessness through helping staff get to know the person, which in turn facilitates communication and anticipation of needs.

2.5.6. Sensitivity analysis

Sensitivity analyses have been proposed as a way to explore the impact of including lower quality evidence in qualitative systematic reviews and to avoid unnecessarily excluding articles [173]. However, we found that one of the top scoring studies [199] on appraisal using a modified CASP [182] contributed relatively little to findings, whilst a lower scoring article [196] contributed much more. We noted that in the former study it was not possible to discern whether some sections of text related to the experience of tracheostomy or long-term mechanical ventilation and these sections of the manuscript had therefore been excluded from analysis. The lower scoring article received fewer points in critical appraisal for clarity of reporting of aims, recruitment strategy, and ethical approvals. However, the authors provided a comprehensive theoretical framework for findings and their primary data gave revealing insights into the perspectives of the participants, who matched the target sample of this review well. This may highlight the strengths and weaknesses of the CASP in capturing quality of reporting in studies versus their conceptual value [177].

In order to address this issue, we completed two sensitivity analyses: one based on scores using the CASP and one based on a three-point grading of relevance of the study to the review question. Points were awarded depending on how closely studies met the target of reporting on experience of tracheostomy in the ICU setting, for example Tolotti et al's study [198] collected data during ICU admission on experience of communication with a tracheostomy and therefore scored three points for relevance, whereas Drystad et al's [195] data included data from the ICU admission period but was primarily focused on the experience of home mechanical ventilation via a tracheostomy. The latter study therefore scored one point for relevance.

Table 2.8.: Study rankings by modified CASP and Relevance scores

(a) CASP score

Studies ranked by CASP score	CASP total
Briscoe [199]	18
Carroll [197]	18
Sherlock [201]	18
Drystad [195]	17
Donnelly [200]	17
Nelissen [193]	17
Freeman-Sanderson [190]	17
Arslanian-Engoren [202]	16
Tolotti [198]	16
Segaran [194]	15
Foster [192]	15
Flinterud [196]	14
McGrath [39]	14

(b) Relevance score

Studies ranked by relevance score	Relevance score
Sherlock [201]	3
Freeman-Sanderson [190]	3
Tolotti [198]	3
Segaran [194]	3
Foster [192]	3
Flinterud [196]	3
Carroll [197]	2
Donnelly [200]	2
Nelissen [193]	2
Arslanian-Engoren [202]	2
McGrath [39]	2
Briscoe [199]	1
Dyrstad [195]	1

Table 2.9.: Impact of including studies with lower risk of bias scores

Descriptive theme	Impact of including studies with lowest CASP scores [39, 196]	Impact of including studies with lowest relevance scores [195, 199]
Voice and disrupted communication	Both studies contribute to the sub-theme on negative emotions relating to not being able to communicate. Some participants in one study [196] were surprised and disappointed to find they were unable to use communication aids; this was not reported by other studies. No unique findings were drawn from the other study [39].	Anger at communication difficulties was not present in these two studies, possibly reflecting change and adaptation to participants' situation over time
Autonomy and self-identity	One study reported a sense of powerlessness in line with higher scoring studies. Loss of control was described in relation to participants' sense of coping rather than having agency and participating in treatment decisions. This study also observed that communication impairment prevented patients expressing their personality, contributing to the self-identity facet of this theme [196]. The other study provided data supporting the importance of family connections to patients [39].	Nuanced differences in nature of struggles for autonomy and self-identity: LTMV users fought for autonomy related to discharge destination, relationships with professional carers and day-to-day activity. Identity issues related to long-term changes in concept of self and ongoing changes in role, rather than struggles to convey self-identity and build connections with others during the acute phase. Some participants highlighted the process of coming to terms with being permanently dependent on technology to survive whilst fighting to not be defined by the same technology [199]. As with studies in the hospital setting, some of the other study's participants felt they were not 'seen' and that staff were more interested in the ventilator than them as a person

Descriptive theme	Impact of including studies with lowest CASP scores [39, 196]	Impact of including studies with lowest relevance scores [195, 199]
Cognitive, psychological and emotional needs and experiences	Both studies contributed to findings on fear and anxiety related to tracheostomy in ICU. One added to the findings that staff behaviours and attitudes were important in delivery of care by highlighting the specific role of touch and eye-contact [196]. They also emphasised that patients could experience feeling well cared for despite the difficulties cause by communication impairment. The other contributed to the information needs facet of this theme, supporting other authors who found these patient needs were often not met [39]. One study added to review findings relating to the experience of time, highlighting that communication, including use of communication aids, improved over time [196].	Similar levels of fear and anxiety were described by both studies' participants relating to their ICU experience. Qualitatively different information coded under 'life vs death' in the studies of long-term ventilated patients: the benefits of ventilation included relief from long-term symptoms, increased energy levels and the ability to function better cognitively. Paradoxically, for this group, ventilation also represented greater restrictions due to patients' reliance on it for life beyond hospital discharge
Physical needs and experiences	One study did not provide data contributing to physical sensations related to tracheostomy [196]. The other added unique findings relating to pain caused by tracheostomy stitches, the material of the tube and large tubes, and that some patients reported no tracheostomy related pain [39]. One of the studies contributed to the sub-theme of 'Meeting physical needs', illustrating the distress caused by inability to signal care needs due to impaired communication [196].	One patient recounted difficulty synchronising breaths with the ventilator which was not mentioned in other studies. However, this is not specific to the experience of tracheostomy.
Facilitators to wellbeing and recovery	Both studies contributed to the sub-themes of 'Improving communication' and 'The essentialness of families and relationships with others'. Both reported data on warm attitudes of staff contributing to a sense of feeling well looked after.	One study did not feed into the final theme [199]. Participants in the other study [195] faced slightly different challenges relating to relationships with others and the sense of feeling safe in the residential setting; changes of staff were challenging as new relationships had to be built and some healthcare professionals were more competent and confident than others.

2.6. Discussion

This review suggests a discrepancy between the evidence base on tracheostomy management and the primary concerns of patients; while researchers have largely focused on technical issues of tracheostomy insertion and epidemiology, the core priority of patients with a tracheostomy on ICU was to be seen and treated as a human. This discrepancy could yield significant detrimental impact on the clinical care offered to patients.

2.6.1. Descriptive Themes

The descriptive themes in stage two of the analysis provided the building blocks for analytical themes and the inferred practice implications. The first descriptive theme concurred with previous studies that have found an inability to communicate is one of the hardest things ICU patients have to face and leads to anxiety, frustration, anger, and untreated pain [73, 74, 76, 77, 203]. Alternative forms of communication and staff training have been shown to improve patient communication [204–207]. However, supporting previous research findings this review highlighted that augmentative and alternative communication often fails [208], and the data corroborate previous assertions that patients most highly value having their own voice [143, 209]. In line with theories of stress and coping [210, 211], our second descriptive theme showed that sense of autonomy and self-determination aided coping whereas lack of control could lead to loss of coping and withdrawal, with implications for rehabilitation and recovery. This theme also described the impact of being on ICU with a tracheostomy on patients' sense of identity and interpersonal connections. Little other evidence of this was found in the literature. The third descriptive theme found many patients were fearful and anxious, which is known to be common in ICU patients [2, 212–214]. This review found a lack of information and situational understanding contributed to fear and anxiety and is intensified by voicelessness. The fourth theme, relating to physical experience, identified sources of pain and discomfort that have been described elsewhere. However, pain and difficulty breathing were less dominant than experiences of thirst, swallowing difficulties and sense of physical restriction that resulted from being voiceless. The fear of not being able to flag physical needs or call for help appeared to cause more distress than the physical experience itself. The fifth theme described positive influences on patient experience. Of note, four of the five themes characterising experience of tracheostomy on ICU related to social, psychological and emotional experiences, not physical ones. Similarly, in a qualitative metasynthesis of the experience of being mechanically ventilated [215], 13/15 abstracted findings related

to non-physical experiences, and experiences relating to communication; the presence of staff; and fear, anxiety and loneliness; were more commonly reported than difficulties breathing or the experience of being suctioned.

2.6.2. Analytical Themes

The analytical themes moved beyond the initial findings to develop a cohesive, conceptual picture of patient experience and provide interpretations of what matters most to ICU patients with a tracheostomy. This stage of the metasynthesis of study findings was supported by a model of humanisation [157].

The finding of the fundamental need to be seen and treated as a whole person fits with philosophical theories of humanism [157, 216], phenomenological embodiment [217] and person-centred care [111, 114, 218] and contradicts Cartesian views of mind-body separation or Maslow's hierarchy of needs model [219]. The psychological, social and emotional needs of ICU patients with a tracheostomy were found to be of fundamental importance, and that ignoring this risked patient dehumanisation. Findings suggest that the provision of adequate information that is tailored to patients' needs helps satisfy the fundamental human need to make sense of what is happening. This is consistent with the theory of 'facilitated sense-making', which, though developed to guide interventions to support families of ICU patients, states that when faced with crisis humans need to make sense of the situation and of their new role [220]. Participants in the selected articles placed great importance on relationships with others. Family presence brought solace and could facilitate communication, consistent with previous literature [69, 221, 222]. In contrast, Halvorsen et al [223] found that family presence could in some circumstances be a source of distress, for example when patients were aware of the impact of their own illness on their family and advocated a tailored approach to family visiting. Additionally, Broyles et al [224] identified that families often lacked skills to support their non-vocal relative to communicate, which could be upsetting to both family and patient. Interestingly, a recent development of facilitated sense-making has added 'patient-family communication' to the model [225]. Staff relationships were also important, and patients distinguished between two types of care: competent completion of tasks versus caring attitudes and behaviours, including efforts to communicate with them and being present at the bedside, echoing previous research [226–229]. Presence in turn supports communication and information exchange, allowing staff to get to know the 'person' in the patient. The Humanisation Value Framework [157] concept of 'togetherness' may help explain why nurse and family presence and caring attitudes and behaviours were significant to patients. This review found that

non-verbal communication from staff such as touch was an important means of connecting which fits with studies of the role of touch in human social bonding, stress and pain relief [230–232].

This review supports Happ's [88] concept of 'voicelessness' in intensive care, which describes the complex impact of communication impairment on the feelings and actions of patients, clinicians and families. Additionally, it highlights the importance of voice to identity and autonomy, lending support to the theory of voice as an embodied entity as described in one of the selected studies [197]. Interesting parallels are drawn between this review and Pound and Jenson's [233] investigation of humanising and dehumanising aspects of care reported by aphasic patients. In common with them, this metasynthesis found good communication between staff and patients was key to achieving humanised care. Interestingly, whilst augmentative and alternative forms of communication was often associated with failed attempts at communication and frustration, non-verbal communication such as touch and eye contact was powerful in conveying caring and safety. It may be that this fits with findings of patients valuing naturalness of communication or the ease of interpreting non-verbal communication. Future research would be useful to investigate the apparent contradiction and explore ways to harness the broader spectrum of human modes of communication [234] to mitigate the impact of voicelessness on adults with a TT in ICU.

2.6.3. Clinical implications

There are notable similarities between the clinical implications identified here (see Table 2.5, Table 2.6 and Table 2.7), and recommendations from the International Research Project for the Humanisation of Intensive Care Units (HU-CI) [235–237], a Spanish-based group whose aim is to promote the humanisation of ICU through research, training and education and a certification programme for healthcare organisations. Unlike the HU-CI team, no recommendations were identified for end-of-life care or improving staff experience, which is likely due to the focused research question and search strategy of this review. However, since approximately one in five patients with a tracheostomy will not survive to hospital discharge, the focus on what matters most to patients is all the more relevant for this group to enable dignity at the end of life [238]. The importance of patient communication is clearly reflected in HU-CI's standards, as in this review [239]. A principal difference is the fundamental importance of voice to patients found in this review and its role in supporting whole-person, humanised care. This review indicates that voice should be given high priority in TT sizing decisions at time of initial insertion and

that speech and language therapists should be core members of the multidisciplinary ICU team. It also indicates that voice restoration is a core outcome measure that should be used when assessing quality of care and impact of interventions for ICU patients with a tracheostomy.

2.6.4. Strengths and limitations

The quality of review findings are inevitably impacted by the quality and availability of primary data. Methodological weaknesses were noted in selected articles and there was limited ethnic diversity of the pooled sample, which affects transferability of findings. The number of included articles may appear low compared to a quantitative systematic review. However, the intent of qualitative metasynthesis is interpretation and theory development and not prediction [152, 176, 240]. Value is given to the richness of data and contextual relevance, or 'information power' (see Section 2.2.2). The sample size of this review reflects its focussed topic and is in keeping with the sample sizes of other published metasyntheses [241–245]. A strength this review's design was the inclusion of the voices of over 200 patients, supporting the credibility and transferability of findings and providing important knowledge that could shape future clinical practice.

It is acknowledged that the exclusion of patients in the primary studies due to language barriers and language or cognitive impairment, including ICU-related delirium, limits transferability of the review findings to non-Western cultures and patient groups with language or cognitive impairment, particularly in the early days of intensive care admission. However, given the importance of patient communication in assessing delirium (and moreover, capacity to consent or decline treatment), it is suggested that the findings around the importance of voice restoration are applicable to those patients deemed to have delirium in ICU. This is highlighted by a PPI group member's experience of being incorrectly diagnosed as delirious rather than in pain, and consequently being sedated.

A change in analytical methods from those outlined in the protocol is also acknowledged with the introduction of the Humanisation Value Framework [157]. However, transparency in the reporting of the rationale for this step and its enhancing influence on findings is proposed as justification for the amendment.

2.7. Conclusion

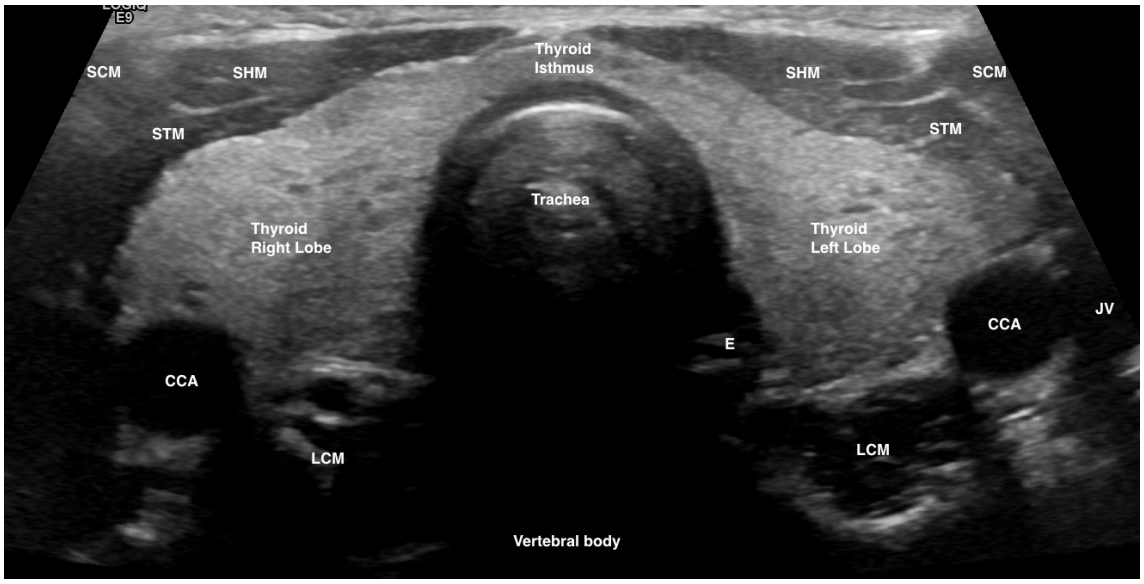
The key finding was that ‘Patients want to be seen and treated as a whole person, and having a voice makes this easier’. This finding should be used to inform quality improvement initiatives in tracheostomy care. It is recommended that voice restoration take high priority in tracheostomy management decisions such as tracheostomy tube size selection, cuff deflation, and use of OWVs. Staff tracheostomy training should focus on both technical skills and compassionate, whole person care. Improving technical aspects of tracheostomy management is important, but should be addressed in conjunction with, and not at the expense of, improving human experience.

3. Cadaver Study

3.1. Introduction

This chapter describes a series of small studies undertaken in response to questions raised during ultrasound training and during the process of collecting measurements of inner tracheal diameter for the observational study presented in Chapter 4. Ultrasound refers to soundwaves with frequencies above human hearing. Ultrasound can be used clinically as an imaging modality. A transducer containing piezoelectric crystals connected to an electrical pulse generator emits and receives soundwaves which are converted back to electrical signal and then greyscale images [246, 247]. The acoustic impedance of body tissues, which is related to their density, and the relative density of adjacent structures dictates the level of brightness of a structure on the ultrasound image. The higher the frequency of the soundwaves, the higher the resolution of the image and vice versa. Ultrasound is used by head and neck surgeons, radiologists and endocrinologists to examine head and neck malignancies and thyroid disease, and guide needle biopsies or botox injections [248, 249]. Figure 3.1 is a transverse view of the anterior neck, illustrating the appearance of various structures on ultrasound [250]. Ultrasound is increasingly used on ICU where multiple applications of airway ultrasound have been described including: evaluation of airway size and prediction of airway tube size; prediction of difficult intubation; confirmation of endotracheal tube placement; identification of cricothyroid membrane for emergency airway placement; screening for vessels prior to percutaneous tracheostomy; screening for airway pathology; and predicting post-extubation stridor [95, 98, 251, 252]. Several groups have documented the use, including validity and reliability, of ultrasound in measurement of airway diameter [96, 98, 253–256]. Others have found that ultrasound measurement of the trachea improved size selection of double lumen airway tubes in adults and children [257–259]. Some have reported that airway ultrasound is relatively simple and quick to learn [98]. However, tracheal ultrasound can be challenging, largely due to the presence of air in the trachea, which generates artefact and can make interpretation of images difficult, but also due to the round shape of the anterior trachea, complex

nature of neck anatomy that makes anatomical landmarking difficult, and calcification of cartilages [261, 262]. However, in some fields the presence of air and its related artefact has been studied and led to the ability to use air artefact in images to aid differential diagnosis, for example in lung ultrasound [263].



SCM - sternocleidomastoid muscle; SHM - sternohyoid muscle; STM - sternothyroid muscle; CCA common carotid artery; jugular vein; LCM - long cervical muscles; E - oesophagus

Figure 3.1.: Ultrasound view of the transverse anterior neck [264]

The shape of the trachea varies between subjects but is generally described as a horseshoe shape, with a round anterior cartilaginous portion and a flat muscular posterior portion. The antero-posterior dimension is usually longer than the transverse dimension and more markedly so in some airway disorders such as saber-sheath trachea [91, 92, 94]. Ultrasound-acquired measurements of the anterior-posterior dimension have been found to poorly correlate with other imaging modalities due to air artefact preventing imaging from an anterior approach and difficulty gaining a suitable view from a lateral approach [96, 98]. The uni-dimensional ultrasound measurements obtained of the non-circular cross-sectional slice of the trachea are acknowledged as a limitation of this tracheal measurement technique in the context of tracheostomy tube size decision making. However, TTs are circular in cross-section, and since transverse tracheal diameter was smaller than antero-posterior tracheal diameter, it was felt to be more important in terms of ensuring a TT fitted without contacting the tracheal wall.

Early in ultrasound training it proved difficult in some cases to distinguish the cricoid cartilage from tracheal rings and to be certain of which part of the ultrasound image represented the inner tracheal wall. The literature was reviewed again for specific details of methods used to obtain ultrasound measurements of the trachea. No evidence on tra-

cheal ultrasound was found in educational sources for head and neck sonography, which largely focus on head and neck carcinomas and other thyroid and salivary gland pathologies [265]. Review of primary research evidence revealed inconsistencies in labelling of anatomy, for example Lakhal et al. [98] presented a figure that shows a homogeneous pale grey arch and dark horse-shoe shaped forms within it (see Figure 3.2). The authors labelled the inner dark horse-shoe shape as the cricoid and described the air-mucosa interface (AMI), i.e. the inner wall of the airway, as hypoechoic (dark on ultrasound). However, a pale grey arch around cartilage would suggest the image showed the thyroid gland around a tracheal ring and, in ultrasound literature, the border between adjacent objects of strongly contrasting echogenicity are described as *hyperechoic* (bright white), with the brightest white line on tracheal ultrasound usually identified as the AMI [252, 261, 266–268]. In Lakhal et al's [98] figure, the brightest white line has been labelled the external cricoid perichondrium. An alternative explanation is that the pale grey arch is the cricoid itself, since in paediatrics the non-calcified cartilage can appear a paler grey rather than dark or black [269], which would mean Lakhal et al. [98] had incorrectly labelled air artefact as the cricoid cartilage. The latter explanation is plausible since participants in their study were young adults.

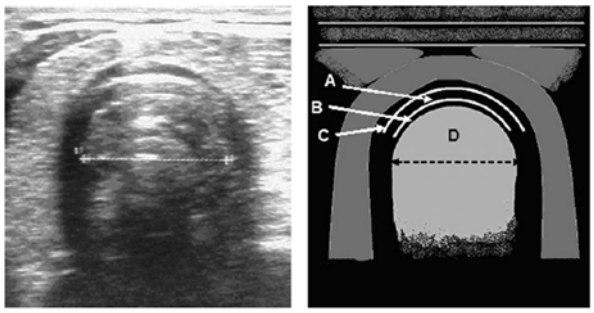


Figure 1. The cricoid arch and the air-column, ultrasonography view. Cricoid cartilage is a round hypoechoic structure (the medulla (A)) with hyperechoic edges (the internal (B) and external (C) perichondrium). The air-column (D) appeared hyperechoic and created a posterior acoustic shadow. The mucosa–air interface, a hypoechoic edge, was easily recognized. The dotted line represents the measured air-column width.

Figure 3.2.: Labelling of airway anatomy in Lakhal et al. [98]

While it appeared likely that Lakhal and colleagues had misidentified airway cartilage, others have similarly presented tracheal rings as cricoid cartilage or cricothyroid membrane [254, 270], or reverberation artefact as airway cartilage or the AMI [254, 259], indicating that image interpretation could be challenging. In addition, patterns of tracheal artefact seen during data collection did not always fit the picture of air-induced reverberation artefact, which is described in the literature as equally spaced repeating lines descending the image (see Figure 3.3). Instead, some images showed distinct shapes within the air column and no repeated lines (see Figure 3.4). A similar pattern can be seen in images presented by Jain et al. [271] where two thick black rings are bordered by thin white lines and separated by a thicker white line and within the rings, dark shapes are seen on a

mid-grey scale background (see Figure 3.5). Again, authors have labelled the cartilage as the cricoid, however there is thyroid tissue anteriorly and laterally to the cartilage which suggests it is a tracheal ring. From the positioning of measuring calipers, they also appear to have interpreted the inner white line bordering the thick black rings (and not the central brightest white line), as the AMI.

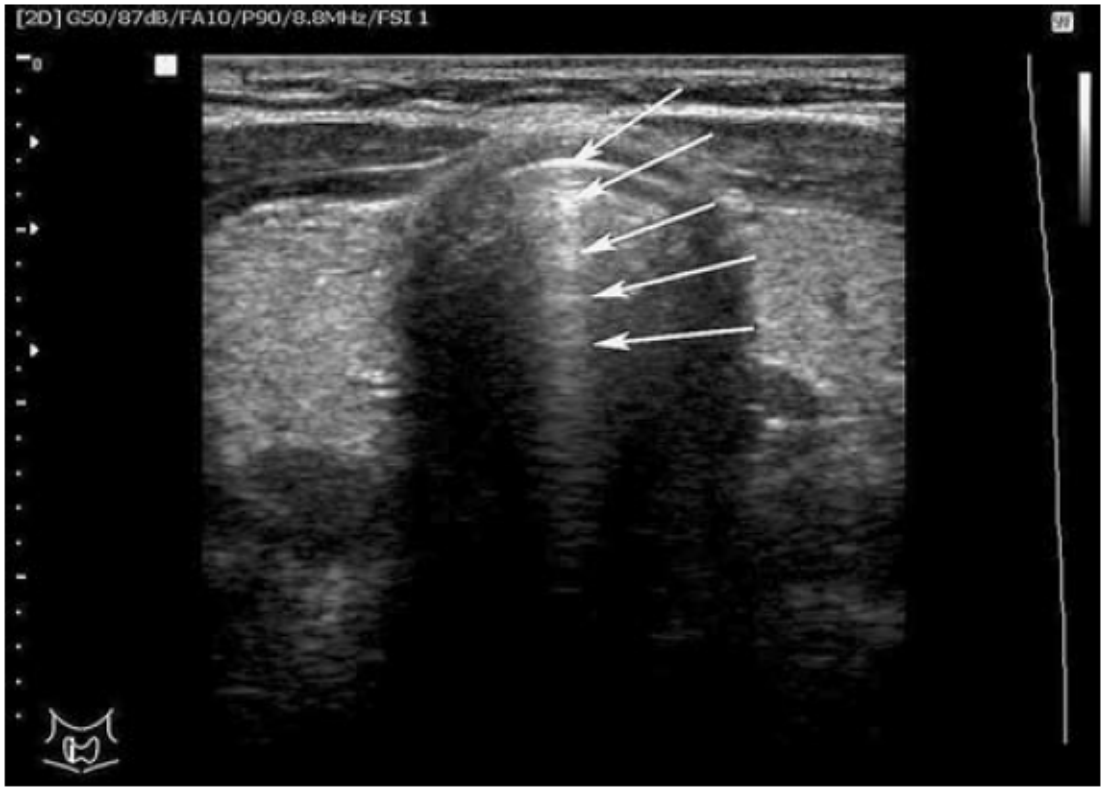


Fig 3. Transverse view: reverberation artifact behind the trachea wall (white arrows).

Figure 3.3.: Reverberation artefact within the air column [272]

In order to better understand the sonoanatomy of the trachea to support decisions on where to place measurement calipers on ultrasound imaging, additional work was undertaken prior to and following data collection for the observational study presented in Chapter 4.

The primary and secondary objectives of this work were to:

1. support ultrasound tracheal measurement procedures through identifying and describing the appearance of the inner tracheal wall and other airway structures on ultrasound imaging, and distinguish these from artefact
2. assess validity and inter-rater reliability of ultrasound measurements of the trachea

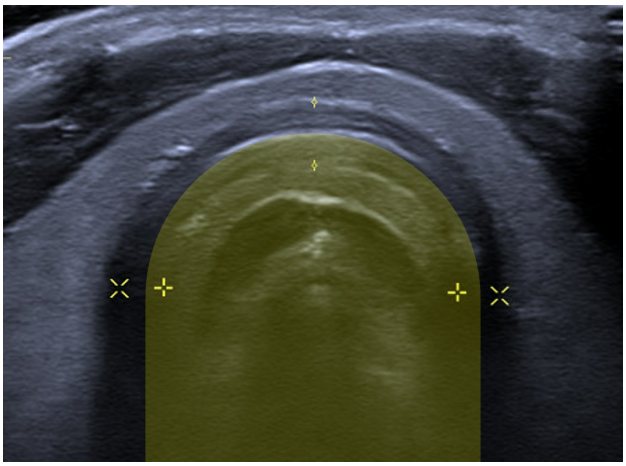


Figure 3.4.: Observational study image of non-reverberation artefact within the air column (yellow shaded area)

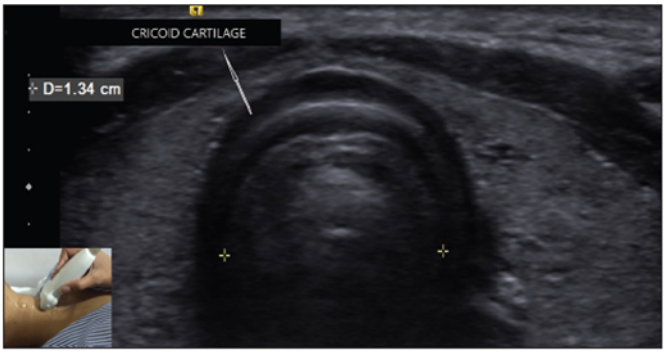


Figure 5: Subglottic diameter (air column measurement) for determination of appropriate endotracheal tube size

Figure 3.5.: Published image showing non-reverberation air artefact [271]

3.2. Methods

Sonoanatomy of the trachea was investigated using ultrasound imaging of a pig, sheep and human cadaver trachea. Animal models have been used in medical research for many decades. Porcine and ovine models have been used in respiratory medicine research due to the similar size and anatomy to human respiratory anatomy, and due to the relative expense and scarcity of human cadavers [273–276]. The pig specimen comprised of an intact larynx, trachea and lungs and was a by-product of the food industry, obtained through a local butchers. Images from the pig trachea were captured in collaboration with a consultant intensivist who was leading on training and education in point of care ultrasound (POCUS), for critical care, including airway ultrasound. The sheep specimen had been involved in a trial of hypothermic machine perfusion for the preservation of donor hearts for transplantation by the Critical Care Research Group (CCRG), in Brisbane, Australia. Animal ethics for the trial was approved by the QUT Animal Ethics Committee (AEC)(16000001109 and ratified by the University of Queensland AEC (QUT/393/17/QUT)) [277]. Access to the post-mortem specimen and collection of images was through collaboration with the CCRG following a clinical academic placement visit to Australia as part of my PhD fellowship. No animals were sacrificed specifically for this study. Data collection involving human cadavers was undertaken in a collaboration with Kings College London Anatomy Department. Fresh and fresh-frozen cadavers were obtained and stored under licence (licence number 12123) and in accordance with the Human Tissue Act 2004. Use of fresh (non-embalmed) specimens allowed imaging under tissue conditions similar to those in living subjects. The use of ex-vivo subjects permitted flooding of the trachea with water without causing risk to life. Flooding the trachea enabled elimination of air and therefore air-related artefact, which was a principal cause of the difficulties encountered in airway sonography. Comparison of images of water-filled versus air-filled tracheas aided discrimination of true anatomical landmarks from artefact.

The accuracy and inter-rater reliability of ultrasound measurements of the trachea were investigated by calculating agreement between ultrasound measurements of the trachea and reference measurements. Reference measurements were obtained using endoscopy and a marked needle in fresh-frozen human cadavers (see Section 3.2.2.1). This part of the study was also performed in collaboration with King's College London Anatomy Department.

3.2.1. Sonoanatomy and artefact

3.2.1.1. Pig

Images of a fresh resected pig trachea were obtained using a Fujifilm Sonosite^{TM} POCUS machine (Amsterdam, The Netherlands), and linear high frequency transducers. POCUS machines are portable ultrasound machines that can be used at the bedside outside of the radiology department. The high frequency transducers are suitable for imaging superficial anatomy. Settings were selected based on image clarity, commencing with 'MSK' (for musculoskeletal imaging) or 'Superficial' initial presets with tissue harmonic imaging on and adjusting other settings (depth, dynamic range and gain), as required. Still and video images were collected of the dry trachea, intubated trachea with a water-filled endotracheal tube cuff, and trachea submerged in water. Following ultrasound imaging, photographs were taken of the whole specimen and longitudinal and transverse slices to compare with ultrasound images.

3.2.1.2. Sheep

Video and still images of the in-situ sheep trachea were obtained using a GE Venue^{TM} POCUS machine (Chicago, US), with a high frequency linear transducer and tissue harmonic imaging on. Ultrasound settings were adjusted as required to obtain a clear image. Transverse and longitudinal views were obtained with the sheep in side-lying position, with and without water in the trachea.

3.2.1.3. Human

Static and video images of an in-situ cadaveric trachea were captured using a Mindray TE7^{TM} POCUS machine (Huntingdon, UK), with a high frequency linear transducer and tissue harmonic imaging on. A nerve preset was selected (suitable for superficial imaging) initially. Ultrasound settings were then adjusted as required to obtain a clear image. A non-embalmed cadaver was selected as it was assumed that the dehydrating and stiffening effect of the embalming process and change in relative density of adjacent tissues would impact image quality and likeness to in vivo images. Longitudinal and transverse ultrasound images of the upper airway were taken from the thyroid cartilage down to the tracheal rings. The trachea was then filled with water via an endotracheal tube inserted

through the mouth and imaging was repeated to facilitate identification of true anatomical landmarks from air artefact. Images of the air-filled and water-filled trachea were compared. Video imaging was captured of the water-filled trachea as an air-pocket was introduced. This was achieved through raising and lowering the mandible which raised the trachea slightly and allowed observation of the appearance and disappearance of air artefact.

Longitudinal and transverse video images were compared to images obtained earlier on the day of data collection from a human volunteer using the same ultrasound machine and settings, and to images obtained from volunteers during training on a high-end radiology ultrasound machine (Siemens Acuson S3000 ^{TM}, Forcheim, Germany).

3.2.1.4. Analysis

Analysis of the anatomy and artefact seen in ultrasound images involved comparing images across specimens and conditions (i.e. whether the trachea was filled with water or air). Similarities and differences were identified and described.

3.2.2. Validity and reliability of ultrasound measurement of the trachea

Comparison of ultrasound measurements with reference measurements and inter-rater reliability were investigated in fresh frozen cadavers for the same reasons given above. The sampling strategy was limited by availability of cadavers. Sample size was expected to be small since fresh frozen cadavers are less frequently available than embalmed cadavers and dependent on donation rates at the time. The same POCUS machine and settings were used in this work as for the work on identifying and describing tracheal sonoanatomy.

3.2.2.1. Reference measurement

Reference and ultrasound measurements of tracheal width were taken at an agreed distance below the thyroid cartilage which was marked on each specimen with a surgical marker pen. Reference measurements were obtained by ultrasound reviewer 3 and a 3rd year BSc Anatomy student. No standard approaches to obtaining measurements of the trachea that did not involve resecting or dissecting the trachea were identified in the literature or by the Anatomy Department faculty. The cadavers could not be dissected as this

would prevent them being embalmed later. It also risked distorting the anatomy and resulting in a larger or smaller tracheal diameter than at the time of ultrasound measurement. No local facilities were able to offer CT or MRI imaging on cadavers. A novel approach was therefore developed. This involved passing a nerve block needle with small ridges along the first 2 cm of its length transversely through the trachea (see Figure 3.6 and Figure 3.7). Insertion was under ultrasound and/or endoscopic guidance to ensure correct position across the full width of the trachea. Once in place, endoscopic images of the needle in the trachea including entry and exit points were captured using a small bore H-SteriScope bronchoscope^{TM} (Olympus, Hamburg, Germany). This was repeated for each cadaver. A still image was taken of the needle next to a 15cm ruler from a surgical skin marker pack (Bunzl Universal, London, UK). Images were imported into ImageJ imaging software [278] (open source). The original plan was to calibrate the software measuring tool and measure from one end of the visible needle to the other. However this was not possible due to a slight fish-eye effect on the bronchoscope which meant variable pixel-to-millimetre correspondence across the image, with greater effect on measurements when the bronchoscope was not central in the trachea. Instead, measurements were based on the needle ridges visible on endoscopy as follows:

- for each endoscope image, the points on the needle at lateral insertion points were identified
- the same points were identified on the needle in the image with the surgical measure
- ImageJ measuring tool was calibrated against the ruler
- the distance between the two insertion points on the needle was then measured using ImageJ measuring tool

Measurements were obtained by the anatomy student and ultrasound reviewer 3 using these methods.

3.2.2.2. Ultrasound measurement

Ultrasound measurements were obtained independently by three reviewers using a predefined measurement protocol (see Appendix F). The reviewers were all members of the International Group of Speech and Language Therapists (SLTs) working in Ultrasound. Two were SLTs and the third was a head and neck sonographer. Ultrasound reviewers met prior to data collection for training in the measurement protocol including identification of the cricoid cartilage, tracheal rings and AMI (at the level of the trachea, i.e. where

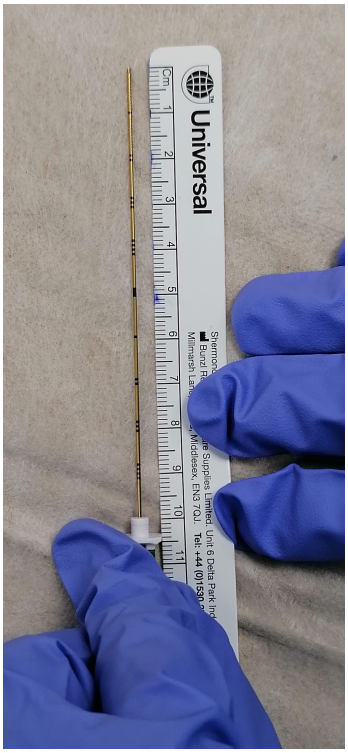


Figure 3.6.: Needle used in reference measurements

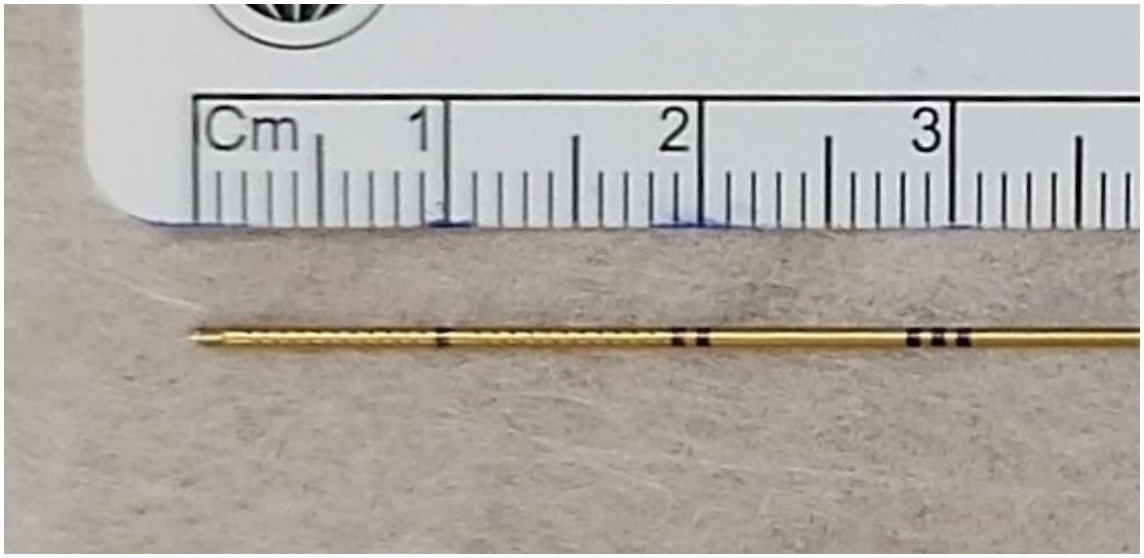


Figure 3.7.: Close-up showing ridges on needle used in measuring

the AMI indicated the inner tracheal wall). Since the AMI signal did not extend laterally enough to be seen at the full width of the trachea, the internal diameter of the trachea was calculated as the average of the diameters of the outer tracheal wall and its reflection within the tracheal air-column (see Figure 3.8). This decision was supported by the work on describing the sonoanatomy of the trachea, which confirmed that the central bright line was the AMI and that structures seen below this line (within the tracheal air column) were reflections of structures surrounding the trachea.

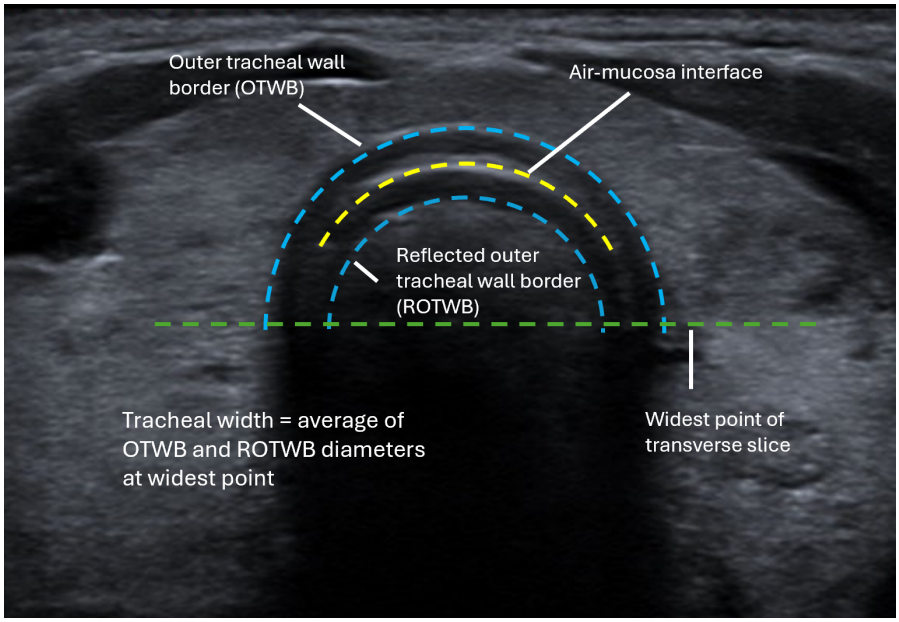


Figure 3.8.: Method for obtaining tracheal width from the diameters of the outer border of the tracheal wall and its reflection within the air column

Reviewers were given a reviewer number which was concealed from the other reviewers. Each reviewer captured images and took measurements of each cadaver with the screen concealed from the other viewers. Measurements obtained were transverse diameter of the outer tracheal wall (outer edge of tracheal ring) and transverse diameter of the reflection of the outer tracheal wall within the air column. Internal diameter of the tracheal wall (the AMI) was calculated as the mean of these two measurements since the AMI was the plane of reflection in the centre of these sonographic signals. Images containing calliper measurements, specimen number and whether it was the first or second measurement attempt were saved by reviewers against their reviewer number before clearing the screen for the next reviewer.

3.2.2.3. Analysis

Data including measurements, specimen number and reviewer number were uploaded as individual survey entries in a Research Electronic Data Capture (REDCap) database [279]

stored on a secure UCL network. The results table was exported for statistical analysis in RStudio [280]. To determine accuracy of ultrasound measurements, the average of and difference between ultrasound and reference measurements for each specimen was displayed on a Bland-Altman plot. Values used for each method were averaged values across reviewers. Inter-rater reliability between ultrasound reviewers was determined by calculating the intra-class correlation coefficient, based on a two-way random effects, single rater, absolute accuracy model [281].

3.3. Results

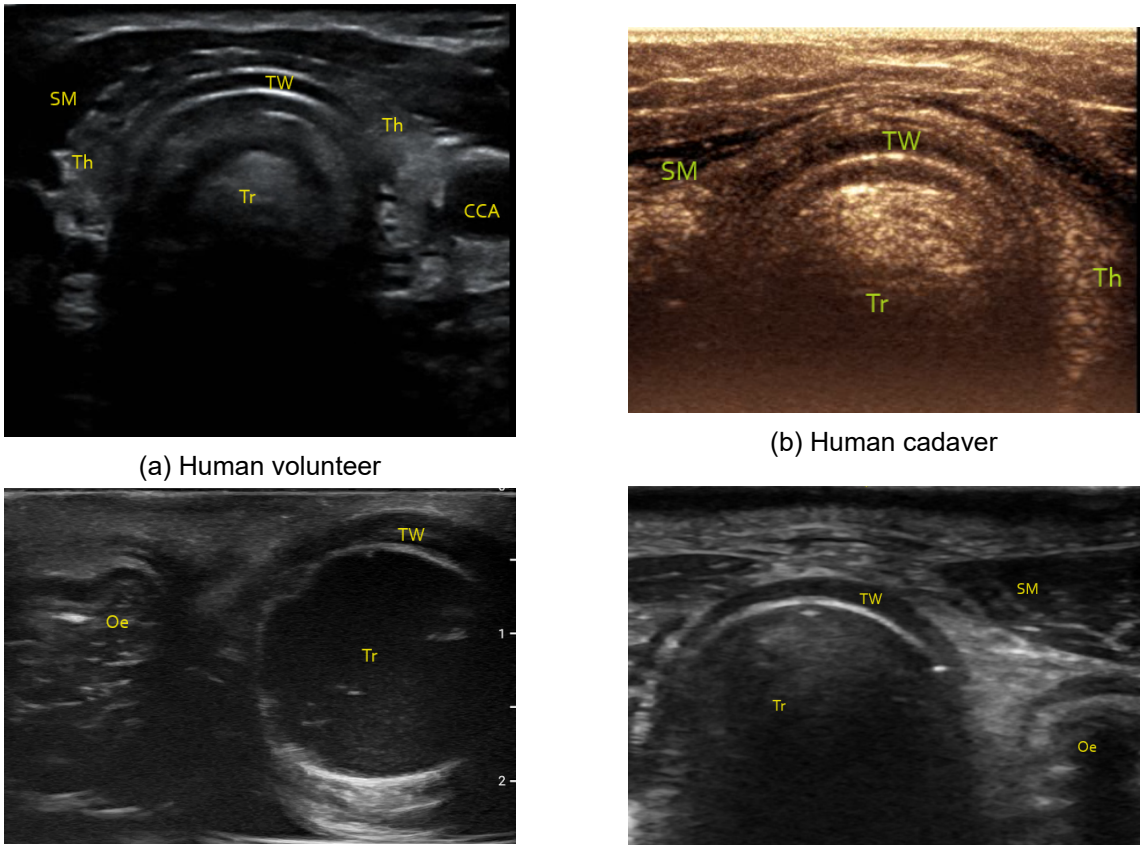
3.3.1. Sonoanatomy and artefact

3.3.1.1. Anterior neck and non-airway structures

The strap muscles of the neck were visible on the live human, cadaver and sheep specimens (see Figure 3.9a; Figure 3.9b; Figure 3.9d, these had been removed from the pig specimen). In transverse views a distinctive grey arch of the isthmus of the thyroid gland was seen anteriorly to the trachea and left and right lobes were seen laterally in the live human and cadaver trachea but not in the pig or sheep specimens (see Figure 3.9a, Figure 3.9b). Blood vessels were observed in the live human at the thyroid isthmus. Small cysts were seen in the cadaver's thyroid. Another cadaver used for measurement data collection was found to have a large thyroid goitre. The isthmus of the thyroid gland could be seen over the tracheal rings but not in front of the cricoid in longitudinal images of the live human and cadaver Figure 3.16a. The thyroid gland was not identified in the sheep specimen. The oesophagus was viewed in some images as an oval/circular object with a hypoechoic centre and hyper- and hypoechoic concentric outer rings, either to the left or right of the posterior trachea in the pig, sheep and cadaver ultrasound images.

3.3.1.2. Thyroid and cricoid cartilages

The thyroid cartilage was only imaged in human subjects. On transverse view in the cadaver trachea, the thyroid cartilage was identified by a thin hyperechoic inverted 'v' shaped anterior border and hypoechoic body that cast shadow over deeper structures. Shadowing appeared stronger in the upper thyroid cartilage, with faint views of the right arytenoid and false vocal folds in the air- and water- filled trachea. In the live human, shadowing



(a) Human volunteer

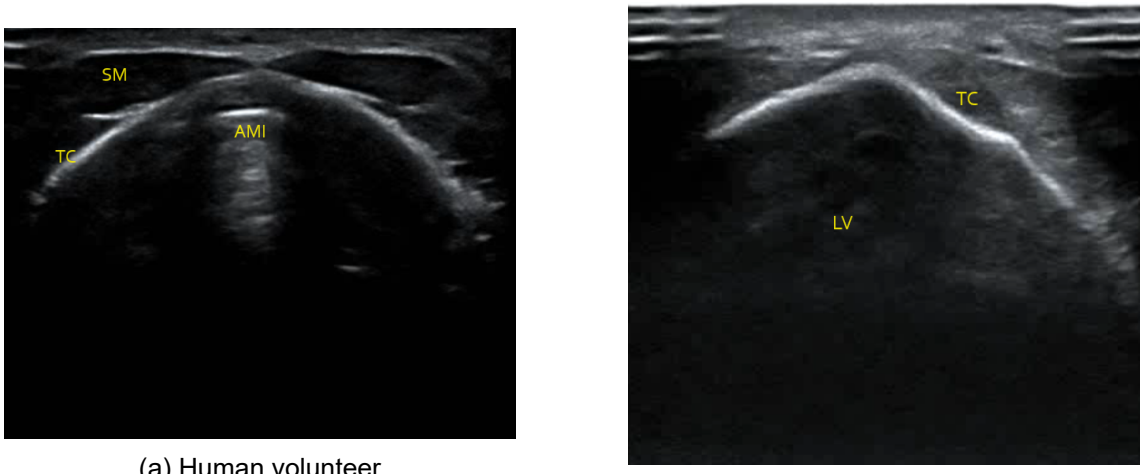
(b) Human cadaver

(c) Pig

(d) Sheep

Figure 3.9.: Anterior neck anatomy in a human volunteer, human cadaver, and sheep and pig specimen. The pig specimen is submerged in water. Tr - trachea; TW - tracheal wall; SM - strap muscles; Oe - oesophagus; Th - thyroid gland

was less pronounced, with the most hyperechoic line at the anterior AMI (internal surface of thyroid cartilage/mucosa).



(a) Human volunteer

(b) Cadaver

Figure 3.10.: Thyroid cartilage in human volunteer and cadaver. TC - thyroid cartilage; AMI - air-mucosa interface; SM - strap muscles; LV - laryngeal vestibule

The cricoid was viewed as a thick cartilaginous structure in the pig, human volunteer and cadaver ultrasound images (see Figure 3.12). Two layers were discernible in the pig cricoid on ultrasound (see Figure 3.11) but not in the human cricoid cartilages. Figure 3.12 and Figure 3.13 show the changing profile of the cricoid cartilage from superior to inferior borders and comparison with neighbouring structures in a human volunteer and cadaver (water-filled) trachea. The lateral walls of the cricoid appeared first in a descending sweep of the ultrasound probe (see Figure 3.12). These then came progressively closer to meet at the midline. The cricothyroid membrane was visible as a hyperechoic line at the anterior midline of the airway until the lateral edges of the cricoid met. The cadaver's cricoid cartilage was densely hypoechoic, completely shadowing deeper structures, whereas in the live subject the internal walls of the cricoid could be traced as the lateral walls approached the midline. A bright white line was visible deep to the thick cartilage, behind which the cricoid cartilage and strap muscles appeared to be reflected within the space of the air column (see Figure 3.13e).

3.3.1.3. Trachea

The upper trachea was bordered anteriorly and laterally by the thyroid gland. Two distinct transverse profiles were seen within the tracheal wall of each trachea: portions containing cartilage and between these, portions containing soft tissue (see Figure 3.14a and Figure 3.14b). In the pig trachea there appeared to be two layers within the soft-tissue sections of the tracheal wall that correlated with layers shown on photographic images

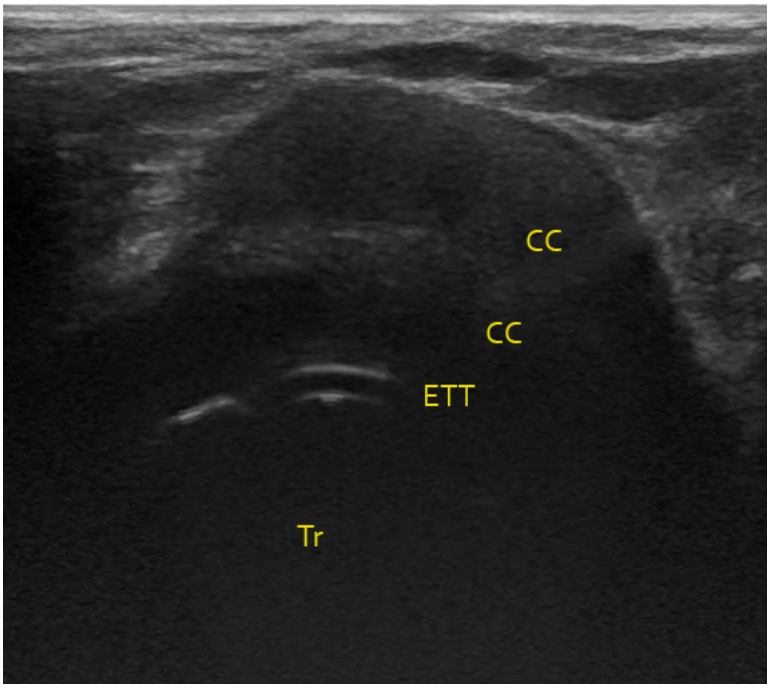
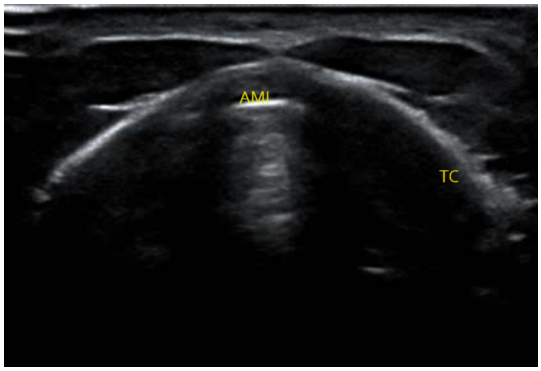


Figure 3.11.: Two layers seen in pig cricoid cartilage. CC - cricoid cartilage; ETT - endotracheal tube; Tr - trachea

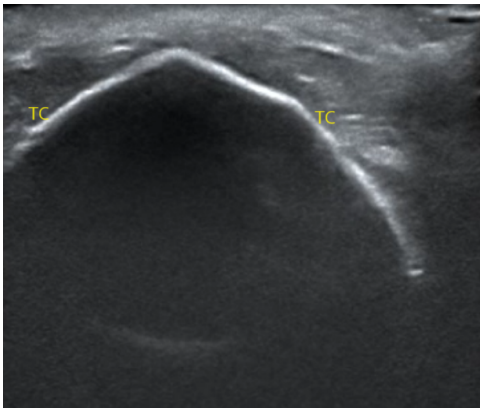
(see Figure 3.15b and Figure 3.15a). Two layers were also seen on ultrasound images of the sheep trachea at inter-cartilaginous portions (see Figure 3.14d) but not in images of live or cadaveric human tracheas. In the cadaver the tracheal ring was densely hypoechoic and shadowed deeper structures. In the live human and sheep, the inner and outer border of the tracheal ring could be seen anteriorly (the AMI marked the inner border anteriorly) and the outer border could be seen laterally. The AMI line became progressively less bright laterally and was not visible at the widest section of the trachea, whereas the reflected tracheal ring could usually be seen within the tracheal air column from the anterior section to widest point when the transducer was held perpendicular to the trachea. In inter-cartilaginous transverse views of all tracheas (including the cadaveric trachea), and cartilaginous sections of the pig, sheep and live human, the inner border of the tracheal wall was brightly hyperechoic. There was shadowing at the lateral aspects of the outer wall of the trachea. A larger number of rings were visible in the live human - at least five on longitudinal view. This was similar to views obtained of participants in the observational study reported in Chapter 4, except in the elderly or those with a higher body mass index. Only one tracheal ring was identified in the cadaver, whose sternum obscured views of the others.

Visual appearance of the space representing the tracheal air column differed across and within subjects/specimens and across images of the air-filled versus water-filled trachea. The angle of the probe also impacted whether mirroring was seen. Except for in the re-

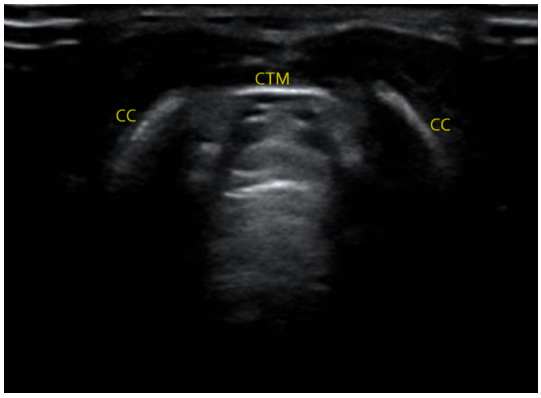
Key for Figure 3.12 and Figure 3.13 : TC - thyroid cartilage; AMI - air-mucosa interface; CTM - cricothyroid membrane; Tr - mirror - mirror of tracheal ring within the air column; Th - thyroid gland; PTW - posterior tracheal wall; TWST - tracheal wall soft tissue (not cartilage)



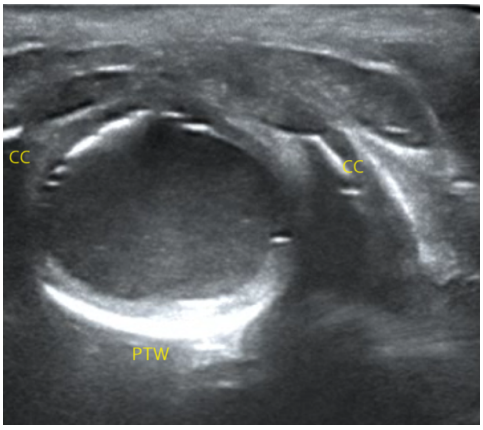
(a) Human 1: thyroid cartilage



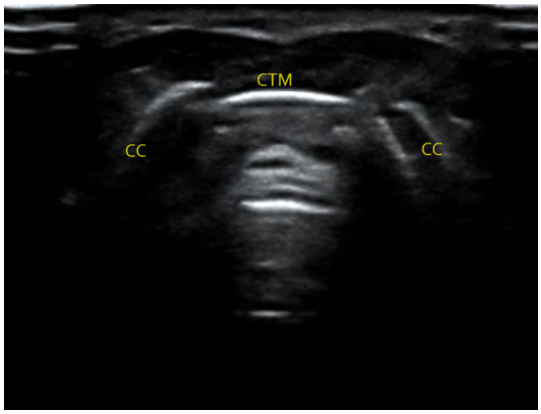
(b) Cadaver 1: thyroid cartilage



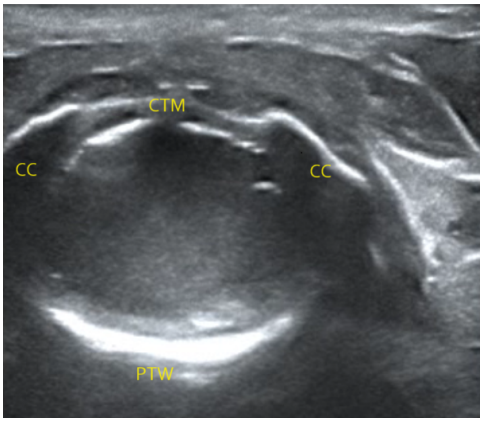
(c) Human 2:cricoid cartilage



(d) Cadaver 2: cricoid cartilage

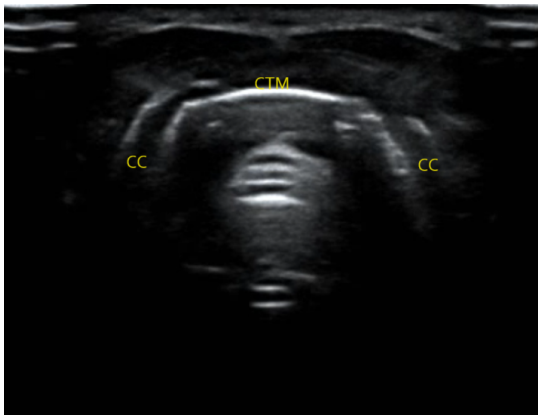


(e) Human 3: cricoid cartilage

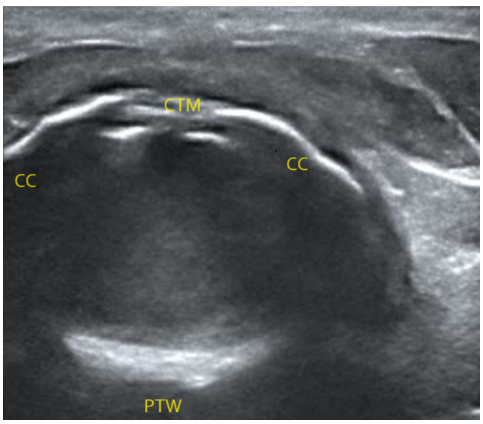


(f) Cadaver 3: cricoid cartilage

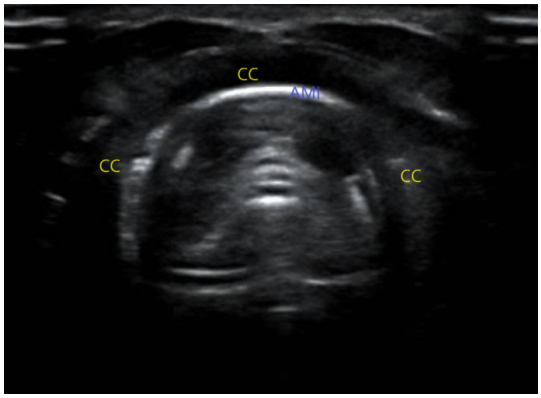
Figure 3.12.: Changing transverse profile of laryngeal and tracheal structures, Part A - from thyroid to level of the crico-thyroid membrane and in a human volunteer and cadaver (water-filled) trachea



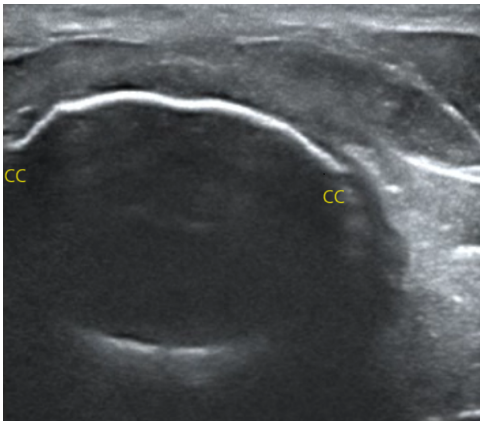
(a) Human 4: cricoid cartilage



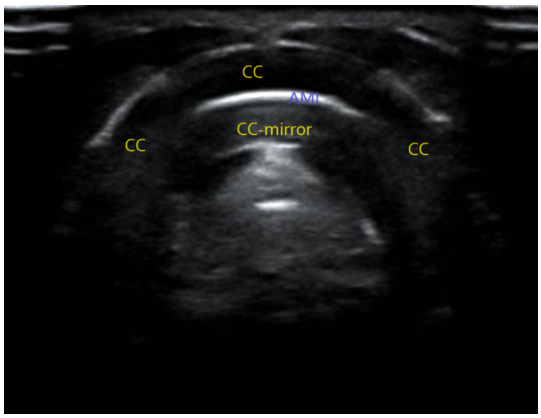
(b) Cadaver 4: cricoid cartilage



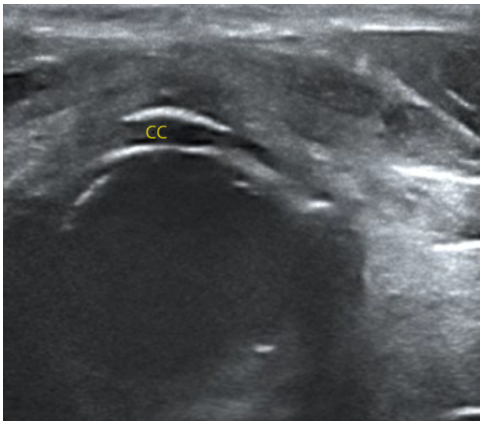
(c) Human 5: cricoid cartilage



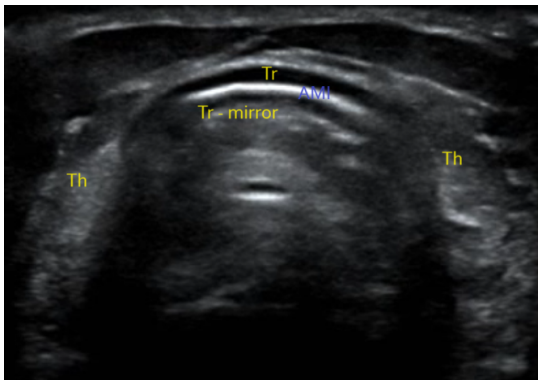
(d) Cadaver 5: cricoid cartilage



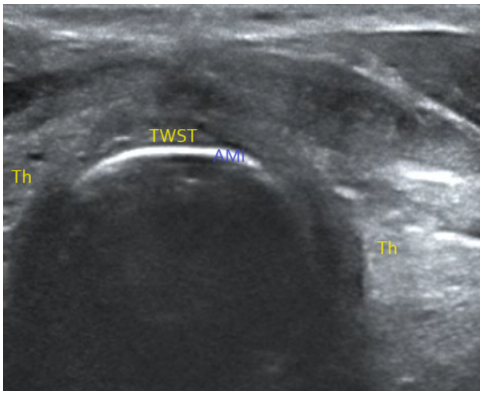
(e) Human 6: cricoid cartilage



(f) Cadaver 6: cricoid cartilage

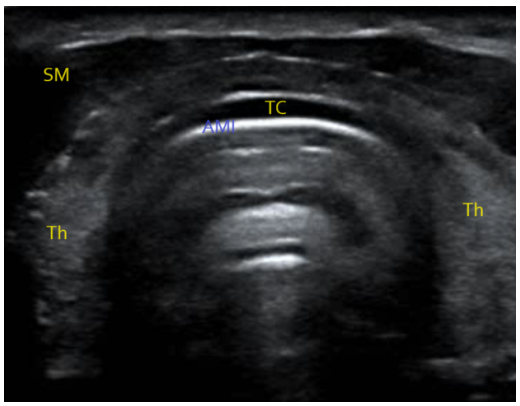


(g) Human 7: first tracheal ring

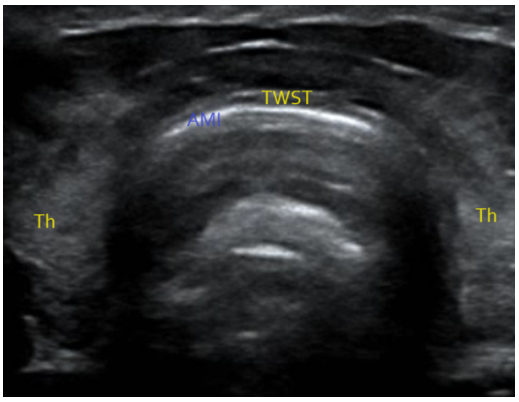


(h) Cadaver 7: trachea

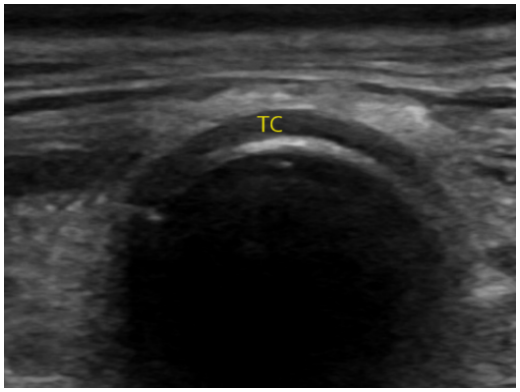
Figure 3.13.: Changing transverse profile of laryngeal and tracheal structures, Part B - from superior border of the cricoid cartilage to the first tracheal ring in a human volunteer and cadaver (water-filled) trachea.



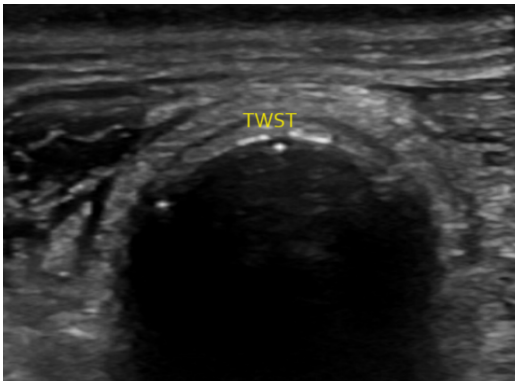
(a) Transverse view at tracheal ring in human



(b) Transverse view between tracheal rings in human



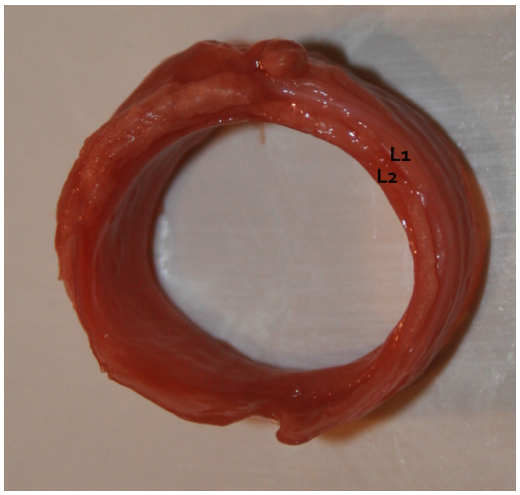
(c) Transverse view at tracheal ring in sheep



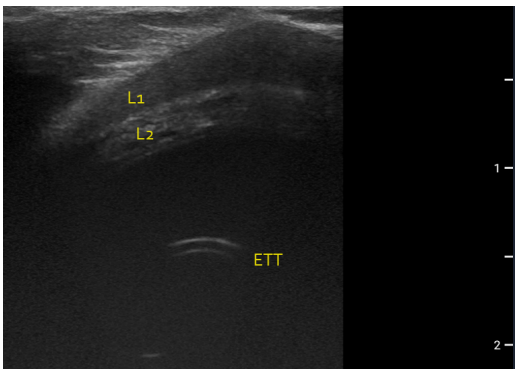
(d) Transverse view between tracheal rings in sheep

SM - strap muscles; Th - thyroid gland, TC - tracheal cartilage; AMI - air mucosa interface; TWST - tracheal wall soft tissue

Figure 3.14.: Transverse views of the trachea at the level of a tracheal ring and between tracheal rings in human and sheep tracheas



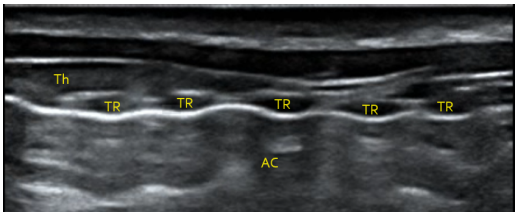
(a) Two layers in tracheal wall - pig trachea photos



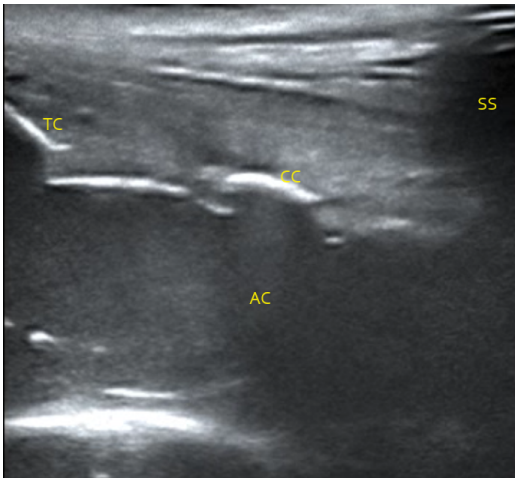
(b) Two layers in tracheal wall - pig trachea ultrasound

L1 - layer 1; L2 - layer 2; ETT - endotracheal tube

Figure 3.15.: Photograph and ultrasound image showing layers of tracheal wall in pig trachea



(a) Longitudinal view - human volunteer

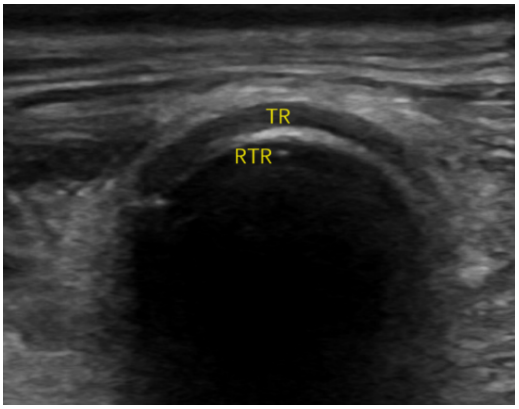


(a) Longitudinal view - cadaver

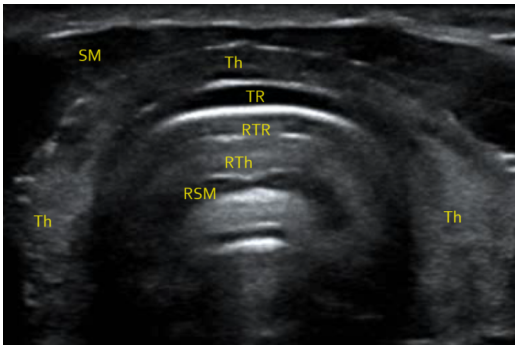
TR - tracheal ring; CC - cricoid cartilage; AC - air column; SS - shadow of sternum.

Figure 3.17.: Longitudinal views of trachea in volunteer and cadaver

sected (pig) trachea and at tracheal rings in the cadaver, a mirror image of the tracheal wall could be seen reflected around the AMI (see Figure 3.9a and Figure 3.18a). In some images from the live human, shapes could be discerned within the air column space that correlated with views of thyroid tissue and strap muscles, sometimes with additional artefactual shapes deep to this (Figure 3.18b). Vessels in front of or within the tracheal wall were also reflected within the air column space.



(a) Mirrored tracheal ring - sheep



(b) Mirrored thyroid gland and strap muscles - human

TR - tracheal ring; RTR - reflected tracheal ring; Th - thyroid gland; Rth - reflected thyroid gland; SM - strap muscles; RSM - reflected strap muscles

Figure 3.18.: Mirror image of peri-tracheal anatomy within the tracheal air column

Water-filled and partially water-filled images allowed direct comparison of anatomical appearance with and without air artefact. Figure 3.19 shows an anterior transverse view of the sheep trachea in side-lying, with water filling the right side of the air column space and

air in the left. The AMI seen on the left half of the anterior tracheal wall is bright white and there is a faint reflection of tracheal ring, with an additional beam of ring down artefact descending almost vertically. In comparison, the water-mucosa interface (WMI) seen on the right side is not as echogenic (less bright) and there is no artefact within the air column space. A homogenous layer of soft tissue can be seen deep to the cartilage and before the WMI on the right side. The corresponding area in the air-filled portion is obscured by the AMI as the AMI line is broader than the WMI line. There is enhancement of the ultrasound beam at the posterior wall of the trachea deep to the water-filled section but shadowing deep to the air-filled section. In longitudinal view of the sheep trachea the interface between mucosa and air is again much brighter than the interface between air and water. Below the AMI there is reverberation artefact which is more dense and descends deeper below inter-cartilage spaces than below cartilage

Key: TR - tracheal ring; AMI - air mucosa interface; WMI - water mucosal interface; ML? - mucosal layer?

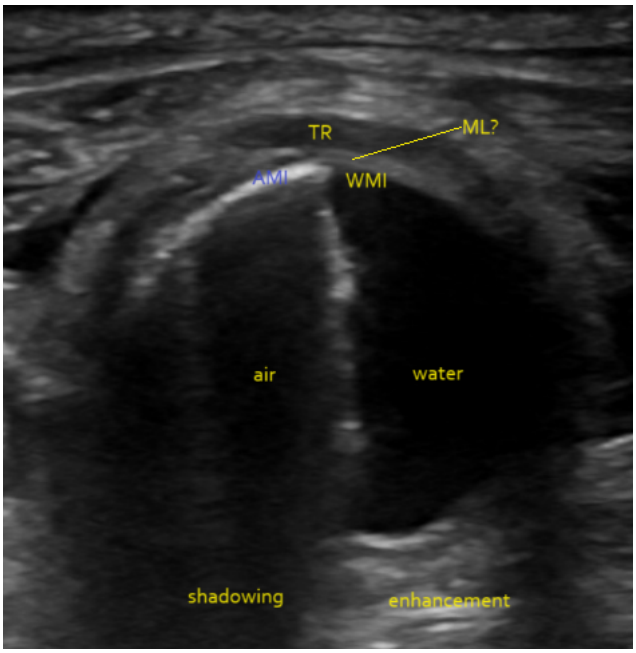


Figure 3.19.: Comparison of sonoanatomy in water- versus air-filled portions of a sheep trachea

A video of the transverse view of the cadaver trachea at the inter-cartilage space below the cricoid whilst a pocket of air was introduced and expelled helped distinguish the AMI from artefact (see Figure 3.20). With no air pocket there was a single bright white line that was interpreted as the WMI. Introduction of an air pocket at the anterior tracheal wall caused two bright curved lines to appear below where the WMI had previously been. Through knowing the position of the WMI, the position of the AMI could be interpreted and distinguished from air artefact. The region above the first artefactual line was similar in

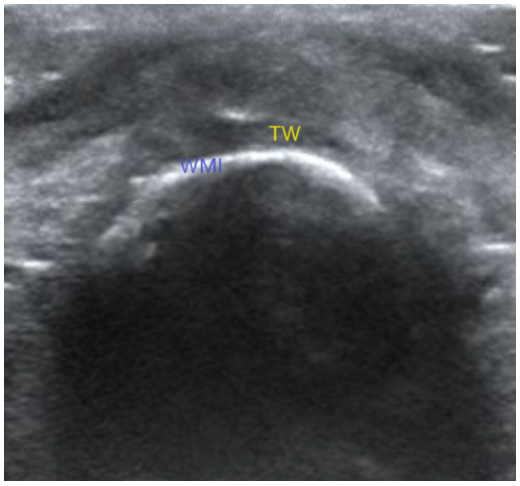
greyscale to the tracheal wall and the region between the first and second artefactual line was similar greyscale to thyroid tissue, suggesting artefact could have been a reflection of these structures. The posterior tracheal wall was shadowed on introduction of air but visible in the water-filled trachea. In the human volunteer the outer border of the tracheal wall and its reflection around the AMI appeared brighter in images over tracheal rings than images between tracheal rings (see Figure 3.14a and Figure 3.14b). The angle of the probe also affected brightness of these features.

3.3.2. Ultrasound measurement

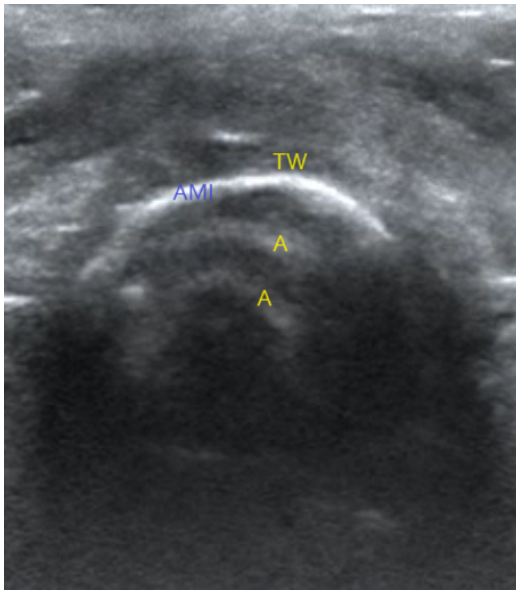
Six fresh-frozen cadavers were available on the day of the study, four males and two females, all elderly (exact ages unknown). One female was excluded from the study as it was not possible to identify the trachea on ultrasound. Attempts at endoscopy were also difficult and appeared to show a collapsed airway. Measurements from two reviewers of specimen 3 were excluded as review of the images showed measurement of the cricoid cartilage instead of the trachea (larger cartilage with no thyroid tissue anteriorly, (see Section 3.3.1). Collection of reference measurements using the marked needle and endoscope technique described in Section 3.2.2.1 above was challenging. Passing the scope via the nasal or oral cavity was physically difficult in some cadavers and further complicated by secretions obscuring the view. To overcome this, a cricothyrotomy was performed by the anatomy student and the scope passed through this into the trachea. There were secretions (specimens 3 and 5), skin puckering on the inner tracheal wall at the needle insertion site (specimen 4) and blurring (specimen 6) affecting some images of most cadavers (see Figure 3.21) . Decisions on the exact point of the needle at entry and exit sites were based on review of the clearest images for a cadaver (three to six images collected for each).

3.3.2.1. Validity

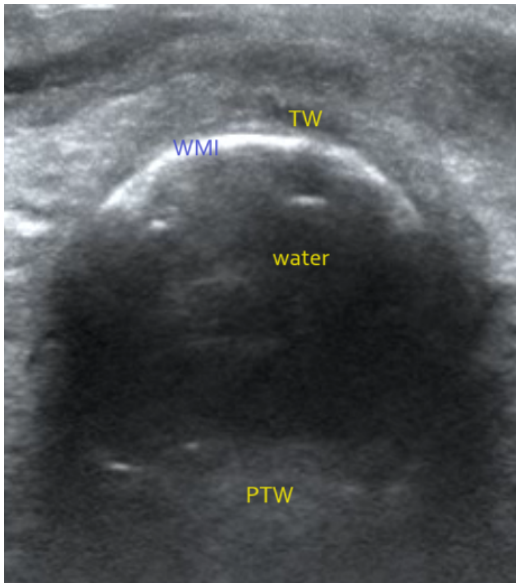
Figure 3.22 shows all tracheal measurements from all reviewers by specimen and method including first and second attempts. Ultrasound measurements were larger than reference measurements for all cases. This difference was substantially greater in specimen 6 than in other specimens, where average ultrasound measurement was almost twice that of the reference measurements (see Table 3.1). The mean cadaveric inner tracheal diameters measured by ultrasound (using the average of the diameters of the outer tracheal wall



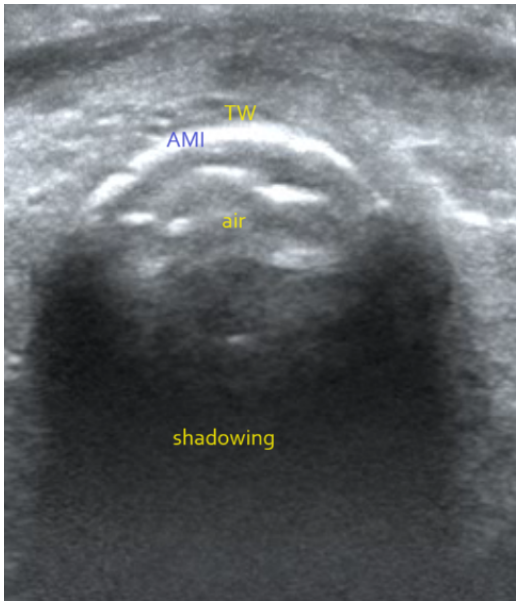
(a) Transverse view of water-filled cadaver trachea



(b) Transverse view of water-filled cadaver trachea on introduction of pocket of air anteriorly



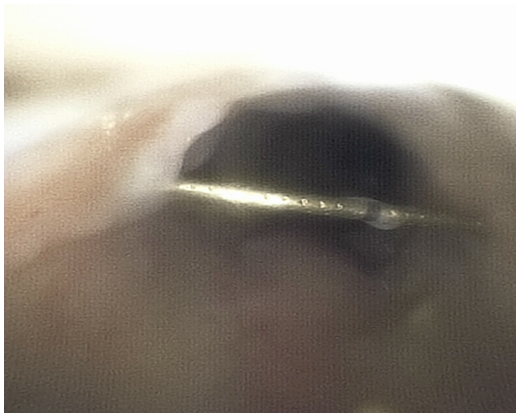
(c) Transverse view of water-filled cadaver trachea, posterior tracheal wall in view



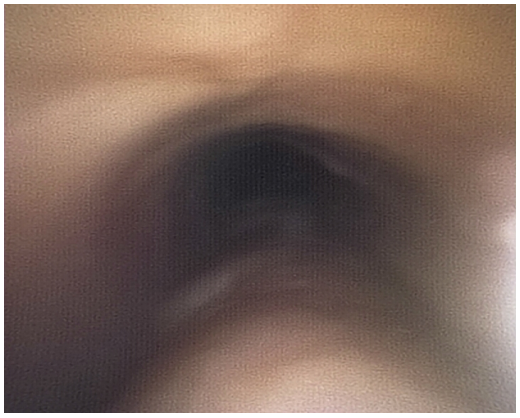
(d) Transverse view of water-filled cadaver trachea, shadowing of deeper structures on introduction of pocket of air

TW - tracheal wall; WMI - water mucosa interface; A - artefact; PTW - posterior tracheal wall

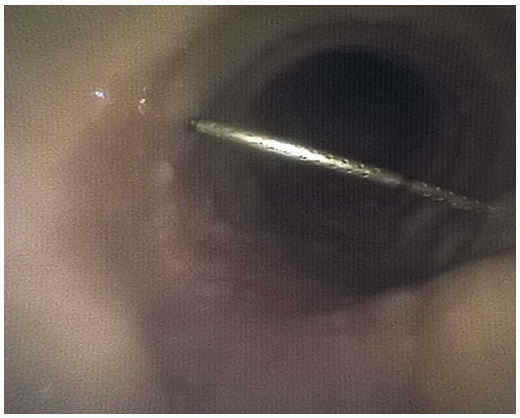
Figure 3.20.: Comparison of air- and water-filled trachea (cadaver)



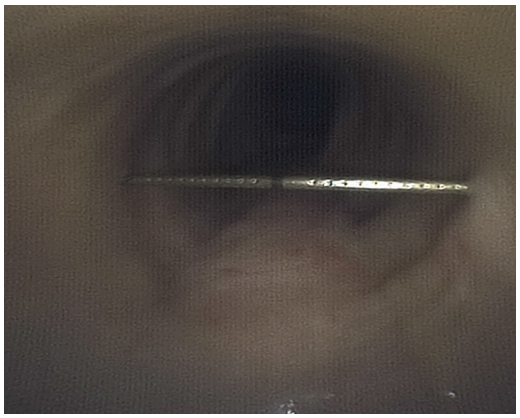
(a) Secretions obscurring view on endoscopy(excluded)



(b) Blurred images on endoscopy (excluded)



(c) Endoscopic image of specimen 6 used in measurements



(d) Endoscopic image of specimen 4 used in measurements

Figure 3.21.: Used and excluded endoscopic images of the trachea

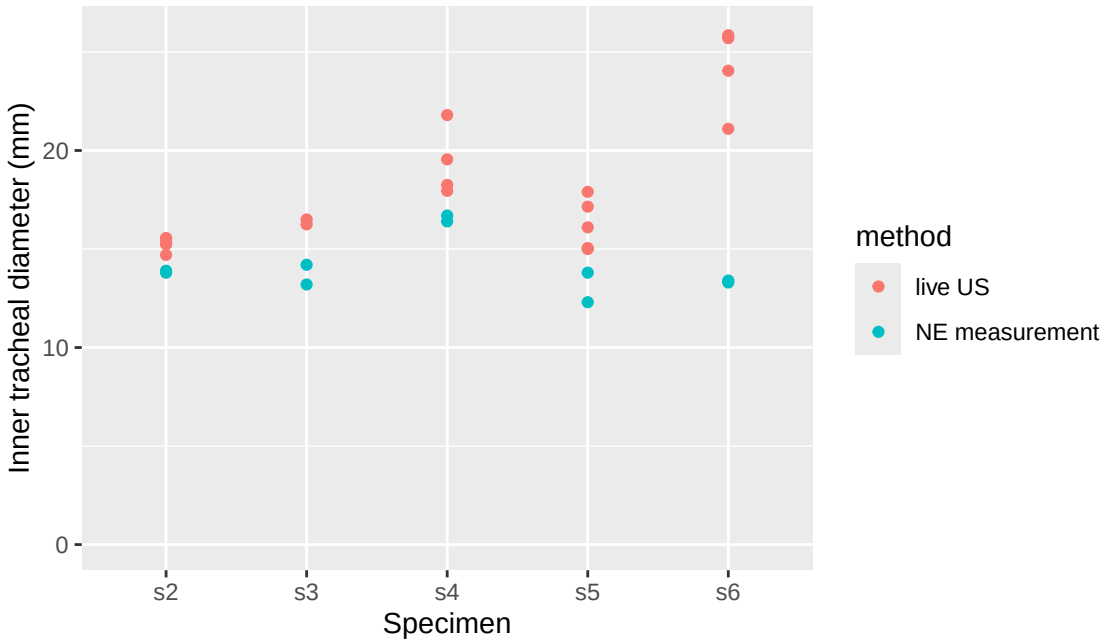


Figure 3.22.: Tracheal diameter by specimen and measurement method. US - ultrasound; NE - needle and endoscope

and its reflection), and a needle and endoscope method were 18.1 mm (range 14.7- 25.9 mm) and 14.1 mm (range 12.3 - 16.7 mm) respectively.

Table 3.1.: Average measurements by specimen and method

specimen_id	NE measurement	live US
s2	13.9	15.3
s3	13.7	16.4
s4	16.5	19.4
s5	13.1	16.2
s6	13.4	24.2

A Bland-Altman plot reflects this difference between methods (see Figure 3.23). The average discrepancy between methods was nearly 5 mm, almost a third of the smallest tracheal measurement using ultrasound. The 95% confidence interval was wide at over 15 mm, with lower and upper bounds of 12.7 and 3.8 respectively, indicating low confidence in the calculated value of the mean.

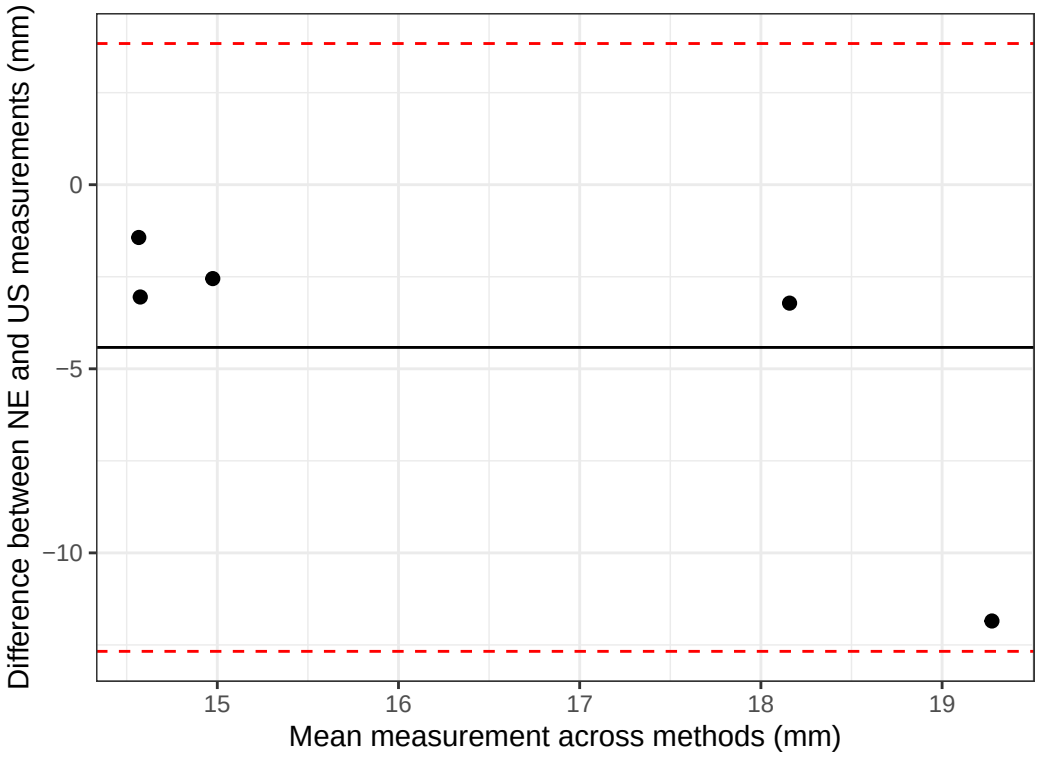


Figure 3.23.: Bland-Altman plot showing the mean of and difference between ultrasound and NE measurements of the trachea

3.3.2.2. Inter-rater reliability

Figure 3.24 shows all measurement attempts by specimen and reviewer. Measurements for specimen three were excluded as review of images used by reviewer 1 and 2 showed they had measured the cricoid cartilage. An estimate of the intraclass correlation coefficient (ICC) was calculated in RStudio [280] to evaluate inter-rater reliability using a two-way random effects, single-rater absolute-agreement model. Inputted values were the last ultrasound measurement for each specimen from reviewers 1-3. This gave an ICC of 0.931 (CI 0.678-0.995).

Table 3.2.: Ultrasound measurements of the trachea by specimen, reviewer and measurement attempt (raw data)

Reviewer and specimen	First attempt (mm)	Second attempt (mm)
Reviewer 1		
Specimen 2	15.55	15.35
Specimen 3	(incorrect anatomy)	n/a
Specimen 4	21.8	n/a
Specimen 5	15.0	15.05
Specimen 6	25.85	n/a
Reviewer 2		
Specimen 2	15.55	15.25
Specimen 3	(incorrect anatomy)	n/a
Specimen 4	17.95	n/a
Specimen 5	17.9	17.15
Specimen 6	21.1	24.05
Reviewer 3		
Specimen 2	14.7	15.25
Specimen 3	16.5	16.25
Specimen 4	18.25	19.55
Specimen 5	16.1	n/a
Specimen 6	25.7	n/a

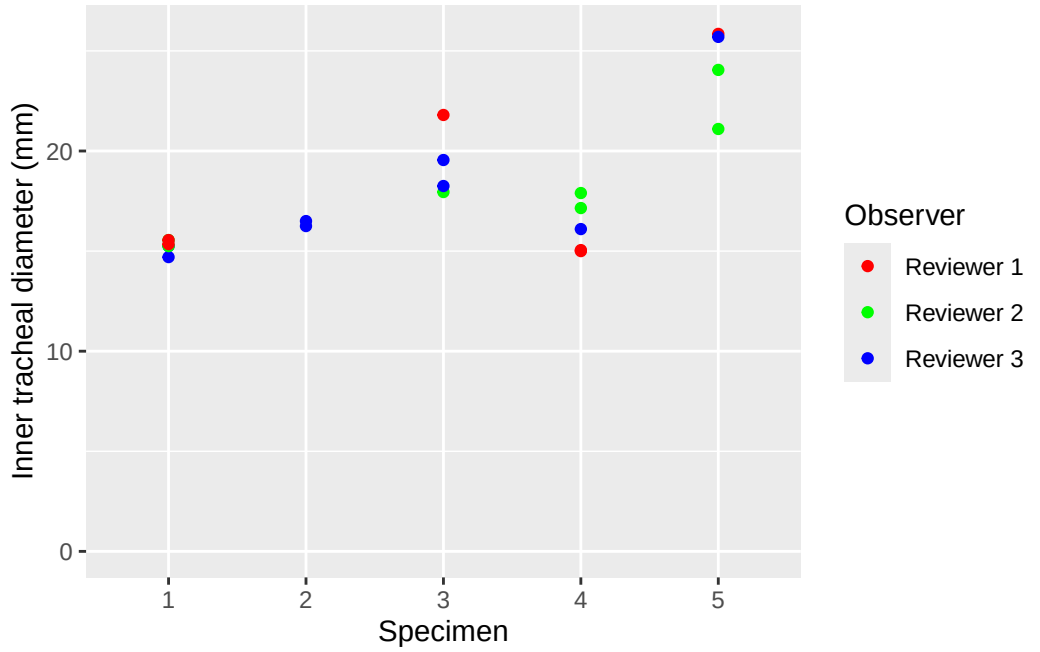


Figure 3.24.: Ultrasound measurements of inner tracheal diameter by specimen and reviewer

```
Single Score Intraclass Correlation

  Model: twoway
  Type : agreement

  Subjects = 4
    Raters = 3
  ICC(A,1) = 0.931

F-Test, H0: r0 = 0 ; H1: r0 > 0
 F(3,7.52) = 36.7 , p = 7.53e-05

95%-Confidence Interval for ICC Population Values:
 0.678 < ICC < 0.995
```

3.4. Discussion

3.4.1. Summary of findings

The main aim of this study was to support ultrasound imaging of the trachea through confirming anatomical landmarks and distinguishing these from artefact. A secondary aim was to investigate validity and reliability of ultrasound measurements. The study generated new knowledge on tracheal sonoanatomy and how to distinguish the inner tracheal wall from artefact. In the absence of signal from the inner tracheal wall at the lateral borders, a surrogate method of obtaining tracheal width measurements was proposed. Inter-rater reliability for ultrasound measurements of tracheal width was high and accuracy scores were low. However, sample size and difficulties with the reference measurement method significantly limit generalisation of measurement reliability and accuracy findings.

The cricoid cartilage was distinguished from tracheal rings by its changing profile from superior to inferior borders, greater thickness and absence of thyroid tissue anteriorly. Comparisons of tracheal images with and without water confirmed the AMI to be the brightest white line, with lines deep to this interpreted as artefact. In cases of dense calcification of cartilage the AMI could not be seen and the brightest white line represented the interface between soft tissue and calcified cartilage. Figure 3.25 illustrates identification of the AMI in an adult volunteer. The AMI was less bright on transverse views at inter-cartilaginous portions of the trachea than at tracheal rings and was not visible at the widest point of the trachea on transverse views. Various types of artefact were found on imaging the airway using ultrasound including reverberation, ring down, mirror, shadowing, edge shadowing and acoustic enhancement. Mirror artefact was more common where thyroid tissue provided an acoustic window and could be deceptive, with reflections having the same appearance as solid objects. Through understanding this phenomenon, the mirror image of the outer tracheal wall could be used alongside the true outer tracheal wall to obtain an estimate for the inner diameter of the trachea by calculating the average of the two diameters.

Validation of ultrasound measurements were hampered by absence of a formally recognised gold standard measurement technique and technical issues in obtaining the reference measurements. Ultrasound measurements were consistently larger than reference measurements. The mean cadaveric inner tracheal diameters measured by ultrasound (using the average of the diameters of the outer tracheal wall and its reflection), and a nee-

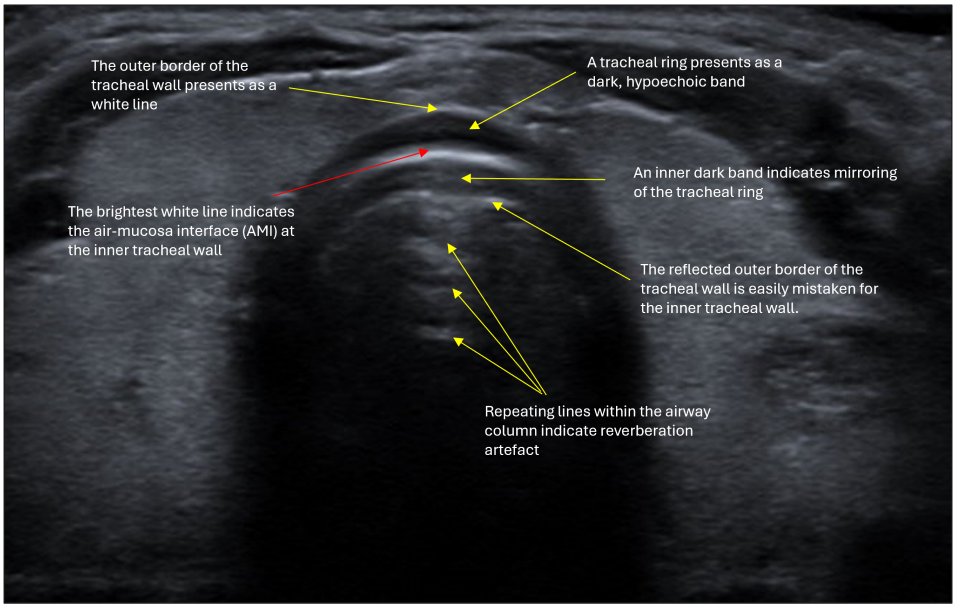


Figure 3.25.: Identification of the air-mucosa interface at the inner tracheal wall in a human volunteer

dle and endoscope method were 18.1 mm (range 14.7- 25.9 mm) and 14.1 mm (range 12.3 - 16.7 mm) respectively. The confidence interval for the mean difference between reference and ultrasound measurements was many times larger than the difference between tracheostomy tube diameters. The ICC value for inter-rater reliability indicated excellent reliability. However, in one cadaver, two out of three reviewers misidentified the anatomy and measured the cricoid cartilage instead of a tracheal ring. With further training this type of error might have been reduced.

3.4.2. Comparison with the published literature

3.4.2.1. Neck anatomy

The observations in this study on neck structures around the trachea are in alignment with the literature on neck sonoanatomy from the fields of radiology, endocrinology, ENT and head and neck cancer [248, 272, 282]. There is comparatively very little evidence on the sonoanatomy of the airway. A number of studies exist on the use of ultrasound measurements of sub-glottic diameter to guide ETT size decisions, mainly in paediatric anaesthetics. However, definitions of the sub-glottis vary; there is mis-labelling of cricoid and tracheal rings; poor or no justification for placement location of measuring calipers; and little discussion of artefact [283, 284, 285]. One study appears to have mistaken a

blood vessel for the trachea, with imaging showing a long almost anechoic (black) structure with clear lower borders and acoustic enhancement rather than shadowing of deeper tissues (Fig. 1 in Dalesio et al. [286]). In contrast, in a study of airway sonoanatomy in cadavers and live volunteers, Tsui et al. [287] methodically describe the changing profile of the cricoid from superior to inferior borders with illustrative images that match the descriptions and images in this study.

Tracheal sonoanatomy has received less attention than the sub-glottic/cricoid region. The anaesthetic literature describes the tracheal rings as a 'string of pearls' in longitudinal view, which provides a key landmark in studies of sonographic identification of the crico-thyroid membrane for emergency front of neck access [271, 288]. The radiology literature describes it as alternating hypo- and hyperechoic bands of cartilage and annular ligaments [282]. On transverse view almost all descriptions relate to the tracheal rings, with no consideration of the intra-cartilage spaces. In this study it was shown that cartilaginous portions differed in appearance to the spaces in between; the former being more densely hypoechoic with brighter borders and more prominent mirror artefact. This may be due to the increased contrast in density between air and cartilage. No in-human studies described layers of the tracheal wall as seen in the porcine and sheep models in this study and described in histology literature [289], though images from an investigation of ultrasound measurements in a porcine model also appear to show two layers [256] and studies using endobronchial ultrasound in the small airways have depicted more layers [290]. Absence of layers may be explained by the presence and comparative densities of adjacent tissues, age of tissues, and ultrasound settings including depth and frequency. This study showed that the 'string of pearls' appearance of the tracheal rings in longitudinal view may be dependent on age, with more tracheal rings visible in younger subjects and potentially only one or none in older subjects.

3.4.2.2. Artefact

Reverberation artefact on tracheal ultrasound has been described before [293]. However, there are differences in how the term is applied by different authors, with some using it to describe the AMI and others to describe patterns seen within the tracheal lumen. Appearance of artefact in presented images also differs, for example in some there are equally spaced bright curved lines, whereas in others there is more irregular signal. In this study and images collected for the observational study there was also variation in appearance of tracheal artefact. This may be explained by angle of insonation, age of participant/specimen and individual differences in anatomy, for example thickness of

the thyroid gland, strap muscles, and adipose tissue [294]. Mirror artefact is mostly described in association with reflection of the gall bladder around the diaphragm. There is little mention of it in relation to the trachea, though a review in an ultrasound journal describes the same effect observed in this study [295]. Recognition of mirror artefact was important in the current study, since it prevented erroneously interpreting reflected objects as true anatomical landmarks, for example mistaking the reflected outer tracheal wall for the AMI (inner wall of the trachea). A case of a thyroid cyst mirrored within the tracheal lumen which disappeared on aspiration of the cyst supports the description of mirror artefact involving tracheal cartilage and adjacent structures described in this study (see Figure 3.26) [296]. Images from the study validating ultrasound measurements in a porcine model mentioned above also appear to show mirror artefact that includes the two layers of trachea, the surrounding water balloon stand-off and the gel in between (see Figure 3.27) [256]. A further consideration is that tissue harmonic imaging can attenuate reverberation artefact [297]. This processing feature was used during data collection and may possibly explain the increased visibility of mirror artefact and reduced reverberation artefact in study images.

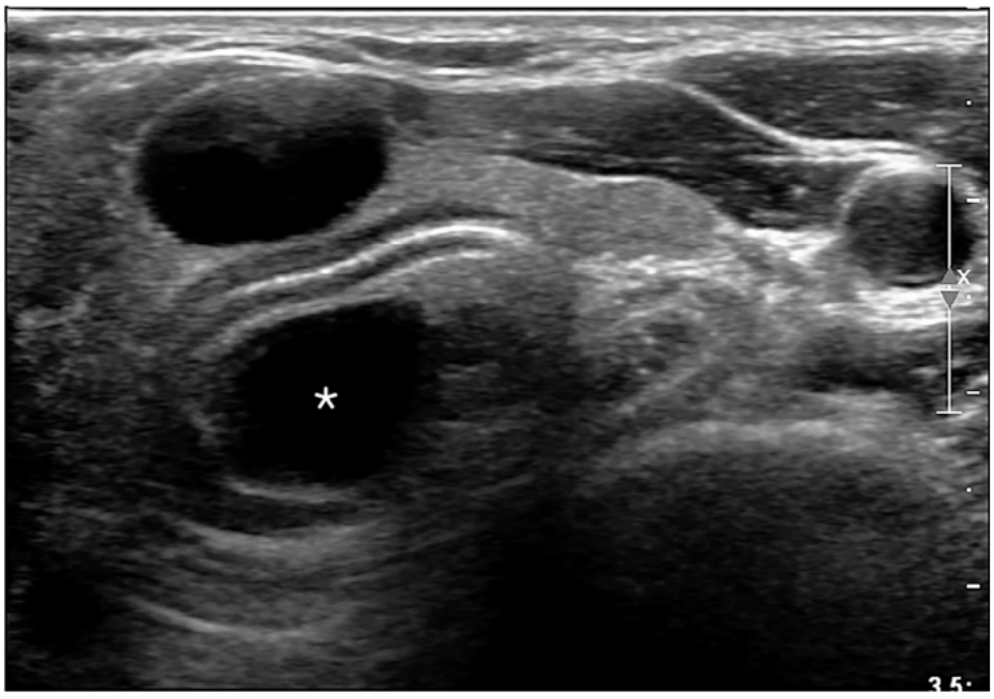


Fig. 1 – Transverse sonogram demonstrates a 1.5 × 1-cm-sized movable thyroid cyst. Another cyst (asterisk) is noted within the tracheal lumen, specular to the thyroid cyst. Anterior tracheal wall is flattened between 2 cysts.

Figure 3.26.: Mirror artefact of a cyst within the tracheal lumen, You et al. (2021)

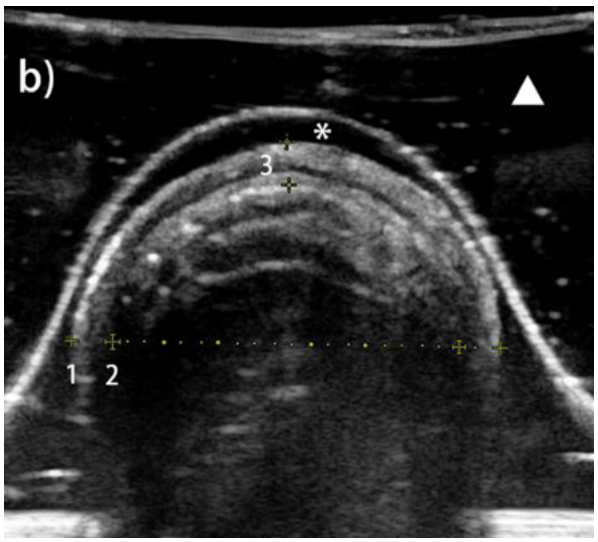


Figure 3.27.: Mirror artefact and two layers of tracheal wall seen in Ye et al. [256]. Crosses indicate outer and inner borders of tracheal wall.

A key difference between this study and other literature was the attempt to confirm landmarks through comparison of images containing air artefact with images of the same specimen where air and its associated artefacts were eliminated by the introduction of water. Others have relied on comparison with reference diagrams, alternative imaging techniques, or findings in cadaveric specimens. This study provided empirical evidence through controlling imaging conditions.

3.4.2.3. Ultrasound measurement

There is no formally recognised gold standard technique for measuring the inner diameter of the tracheal wall, either directly or with imaging modalities. The most widely cited norms for tracheal width are normal ranges of 13-25 mm for males and 10-21 mm for females [91] (note, the authors used means ± 3 SDs to describe normal range). Whole sample means were not provided but means by decile of age show that for males, mean inner tracheal diameter was over 19 mm and for females, over 16 mm. Ultrasound measurements in this study are smaller but more closely fit these norms than the reference measurements used in this study. Moreover, figures obtained by Breatnach et al. [91] may be an overestimate for several reasons: they were obtained by x-ray and the magnification effect was not applied to the results; images were obtained 40 years ago when x-ray equipment was less advanced than today; and imaging was conducted during maximal inspiration, which enlarges the trachea [298].

Kamel et al. [94] used calipers and CT imaging to measure tracheal width directly and through imaging in embalmed resected cadavers and patients respectively. Cadaveric

caliper measurements gave a mean *outer* tracheal diameter of 21.4 mm (+/- 1.6) in males and 17.8 (+/- 1.5) in females; patient CT measurements returned inner diameter measurements of 27.1 mm (+/- 3.4) and 22.9 (+/- 2.6) for males and females respectively. Ultrasound measurements in this study fall in between these values which might be explained by issues with CT and caliper data collection methods. Firstly, the embalming process may have shrunk cadaveric tissues creating a smaller lumen. Secondly, technicalities in CT measurements may have caused over-estimation, since measurements were taken from axial slices with lower resolution than ultrasound, which may have caused over estimation of width if the trachea was not orthogonal to the plane of the slice. Additionally, the wide CT window width (1500) may have missed the soft-tissue lining of the trachea. The authors also reported the largest transverse diameter from the full length of the trachea, not necessarily the cervical portion viewed on ultrasound, and CT imaging was taken during breath-holding.

Gomez-Tamayo et al. [254] concluded their study of intra- and inter-rater reliability of ultrasound measurements of the sub-glottis demonstrated accuracy and reliability of ultrasound measurements of the subglottis. However, they did not benchmark against another measurement method or discuss confirmation of sonoanatomy and distinction from artefact. Moreover, illustrations show that they measured the trachea, not the space above the cricoid as described.

Or et al. [96] compared 3D ultrasound with MRI for viewing and measuring the airway including transverse subglottic and tracheal diameter. Landmarks were compared with relevant slices from the visible human project but not explicitly discriminated from artefact. The authors found 3D ultrasound agreed strongly with MRI measurements (15+/-2.3 mm versus 14.7+/-2 mm respectively, p=0.22). These values are smaller than observed in this study which may be partially explained by the sample demographics (young, Chinese versus elderly caucasian).

A few studies have used bronchoscopy to evaluate airway diameter in tracheal stenosis and normal tracheas [299–302]. Issues around lens distortion were approached in one by simply aiming to keep the scope central in the airway, which is unlikely to have fully mitigated the distortion effect [301]. Another used a calibrated grid-based computer software correction system [302]. A third study comparing endoscopic and ultrasound measurements of tracheal diameter acknowledged similar difficulties to this study relating to scaling the reference instrument for measurement, and clarity of lateral views [299]. In contrast to their right-angled probe reference, the needle used in this study had a series of closely spaced ridges that aided derivation of measurements. However, secretions

and ensuring perpendicular positioning of the needle to the trachea meant endoscopic measurement remained challenging in the present study. To overcome endoscopic image distortion, Dorffel et al. [302] combined bronchoscopic laser distance-measuring with image processing to obtain cross-sectional areas of large airways. Validation on plastic tubes of known diameter found excellent correlation though comparison with patient CT showed slight underestimation of stenosis. However, this may reflect sub-optimal CT settings as described above. A search for endoscopes with laser measurement capabilities prior to the commencement of data collection in this study found no available equipment for in-human use.

3.4.2.4. Training

As described in Section 3.1, some have claimed that developing skills in airway ultrasound is easy. However, as highlighted by the errors and inconsistencies in the literature and experiences during the current study, airway ultrasound for tracheal measurement is not an easy skill to learn. This discrepancy may be due to the specific anatomy being studied and the type of information being sought; many of the applications of airway ultrasound focus on structures adjacent to the airway and seek to answer binary questions, for example, 'are there any blood vessels anterior to site of intended tracheostomy insertion?', or 'is the ETT in the oesophagus?' [95]. These applications do not require precision measurement or interpretation of air artefact within the air column. The presence of air artefact does not prohibit future use of ultrasound for tracheal assessment and measurement, however. Lung ultrasound is a growing field which, like airway ultrasound, involves imaging air-filled anatomy. Unlike airway ultrasound, a substantial body of work has been undertaken to identify artefact and understand the mechanisms that produce it. Clinicians can now receive training in interpreting the diagnostically useful information that can be gained from artefact, though challenges in interpretation still exist [303–305]. Similarly, this study provides evidence that could support training in tracheal ultrasound interpretation. Future research should attempt to validate ultrasound measurement of the airway in an appropriately sized sample, drawing on the information on tracheal sonoanatomy presented here. This will require identification of a suitable measurement technique with which to compare.

3.4.3. Limitations

The following table lists a number of identified limitations of this study, the implications for findings, alternative approaches, and mitigations or mitigating circumstances.

Table 3.3.: Table of study limitations

Limitation	Implications	Alternative approaches	Mitigation
Study Design			
Sample size	Unable to generalise findings	Increase sample size, however limited availability of fresh-frozen cadavers	
Training of reviewers - absence of evidence to support it, short training programme	Misidentification of anatomy, incorrect placement of calipers	Longer training period	Based training on best available evidence and preliminary imaging of pig trachea
Data collection			
Placement of needle	Bias could be caused by needle not being exactly perpendicular to trachea or at same site as ultrasound measurements	Conduct ultrasound measurement on hemi-section cadavers to allow direct visualisation of the trachea, however not possible with resources used	Site of ultrasound measurements marked on skin, needle placed under ultrasound guidance
Lens distortion on endoscopy	Unable to directly measure with calibrated tools in imaging software	Conduct lens calibration prior to data collection, use laser distance-measuring tools	Used ridged needle to enable measurement
Barriers to endoscopic imaging	secretions partially obscuring view and ridges on needle, time constraints limited correction of this	Preparation of specimens prior to data collection, however access limited to 1 day, use of a reference needle with marked measurements	Flushing with water and suction to remove secretions, insertion of endoscope via incision in cricothyroid membrane instead of upper airway
Calcification of cartilage	Age of cadavers meant calcification was common	Use younger specimens, however likely little availablity	View through intracartilage space
Ultrasound equipment	POCUS machines lower specification than radiology machines	Use high spec machines. However no budget for this or availabilty through Reps	
Ultrasound settings	Protocol outlined basic settings but allowed for change with aim of best view. May have impacted artefact produced	Define controlled settings. However, these may have been unsuitable for individual specimens and generated uninterpretable images. Also no evidence to support what settings to use	Transparency in reporting of methods to aid reviewer interpretation

Limitation	Implications	Alternative approaches	Mitigation
Different equipment used for imaging pig, sheep, and human subjects	Findings may not be exactly comparable	Use same equipment in each setting	Same machine used for precision measurements. Description of artefact cross-referenced with literature
Presence of edge artefact due to round shape of the trachea	Reviewers needed to interpret where edge artefact (shadowing) began at the lateral tracheal walls	Nil identified	Discussed in training to improve inter-rater reliability
Analysis			
Derivation of inner tracheal diameter based on outer wall diameter and reflection	Edge shadowing in some subjects makes identification of widest point of lateral wall difficult; mirror of tracheal ring/wall is slightly smaller due to distortion. Estimate therefore likely to be slightly larger	Base estimate on outer tracheal wall and anterior wall thickness	

3.5. Conclusion

Interpretation of tracheal sonography is challenging due to neck anatomy, the round shape of the trachea, calcified cartilages and the presence of air. Artefacts can be deceptive and cause mis-identification of anatomy. However, if properly understood, artefact can aid image interpretation and facilitate measurement of tracheal width. For example, in the absence of the AMI at the lateral borders of the trachea, the average of the diameters of the outer tracheal wall and its reflection can be used as a surrogate for tracheal width. Further investigation of the accuracy of this method would be useful to complete validation of the method but requires identification of a suitable reference method for obtaining tracheal measurements.

4. Observational study

4.1. Introduction

As outlined in Chapter 1, there is no clear guidance on how to choose the best size TT for patients in ICU. The work in Chapter 2 showed that being able to speak was of paramount importance to patients due the intrinsic role voice plays in enabling other processes that make people feel human. This is relevant to TT sizing decisions since sizing decisions impact a patient's chances of being able to speak; larger tubes may not allow sufficient airflow to bypass the TT and be modulated by the vocal folds to generate voice. However, authors of benchtop studies have suggested 'big is best' in order to ensure adequate ventilation [99, 100]. A service evaluation I conducted on tracheostomy size decision-making and anecdotal evidence suggest this is a common approach in practice. A copy of the e-poster of the service evaluation that was presented at the Intensive Care Society State of the Art Congress 2019 can be found in Appendix G. Other factors used to guide size decisions include patient sex or other anthropometrics such as height or 'patient size', which are presumed to correlate with tracheal width. However, no known studies have investigated the outcomes or impact of different sizing methods used in practice, i.e. what size TTs are recommended by what methods or how these sizing methods impact patient outcomes. Moreover, there is conflicting evidence in the literature around the association between anthropometrics and tracheal width [90, 91, 306].

This chapter reports on the fit of TTs within the trachea in relation to the methods used to determine TT size. The primary and secondary aims of the study were to:

1. determine how closely current methods of TT size selection for adult ICU patients agree with a sizing method based on measurement of tracheal width
2. determine the association between tracheal width and other anthropometrics to see if these could be used to guide sizing decisions

4.2. Methods and material

4.2.1. Study design and sampling strategy

This workstream used a cross-sectional observational study design to collect measurements from an adult sample and compare *theoretical* TT sizing decisions based on i) TT sizing methods used in practice and ii) a method based on tracheal diameter measured using ultrasound (see Section 4.2.3.1 for further details of methods used). The same data were also used to investigate the relationship between tracheal width and anthropometric variables.

The study sample was initially intended to mirror the UK ICU tracheostomy population as outlined in NCEPODs audit of tracheostomy care [1], with recruitment from respiratory, cardiology and neurology outpatient clinics. However, at the time of applying for ethical approvals, significant social distancing restrictions relating to the COVID-19 pandemic remained in place, including visiting restrictions and the replacement of face-to-face outpatient appointments with online consultations. Recruitment criteria were therefore widened to achieve a representative sample of the UK adult population from adults already present on the recruiting hospital site: adult patients and staff were eligible if they were eighteen years old or over and had capacity to give informed consent. Exclusion criteria included severe kyphosis of the spine (as this would restrict imaging); inability to stand for height and weight measurement; lack of capacity to consent; prisoners; pregnancy. Inclusion and exclusion criteria are presented in Table 4.1.

Table 4.1.: Inclusion and exclusion criteria for observational study participants

Inclusion criteria	Exclusion criteria
Aged 18 or over	Lacking capacity to consent
Patient or staff member at Barnet General or The Royal Free Hospital	Severe kyphosis of the spine preventing neck ultrasound
Mental capacity to consent	Unable to step onto weighing scales or stand for measurement of height
	Prisoners
	Pregnancy

Ethical approval for the study was granted by the NHS Health Research Authority on 29th July 2021 (REC reference 21/SC/0211). Site confirmation of capacity and capability to

support the study was granted by the clinical host's (Royal Free London NHS Foundation Trust), Trials Feasibility Committee on the 14th July 2021. The Organisational Information Document was signed by study sponsor (UCL) and clinical host on the 13th November, with approval to commence recruitment from 16th November 2021 (see Appendix H).

4.2.2. Recruitment and sample size

Recruitment posters were displayed in hospital offices and patient waiting areas. The study was presented at senior management meetings with subsequent dissemination of information among teams. Clinicians provided Patient Information Sheets (PIS, see Appendix I), and brief verbal explanation of the study to potential patient and staff participants and passed on the names and contact details of those who were interested in participating to me to discuss further. Participants were given time to read the PIS, ask questions and consider whether or not to participate before a research appointment was offered. At the research appointment, details of the purpose, nature, and governance of the study were discussed again. Those wanting to enroll signed a consent form prior to data collection. Demographic data were analysed mid-way through data collection with targeted recruitment as needed, aiming for equal numbers of male and female participants, a spread of ages, and a representative sample of the national population in terms of ethnic diversity.

Sample size calculations were based on concordance analysis of the different TT sizing methods (see Section 4.2.3.1), and conducted in G*Power [307] with the assistance of an expert medical statistician. It was calculated that a sample of 114 participants would provide 90% power to detect a concordance of 65% (null hypothesis = 50%) between methods of selecting TT size, with a 1-sided significance level of 2.5%.

4.2.3. Data analysis

Data analysis was performed through coding in R within RStudio [280]. This method was chosen as it allowed data processing and statistical computations with an auditable record of decisions and without altering raw data files. Use of Quarto markdown files within RStudio provided a single platform in which to present text for study reporting interspersed with statistical analysis code chunks and their output.

Sample demographics were described and presented in a table. Mean (SD) and median (range) values for demographic and other independent variables were presented separately for male and female participants.

4.2.3.1. Concordance analysis

The initial analysis plan was a simple investigation of the association between tracheal width and height and shoulder width. However, following consultation with expert medical statisticians at the UCL Department of Statistical Science, the approach was amended to include a study of concordance between different sizing methods. The concordance analysis was designed to provide the percentage of cases in which recommendations generated for the same subject by different methods matched. Concordance analysis requires a 'gold standard' or best practice method with which to compare other methods. The sections below outline the best practice sizing method and four sizing comparator methods representing approaches used in clinical practice. The rationale for using this method was to provide additional clinically meaningful data, i.e. how frequently clinicians using a given sizing method would insert the best size tube, and how frequently they would insert larger or smaller tubes.

Best practice sizing method

The 'best practice' method for sizing TTs used in this study was based on the 2014 Intensive Care Society Tracheostomy Standards [308] recommendation that the outer diameter (OD) of the TT was no larger than three-quarters of the inner diameter (ID) of the patient's trachea, as illustrated below:

- Participant tracheal width = 14.3mm
- Maximum OD of tracheostomy tube = ¾ x 14.3 = 10.7
- TT size recommended (Portex Blueline Ultra) = 7 (OD = 10.5mm)

This standard was removed from the revised Tracheostomy Standards prior to commencement of data collection [4] due to lack of robust supporting evidence, with no alternative method provided. Advice was therefore sought from the project's clinical steering group, who approved the use of the above method for the purposes of this study, in the absence of alternative methods. For simplicity, this method of selecting TT size based on tracheal width is referred to as the best practice maximum (M-BP-Max) method for the rest of the chapter.

Comparator methods of tracheostomy tube size selection

A service evaluation I conducted in 2019 (see Appendix G) suggested that TT sizing decisions were often based on 'patient size', height, BMI, and sex, though little evidence of this or the exact steps involved in TT sizing methods could be found in the literature. Four

'current practice' methods were therefore developed based on the service evaluation, evidence on sizing techniques for endotracheal tubes and anecdotal evidence [87, 90, 306, 309]. The clinical steering group was asked to consider sizing methods only for standard Portex Blueline Ultra^{TM} TTs in sizes 6-10, and not for adjustable flange or other specialist TTs. This range was used as it was the most commonly used in UK adult ICU patients [310]. Clinical steering group members were asked to review and comment on these, and agreed that the proposed methods reflected current practice.

The four methods were as follows:

1. based on height: five height categories were defined based on the mean +/- one or two standard deviations from the mean of normative data for UK adults [311]. Participants in the shortest height category were recommended a size 6 TT, those in the next height category were recommended a size 7 and so on up to those in the tallest height category who were recommended a size 10.
2. based on shoulder width: similar to method 2, the size of tube depended on participant shoulder width, with categories of shoulder width based on normative data for US adults [312] (no UK data were found). Though no reports were found of shoulder width being explicitly used to determine size of tracheostomy, this method was included in addition to height and BMI to reflect 'patient size', since this generic term was reported as the basis for TT sizing decisions in the service evaluation I had previously undertaken of TT sizing. Additionally, a theoretical association between shoulder width and tracheal width had been proposed by Griscom et al [90] following the observation that shoulder width and tracheal width continue to grow beyond attainment of full stature in males, which the authors proposed might indicate a shared biological mechanism controlling both.
3. based on sex: all participants identified as female at birth were recommended a size 7 TT and those identified as male at birth were recommended a size 8 TT.
4. based on BMI: the five BMI categories of 'underweight', 'healthy', 'overweight', 'obese' and 'extremely obese' described by the NHS (www.nhs.uk/conditions/obesity) were mapped onto TT recommendations of size 6-10.

For brevity from this point onwards these four methods will be labelled 'M-height', 'M-shoulder', 'M-sex', and 'M-BMI' respectively. Table 4.2 shows how each method mapped onto TT sizes.

Table 4.2.: Criteria for tracheostomy tube size recommendations by method

Sizing based on	6	7	8	9	10
Tracheal width (mm) (best practice)	12.3-13.9	14.0-15.8	15.9-17.6	17.7-18.6	18.7
Height (cm)	<157	157-167	168-179	180-191	>191
Shoulder width (cm)	<34.4	34.4-38.8	38.9-43.3	43.4-47.8	>47.8
Sex	n/a	female	male	n/a	n/a
BMI	<18.5	18.5-24.9	25-29.9	30-39.9	>40

4.2.3.2. Association between tracheal width and height and shoulder width

Secondary analyses investigated the association between tracheal width and height and/or shoulder width. Sex, BMI, ethnicity and age were also investigated as potential confounders. Bivariate associations between tracheal width and independent variables were assessed visually with scatterplots. Exploratory multilinear regression models were also built to identify individual or sets of variables that could explain variance in tracheal width.

4.2.4. Data collection and materials

4.2.4.1. Demographic information

Demographic data, staff/patient status, and relevant medical history including trauma or surgery to the airway was collected via interview for the purpose of sample description and analysis of primary and secondary outcomes. The case report form used in data collection is shown in Appendix K

4.2.4.2. Height

Height was recorded in standing for each participant using the same Seca portable stadiometer (Hamburg, Germany), located in the cardiology outpatient department of Barnet Hospital. Participants were asked to remove shoes, stand tall, and position chin slightly downwards to raise the crown of the head. Reported height was also recorded to capture

potential age-related reduction in height in older participants, since it was presumed that tracheal width was more likely to correlate with height at full stature.

4.2.4.3. Weight

Weight was recorded using the same set of regularly serviced Seca 799 electronic weighing scales (Hamburg, Germany), located in the cardiology outpatient department of Barnet Hospital. Participants were weighed in their own clothes or hospital gown if they were an inpatient. Those in their own clothes were asked to remove shoes and any coats or jumpers and empty pockets prior to being weighed. Some participants expressed the wish not to know their weight. They were asked to stand on the scales facing away from the display screen and data were subsequently concealed from participant view.

4.2.4.4. Shoulder width

Shoulder width measurement followed the approach of Haines [313]. Shoulder width was defined as maximal biacromial width. Measurement was taken using the same Accu 600mm (+/- 0.08mm) digital vernier calipers (Huddersfield, UK). Participants were asked to sit upright in a chair, with arms relaxed and hands resting on their lap. Left and right acromion were palpated prior to measurement and calipers rested at the superior lateral surface of the bony landmark to avoid muscle and adipose tissue affecting measurements.

4.2.4.5. Tracheal width

The Intensive Care Society guidelines on which M-BP-Max was based [308] did not describe how tracheal width should be measured. A number of studies have concluded that ultrasound is a valid and reliable method for obtaining tracheal measurements. On this basis and since it was readily available and avoided exposing participants to ionising radiation, ultrasound was used to collect all tracheal width data. However, experiences during ultrasound training and data collection led to re-appraisal of the evidence on anatomical landmarking of the airway on ultrasound and the subsequent work described in Chapter 3. Imaging of the dry and flooded pig trachea was undertaken prior to data collection in the observational study. The cadaver study and imaging of the dry and flooded sheep trachea were undertaken following data collection in the observational study and prior to

data analysis. Following the findings of the extra work, tracheal width values were obtained through calculating the mean of the diameters of the outer tracheal wall and its reflection (see Figure 4.1) within the airway column.

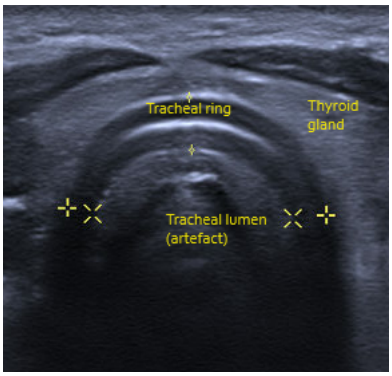


Figure 4.1.: Measurement of the outer tracheal wall (+) and reflected outer tracheal wall (x) diameters

Ultrasound measurements were collected on five identical Siemens Acuson S3000^{TM} machines (Forcheim, Germany), except for one dataset which was collected on a Siemens Acuson Sequoia^{TM} as all other machines were in use at time of data collection. Both are high end machines used by the radiology department for diagnostics and measurement. A standard preset for ultrasound settings was developed during the course of the training programme and with support from a local Siemens ultrasound technician as described below:

- Transducer: 18Mhz, 6cm, linear
- Depth: 4.5
- Focus: at level of widest point of trachea
- dB: 5
- Time Gain Compensation: neutral
- Tissue Harmonic Imaging: on
- Frequency: 16 MHz
- Anatomical landmarks: images taken from lowest part of the trachea where the thyroid isthmus was still visible anteriorly

These settings were adjusted to obtain the clearest picture for individual participants. For example, it was necessary to reduce the depth setting for participants with small necks and little adipose tissue, and to increase depth settings and/or decrease the frequency for patients with large necks and greater adipose tissue. Ultrasound measurement tools were

used at the time of image capture to annotate images with the transverse outer diameter of the trachea and the transverse diameter of the reflection of outer tracheal wall within the tracheal air column (see Appendix J for the measurement reference guide used). At the time of imaging, the latter was believed to be the inner tracheal wall viewed between tracheal rings. However, following the work described in Chapter 3, new understanding of the sonoanatomy of the trachea in transverse view led to the method previously described to obtain the inner diameter of the tracheal wall. This was calculated as the mean of the outer diameter of the trachea and the diameter of the reflected outer tracheal wall within the tracheal lumen. It was also recognised that this view was of a tracheal ring, not the space between tracheal rings. Where possible, two or three images were captured at the time of imaging. Images were reviewed immediately post appointment and measurements including outer tracheal diameter, thickness of the anterior tracheal wall and what was thought to be the inner tracheal diameter (later understood to be the diameter at the reflected outer tracheal wall), from the best quality image in terms of focus and clarity of landmarks were recorded on the case report form. As described above, following the work described in Chapter 3, the mean of the two measurements was taken as an estimate of the inner tracheal diameter.

4.2.4.6. Ultrasound training

Training was bespoke as no ultrasound training courses specifically for imaging the trachea were identified. Training included literature review, observation of musculo-skeletal and head and neck cancer clinics, one-to-one tuition from a senior sonographer, completion of the USabcd e-course in Airway Ultrasonography [314], and use of other online resources (e.g. Youtube tutorials on thyroid ultrasound, and applications of ultrasound in emergency medicine and critical care). The work undertaken in Chapter 3 provided further learning opportunities through working alongside an experienced head and neck sonographer.

4.2.5. Data management

Paper consent and case report forms were used during data collection and stored in a lockable box within a lockable filing cabinet in a lockable clinic room at Barnet Hospital. Data were later transferred into the UCL Data Safe Haven (DSH), a secure facility for digital data storage, processing and analysis.

4.2.6. Inter-rater reliability

Inter-rater reliability was assessed prior to data collection. Data were collected from 10 staff volunteers over a two-and-a-half-week period in October 2021 by the PI and lead sonographer. The PI and sonographer followed the reference guide for measurement of tracheal width that was developed through the initial airway ultrasound training period (see Appendix J). Though understanding of airway sonoanatomy and artefact changed during the cadaver study described in Chapter 3, the features of the ultrasound image that were measured remained the same, i.e. the diameters at the outer tracheal wall and at its reflection in the tracheal air column. Raters collected data for each volunteer at the same session. Rater A captured images, recorded measurements, saved the annotated image, and reset the screen without discussing results with Rater B. Rater B was positioned away from the screen and could not see Rater A's measurements. Rater B then captured new images and annotated these with measurements. This method meant inter-rater reliability encompassed image capture and image interpretation. Measurements were compared at the end of each session to provide opportunity for learning and improving inter-rater reliability. On completion of data collection for 10 volunteers, inter-rater reliability was assessed by calculating the intra-class correlation coefficient (ICC), using the two-way mixed effects absolute agreement model [281].

4.2.7. Process data

The mean time to obtain tracheal measurements was calculated to provide information on the feasibility of ultrasound tracheal measurement as part of tracheostomy tube sizing decisions.

4.3. Results

4.3.1. Sample demographics

In total 125 participants were recruited (male = 61). Data were collected between 19th November 2021 and 8th June 2022. Four participant datasets were excluded (male = 3) as the ultrasound images were not found on the hospital picture storage system (n = 3), or image quality was not sufficient to obtain measurements (n = 1). Data for 121 participants (male = 58) were used in the analysis. Characteristics of the final sample are displayed in Table 4.3.

Table 4.3.: Sample characteristics

Characteristic	**Overall**, N = 121	**M**, N = 58 (48%)	**F**, N = 63 (52%)
Age in years	45 (31, 59)	45 (31, 58)	45 (30, 59)
Age in decades			
18-19	1 (0.8%)	0 (0%)	1 (1.6%)
20-29	27 (22%)	12 (21%)	15 (24%)
30-39	27 (22%)	14 (24%)	13 (21%)
40-49	18 (15%)	9 (16%)	9 (14%)
50-59	20 (17%)	10 (17%)	10 (16%)
60-69	21 (17%)	11 (19%)	10 (16%)
70-79	3 (2.5%)	0 (0%)	3 (4.8%)
80-89	4 (3.3%)	2 (3.4%)	2 (3.2%)
Ethnicity			
Asian	22 (18%)	15 (26%)	7 (11%)
Black	3 (2.5%)	2 (3.4%)	1 (1.6%)
Mixed	5 (4.1%)	3 (5.2%)	2 (3.2%)
Other	3 (2.5%)	2 (3.4%)	1 (1.6%)
White	88 (73%)	36 (62%)	52 (83%)
Airway disease	24 (20%)	12 (21%)	12 (19%)
Comorbidities			
Stroke	1 (0.8%)	0 (0%)	1 (1.6%)
Heart disease	9 (7.4%)	5 (8.6%)	4 (6.3%)
Cancer	7 (5.8%)	3 (5.2%)	4 (6.3%)
Diabetes	7 (5.8%)	4 (6.9%)	3 (4.8%)
Asthma	22 (18%)	13 (22%)	9 (14%)
High blood pressure	22 (18%)	12 (21%)	10 (16%)
High cholesterol	14 (12%)	8 (14%)	6 (9.5%)
Epilepsy	2 (1.7%)	1 (1.7%)	1 (1.6%)
No.comorbidities			
0	64 (53%)	26 (45%)	38 (60%)
1	42 (35%)	25 (43%)	17 (27%)
2	7 (5.8%)	2 (3.4%)	5 (7.9%)
3	5 (4.1%)	3 (5.2%)	2 (3.2%)
4	3 (2.5%)	2 (3.4%)	1 (1.6%)

Most participants were staff members (n = 113). Large numbers of the Therapies department volunteered early in the study. Mid-point analysis of sample characteristics confirmed a suspected bias in towards White female volunteers under the age of 40 and a higher proportion of Asian and lower proportion of Black participants than in the national population. With sponsor approval, an additional 11 participants were enrolled using targeted recruitment to achieve equal numbers of male and female participants, and increase enrolment of participants who were over 60 and/or of a Black ethnic background. Targeted recruitment included disseminating information to managers of teams that were more ethnically diverse or had higher proportions of male and/or older staff and encouraging clinical colleagues to share study information with the relevant staff members and patients they worked with. The PI did not approach any patients or staff directly in order to avoid placing undue pressure on them to participate.

In the final sample participant age ranged from 18 to 85 (median 45, IQR 31-59; males: median = 44.5, IQR 31-58; females: median = 45, IQR 30-59). Eighty-eight (73%) of participants were White, 22 (18%) were Asian, 5 (4%) were mixed, 3 (3%) were Black and 3 (3%) were of another ethnic background. Ethnicity of male and female participants differed, with a higher proportion of White participants and lower proportion of all other ethnic backgrounds in the female sample.

Participant comorbidities increased with age. Participants under the age of 50 reported one or no comorbidities. Approximately half of participants in their 50s reported one or two comorbidities. Above the age of 60 most participants reported at least one and up to 4 comorbidities.

4.3.2. Biometric data

Height was normally distributed for the sample as a whole (mean(SD) = 169.4 cm (9.5)) and male and female sub-groups (mean(SD) = 175.3 cm (7.9), and 163.9 cm (7.3), respectively). Measured height was slightly lower than height reported by participants, with greater difference in the male sample (mean difference: males = 1.6 cm; females = 1 cm). Weight was normally distributed for the whole sample and male and female subgroups (mean(SD) for males = 82.4 kg (14.5), and females = 68.8 kg (15.1). BMI was normally distributed for the whole sample (mean(SD) = 26.2 (5.2)) and for males (mean(SD) = 26.8 (4.4)) but not for females (median = 24.9, IQR 21.3-28.5). Shoulder width was normally distributed in the full sample and female sub-group (mean(SD) = 38.7 mm (2.9) and 36.7 mm (2.0)) but not in males (median(IQR) = 41.3 mm (39.8-42.4). Tracheal width

was normally distributed for the full sample and male and female subgroups (mean(SD) = 16.34 mm (2.39); 17.95 mm (1.91); and 14.85 mm (1.73) respectively). Figure 4.2 shows Tukey's Box and whisker plots of data distribution for biometric variables.

4.3.3. Sizing recommendations

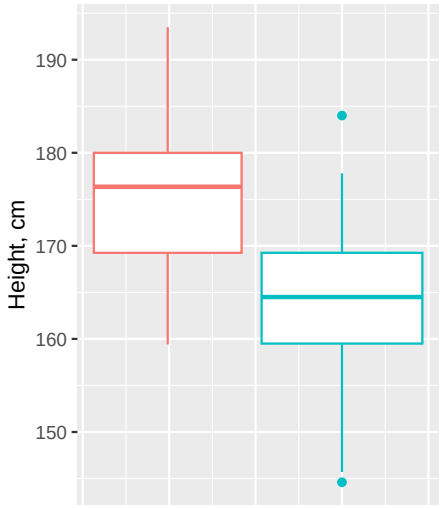
Figure 4.3 shows the distribution of sizing recommendations by sizing method. M-BP-M recommendations differed for males and females, with more recommendations for smaller TT sizes for females. No recommendations were made for size 6 or below using M-BP-Max for males. M-BP-Max recommendations for females ranged from smaller than size 6 to size 10, with data centred around size 7. Differences between the sexes were also observed in M-height and M-shoulder recommendations but not in M-BMI recommendations. M-BMI produced a similar spread of size recommendations across males and females, and the only size 10 TT recommendation using this method was made for a female participant.

4.3.4. Concordance of sizing methods

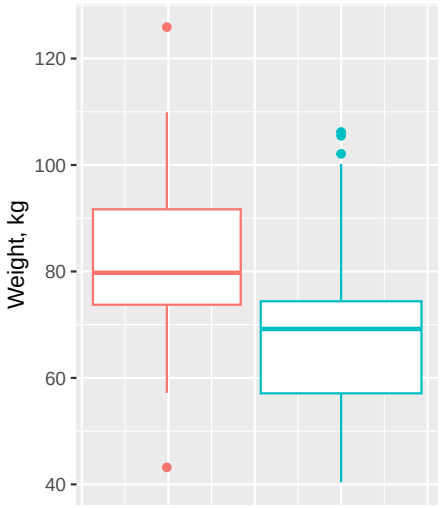
Contingency tables of raw data were created to show concordance of sizing methods with M-BP-Max in the whole sample and for male and female sub-groups (see Table 4.4, Table 4.5 and Table 4.6). This data was converted into percentages to show rates of exact matches between sizing methods based on other biometrics and M-BP-Max recommendations.

4.3.4.1. Concordance of sizing methods with best practice recommendations across the whole sample

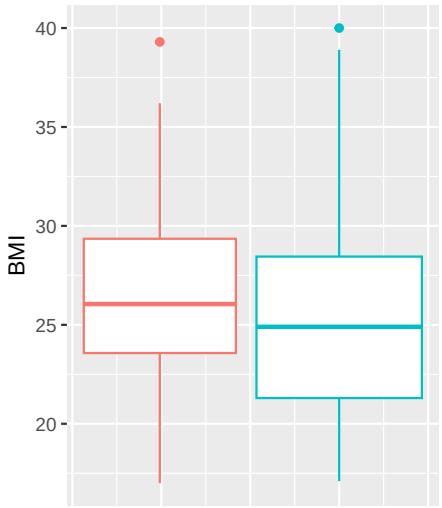
Concordance was low for all methods, with M-sex scoring highest at 38%, followed by M-shoulder (34.7), M-height (34.7%), and M-BMI (28.1%). The contingency tables also illustrate direction of discordance (smaller or larger recommendations than M-BP-Max), and distance from M-BP-Max recommendations (e.g. one, two or three tube sizes difference). Concordance patterns were different for the male and female samples.



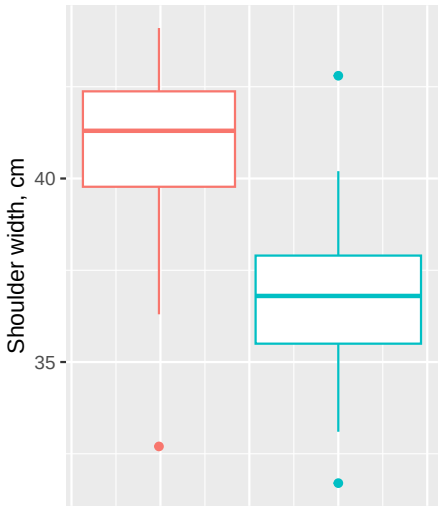
(a) Height



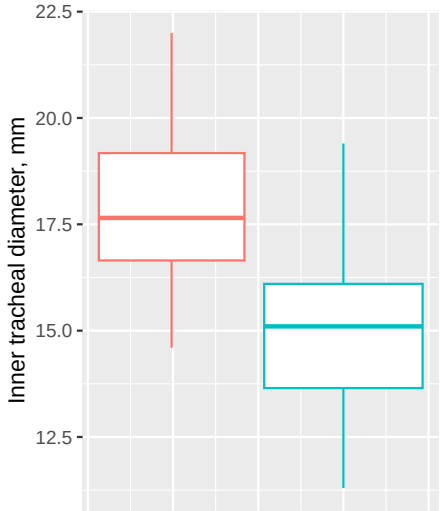
(b) Weight



(c) BMI



(d) Shoulder width



(e) Tracheal width

Figure 4.2.: Distribution of biometric data in male and female sample

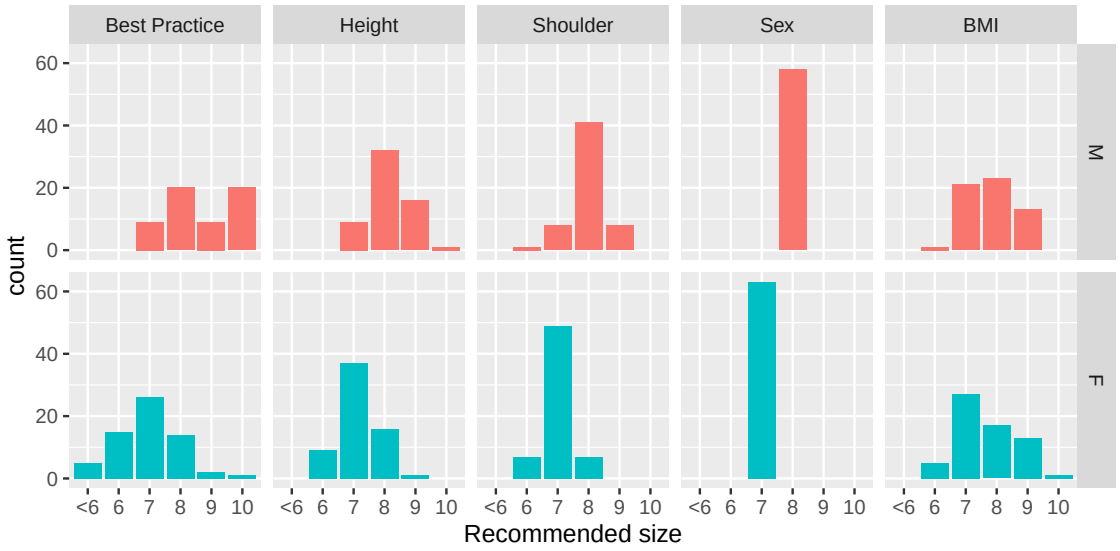


Figure 4.3.: Distribution of sizing recommendations by sizing method

Table 4.4.: Concordance of sizing methods with best practice (BP) recommendations in the whole sample (bold italic font = matches)

(a) Sizing by height vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	3	***1***	4	1	0	0
7	2	8	***21***	10	2	3
8	0	6	9	***16***	5	12
9	0	0	1	6	***4***	6
10	0	0	0	1	0	***0***

(b) Sizing by shoulder width vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	2	***1***	2	2	0	1
7	3	14	***23***	11	2	4
8	0	0	10	***17***	8	13
9	0	0	0	4	***1***	3
10	0	0	0	0	0	***0***

(c) Sizing by sex vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	0	***0***	0	0	0	0
7	5	15	***26***	14	2	1
8	0	0	9	***20***	9	20
9	0	0	0	0	***0***	0
10	0	0	0	0	0	***0***

(d) Sizing by BMI vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	1	***2***	2	0	0	1
7	0	7	***13***	14	5	9
8	2	4	8	***16***	3	7
9	2	1	12	4	***3***	4
10	0	1	0	0	0	***0***

Table 4.5.: Concordance of sizing methods with best practice (BP) recommendations in females (bold italic font = matches)

(a) Sizing by height vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	3	***1***	4	1	0	0
7	2	8	***17***	9	1	0
8	0	6	5	***3***	1	1
9	0	0	0	1	***0***	0
10	0	0	0	0	0	***0***

(b) Sizing by shoulder width vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	2	***1***	2	2	0	0
7	3	14	***20***	9	2	1
8	0	0	4	***3***	0	0
9	0	0	0	0	***0***	0
10	0	0	0	0	0	***0***

(c) Sizing by sex vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	0	***0***	0	0	0	0
7	5	15	***26***	14	2	1
8	0	0	0	***0***	0	0
9	0	0	0	0	***0***	0
10	0	0	0	0	0	***0***

(d) Sizing by BMI vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	1	***2***	2	0	0	0
7	0	7	***11***	9	0	0
8	2	4	6	***5***	0	0
9	2	1	7	0	***2***	1
10	0	1	0	0	0	***0***

4.3.4.2. Concordance of sizing methods with best practice recommendations in the female sample

The order of methods by concordance scores was the same when looking at the female data, with slight differences in percentages as follows: M-sex 41.3%; M-shoulder 38.1%; M-height 33.3%; M-BMI, 31.7%. Looking at direction and magnitude of differences, comparator sizing methods more frequently produced larger TT size recommendations than smaller recommendations compared to M-BP-Max except for M-sex (M-height: larger = 39.7%, smaller = 27.0%; M-shoulder: larger = 36.5%, smaller = 25.4%; M-BMI: larger = 49.2%, smaller = 19.0% ; M-sex: larger = 27%, smaller = 31.7%), and discordant recommendations were out by up to four sizes (M-BMI).

4.3.4.3. Concordance of sizing methods with best practice recommendations in the male sample

The order of methods and percentage concordance agreements in males was different, with highest scores for M-height (36.2%), followed by M-sex (34.5%), M-shoulder (34.5%), and M-BMI (24.1%). Overall, comparator sizing methods more frequently produced smaller TT size recommendations than larger compared with M-BP-Max (method,

Table 4.6.: Concordance of sizing methods with best practice (BP) recommendations in males (bold italic font = exact matches)

(a) Sizing by height vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	0	***0***	0	0	0	0
7	0	0	***4***	1	1	3
8	0	0	4	***13***	4	11
9	0	0	1	5	***4***	6
10	0	0	0	1	0	***0***

(b) Sizing by shoulder width vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	0	***0***	0	0	0	1
7	0	0	***3***	2	0	3
8	0	0	6	***14***	8	13
9	0	0	0	4	***1***	3
10	0	0	0	0	0	***0***

(c) Sizing by sex vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	0	***0***	0	0	0	0
7	0	0	***0***	0	0	0
8	0	0	9	***20***	9	20
9	0	0	0	0	***0***	0
10	0	0	0	0	0	***0***

(d) Sizing by BMI vs. BP

Best practice	<6	6	7	8	9	10
Other method						
<6	***0***	0	0	0	0	0
6	0	***0***	0	0	0	1
7	0	0	***2***	5	5	9
8	0	0	2	***11***	3	7
9	0	0	5	4	***1***	3
10	0	0	0	0	0	***0***

larger/smaller (%): M-height, larger = 19.0%, smaller = 44.8%; M-shoulder: larger = 17.2%, smaller = 51.7%; M-sex: larger = 15.5%, smaller = 50%; M-BMI: larger = 19.0%, smaller = 57.0%). Recommendations were up to four sizes out (M-BMI, M-shoulder).

Figure 4.4 illustrates the differences in concordance with M-BP-Max and recommendations for smaller or larger TTs than M-BP-Max across the other sizing methods. Data for males and females are presented separately. Each comparator method recommended a larger size TT than M-BP-Max more frequently for females than for males and recommended a smaller size TT than M-BP-Max more frequently for males than for females.

4.3.5. Agreement and degree of disagreement

4.3.5.1. Measurement of agreement

Cohen's Kappa was calculated to provide a statistical measure of the agreement on TT size recommendations between the four comparator sizing methods and the best practice method. Calculations were based on binary concordance scores (numbers of exact matches versus non-matches). Kappa was calculated in RStudio for each sizing method, stratified by sex, using the following formula:

$k = (p_o - p_e)/(1-p_e)$

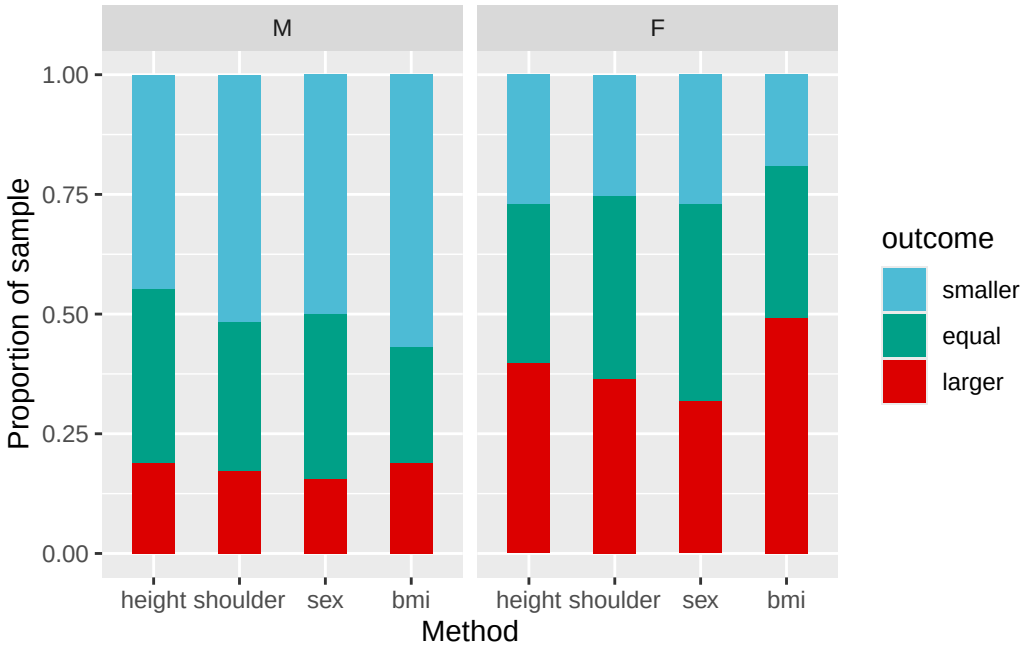


Figure 4.4.: Percentage of smaller, equal and larger sizing recommendations compared to best practice recommendations in females

where

p_o = relative observed agreement among raters

p_e = hypothetical probability of chance agreement

Note: it was not appropriate to calculate Kappa for M-sex for male and female subgroups as there was only one level of outcome - size 7 for females and size 8 for males. As shown in Table 4.7, there was no agreement between any comparator method and best practice sizing recommendations.

Table 4.7.: Cohen's Kappa showing level of agreement in size recommendations between comparator sizing methods and the best practice method

Sizing method based on:	Male sample	Female sample	Whole sample
Height	0.134	0.000	0.135
Shoulder width	0.033	0.014	0.115
Sex	0.000	0.000	0.133
BMI	0.018	0.074	0.060

Interpretation of Cohen's Kappa: 0-0.2 - no agreement; 0.21-0.39 - minimal; 0.40-0.59 - weak; 0.60-0.79 - moderate; 0.80-0.90 - strong, Above 0.90 - almost perfect

4.3.5.2. Degree of disagreement

The Kappa statistic only counts strict agreement. Since sizing of TTs uses an ordinal scale, it was possible to additionally calculate a weighted Kappa to capture information on the *degree* of disagreement between comparator methods and M-BP-Max recommendations. The weighted Kappa penalises responses that are further away from the desired response, reflecting in this case the potential increased impact of sizing decisions that are a greater number of sizes different to M-BP-Max. The weighted Kappa was calculated in RStudio using the vcd package [315]. A linear weighting was applied that increased from zero to one in increments of 0.2, where a weighting of one was applied to exact matches.

Table 4.8 gave minimal agreement for M-height (K = 0.282), M-shoulder (K = 0.257) and M-sex (0.250) and no agreement for M-BMI in the sample as a whole. There was no agreement with best practice recommendations for any method in male and female sub-groups.

Table 4.8.: Weighted Kappa scores showing level of agreement in size recommendations between comparator sizing methods and the best practice method

Comparator method	Male sample	Female sample	Whole sample
Height	0.117	0.086	0.282
Shoulder width	0.049	0.073	0.257
Sex	0.000	0.000	0.250
BMI	-0.106	0.089	0.028

Interpretation of Cohen's Kappa: 0-0.2 - no agreement; 0.21-0.39 - minimal; 0.40-0.59 - weak; 0.60-0.79 - moderate; 0.80-0.90 - strong, Above 0.90 - almost perfect

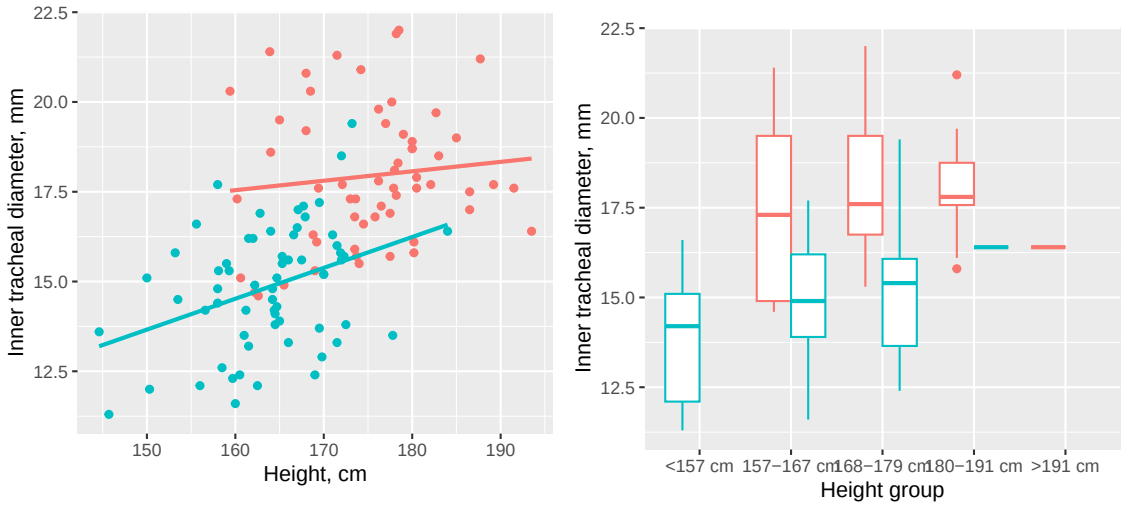
4.3.6. Associations between tracheal width and other variables

Boxplots and scatterplots were created to visualise potential associations between tracheal width and demographic and biometric data, with and without stratification by sex.

4.3.6.1. Height

There was a positive association between tracheal width and height in the sample as a whole, however, this was weaker in the female sub-group than in the sample as a whole

and not evident within the male sub-group (Figure 4.5). Patterns were similar for measured or reported height. There was a positive association between the height groups used in M-height and tracheal width in females but negative association between height groups and tracheal width for males.



(a) Tracheal width plotted against height including line of best fit (linear regression)

(b) Tracheal width by height groups

Figure 4.5.: Association between tracheal width and height in males (red) and females (blue)

4.3.6.2. Shoulder width

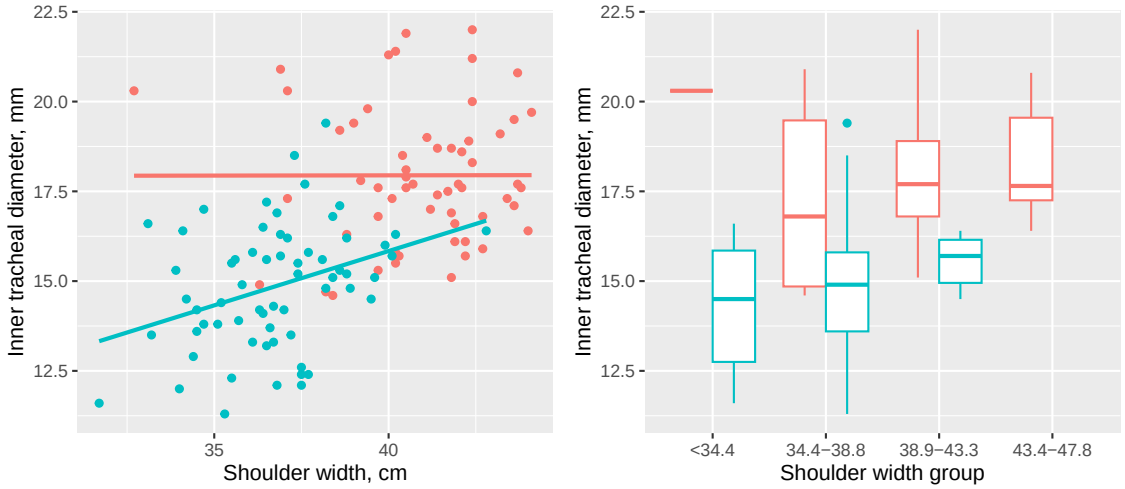
Tracheal width correlated positively with shoulder width in the whole sample and female sub-group but there was no association between tracheal width and shoulder width in the male sub-group (Figure 4.6). Shoulder width groups used in M-shoulder showed a similar pattern. There were no participants in the largest shoulder width group and no females in the second to largest group.

4.3.6.3. BMI

No association was seen between tracheal width and BMI in the whole sample or in the female sub-group. In males there was a weak negative association between tracheal width and BMI (Figure 4.7). The same pattern was seen in BMI groups used in M-BMI.

4.3.6.4. Age

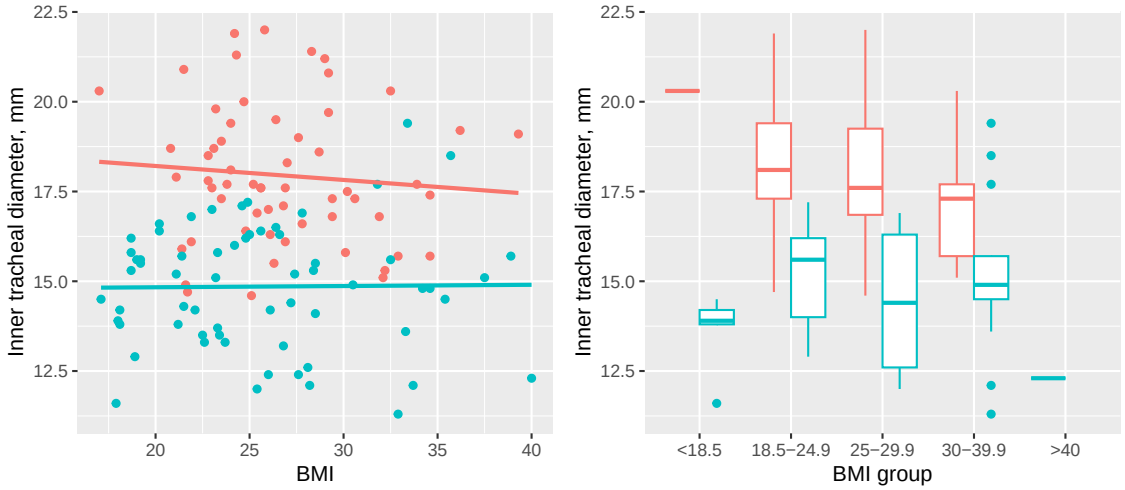
A scatterplot of the whole sample suggested little association between tracheal width and age, however, stratifying by sex showed a positive association in both males and females



(a) Tracheal width plotted against shoulder width including line of best fit (linear regression)

(b) Boxplots of tracheal width by shoulderwidth groups

Figure 4.6.: Association between tracheal width and shoulder width in males (red) and females (blue)

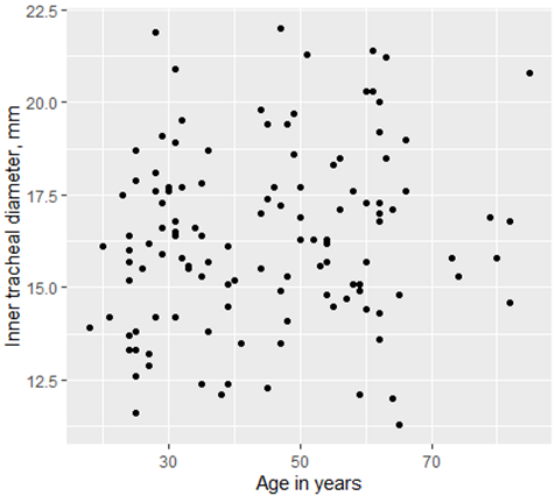


(a) Tracheal width plotted against BMI

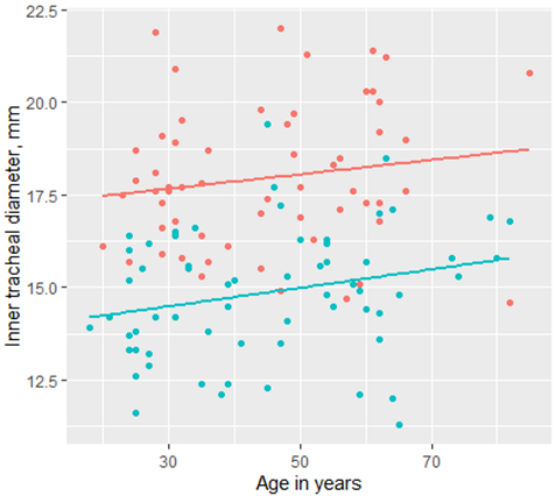
(b) Boxplots of tracheal width by BMI groups

Figure 4.7.: Association between tracheal width and BMI in males (red) and females (blue)

(Figure 4.9). A similar pattern was seen between tracheal width and age in decades.



(a) Tracheal width plotted against age

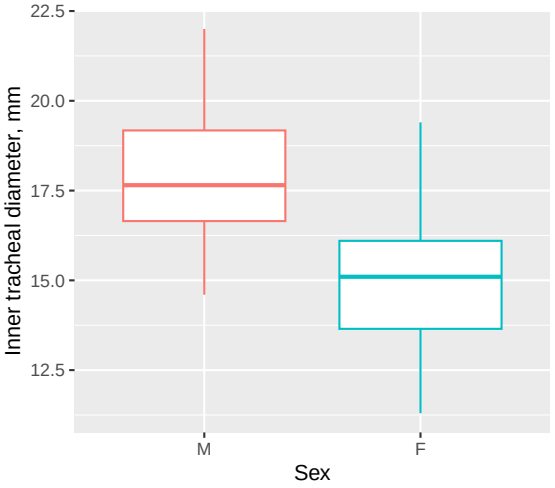


(a) Tracheal width plotted against age stratified by sex

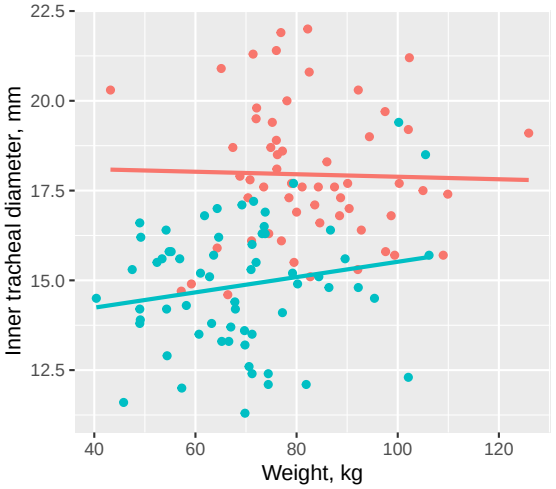
Figure 4.9.: Association between tracheal width and age in males (red) and females (blue)

4.3.6.5. Sex

Boxplots showed an association between tracheal width and sex, with no overlap between interquartile ranges of tracheal width for males and females (see Figure 4.10). Mean tracheal diameters for males and females were 17.9 mm and 14.9 mm respectively. A two sample t-test confirmed a statistically significant difference in means (t = 9.3, difference in means = 3.1 mm, 95% CI 2.4-3.8, p< 0.000).



(a) Boxplots showing tracheal width by sex



(b) Tracheal width plotted against weight

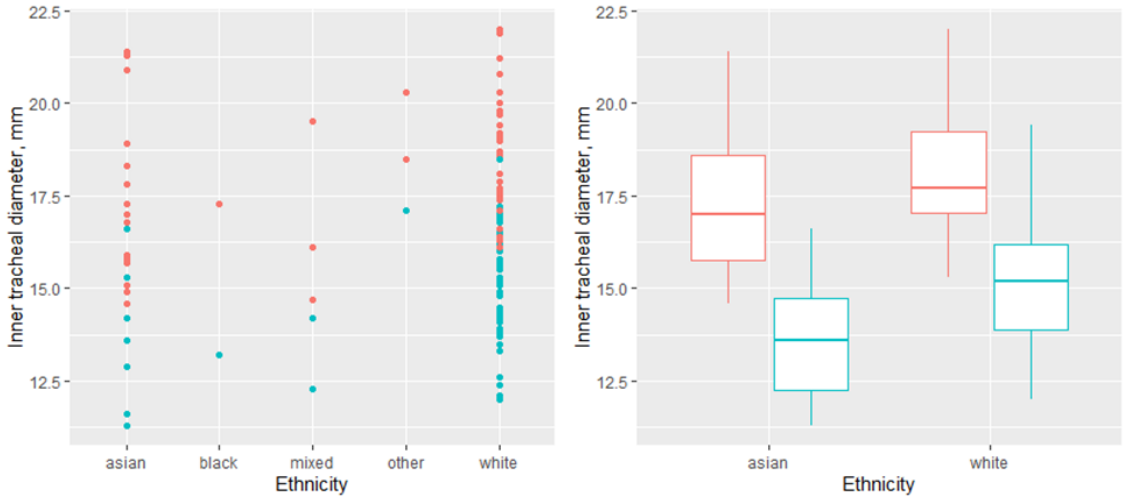
Figure 4.10.: Association between tracheal width and sex and weight in males (red) and females (blue)

4.3.6.6. Weight

There was a positive association between tracheal width and weight in the sample as a whole but stratifying by sex showed a weaker positive association between tracheal width in females and slight negative association for males (see Figure 4.10).

4.3.6.7. Ethnicity

Numbers of participants from Black, Mixed and 'Other' ethnic backgrounds were too small to explore associations between ethnicity and tracheal width. The largest ethnic groups represented were White (n=88) and Asian (n=22). Boxplots of tracheal width in male and female White and Asian participants show larger measurements in White participants but interquartile ranges overlapped (see Figure 4.11).



(a) Tracheal width plotted against ethnic background

(b) Tracheal width in Asian and White participants by sex

Figure 4.11.: Association between tracheal width and ethnicity in males (red) and females (blue)

4.3.7. Multilinear regression models of associations between tracheal width and other variables

Multilinear regression was used to better understand associations between tracheal width and key independent variables with adjustment for other variables. Approaches to fitting multilinear regression models (MLRMs) can be exploratory/explanatory if the aim is to develop understanding of the degree to which variables explain variance in the outcome measure, or predictive if they are designed to provide accurate estimates of the outcome measure from known values of independent variables [160]. The associations observed

between independent variables and tracheal width in this study were not strong, meaning models were likely to have low predictive accuracy, and therefore an exploratory approach was chosen. Since sex was associated with most variables, separate models were fitted for male and female data. To start with, all variables that had a plausible theoretical association and/or a visible association on plots against tracheal width were fitted into the models. Statistical analysis was completed in RStudio [280] using the car package [316]. Outputs of statistical analyses have been copied and pasted from reports produced in RStudio within the Data Safe Haven since for confidentiality reasons the full set of patient data could not be exported for computation within this document.

4.3.7.1. Female multilinear regression model

The first female multilinear regression model (MLRM), used the variables height (measured), shoulder width, weight, BMI and age. This showed statistically significant values for the intercept, height, weight, BMI and age and the model as a whole (see R output below).

```
Call:
lm(formula = dfF$tracheal_wv2 ~ dfF$height_meas + dfF$shoulder_w +
    dfF$weight + dfF$bmi + dfF$age, data = dfF)

Residuals:
    Min      1Q  Median      3Q     Max
-3.3052 -0.8978 -0.0412  0.8451  3.4004

Coefficients:
                Estimate Std. Error t value Pr(>|t|)
(Intercept)     55.97839   21.99800   2.545  0.01367 *
dfF$height_meas -0.30775    0.13768  -2.235  0.02934 *
dfF$shoulder_w   0.22356    0.12155   1.839  0.07109 .
dfF$weight       0.43432    0.15095   2.877  0.00564 **
dfF$bmi         -1.17922    0.40302  -2.926  0.00492 **
dfF$age          0.03379    0.01143   2.957  0.00452 **
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 1.436 on 57 degrees of freedom
Multiple R-squared:  0.3658,    Adjusted R-squared:  0.3101
F-statistic: 6.574 on 5 and 57 DF,  p-value: 6.813e-05
```

R^2 and adjusted R^2 were not used to determine goodness of fit of the model since it was not intended to be predictive. However, the variance inflation factor (VIF) for variables was assessed in order to detect collinearity as a potential source of error in this exploratory model.

Height, weight and BMI had VIFs over 5 (29.9, 156.6 and 166.4 respectively), suggesting collinearity. A correlation matrix was created to identify which variables were most strongly collinear. This showed strong correlation between weight and BMI (r=0.91) and moderate correlation between weight and shoulder width (r=0.55, see R output below).

```
            height_meas shoulder_w    weight        bmi         age
height_meas   1.0000000 0.40414072 0.1526666 -0.2624221 -0.23209938
shoulder_w    0.4041407 1.00000000 0.5531485  0.3805500  0.07745092
weight        0.1526666 0.55314849 1.0000000  0.9104332  0.20457434
bmi          -0.2624221 0.38054995 0.9104332  1.0000000  0.29710060
age          -0.2320994 0.07745092 0.2045743  0.2971006  1.00000000
```

Since BMI is derived from height and weight, and did not show a strong association with tracheal width on scatterplots, it was excluded from model 2. Without BMI in the model, height and age were the only statistically significant variables. VIFs were all below 2, indicating no significant collinearity.

```
Call:
lm(formula = dfF$tracheal_wv2 ~ dfF$height_meas + dfF$shoulder_w +
    dfF$weight + dfF$age, data = dfF)

Residuals:
    Min      1Q  Median      3Q     Max
-3.2073 -1.0637  0.0276  0.8852  3.6436

Coefficients:
                 Estimate Std. Error t value Pr(>|t|)
(Intercept)     -6.818711   5.131240  -1.329  0.18910
dfF$height_meas  0.086231   0.030564   2.821  0.00654 **
dfF$shoulder_w   0.174973   0.128020   1.367  0.17697
dfF$weight      -0.005241   0.015705  -0.334  0.73979
dfF$age          0.032913   0.012146   2.710  0.00884 **
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 1.526 on 58 degrees of freedom
Multiple R-squared:  0.2705,    Adjusted R-squared:  0.2202
F-statistic: 5.376 on 4 and 58 DF,  p-value: 0.0009431
```

Interpretation of the model 2 is as follows:

- For each unit increase of height, tracheal width increases by 0.086 (+/- 0.031), or for an increase in tracheal width of 1 mm, height would increase by 11.6 cm (+/- 4.2)
- For each unit increase of age, tracheal width increases by 0.033 (+/- 0.012), for an increase in tracheal width of 1 mm, age would increase by 30.3 years (+/- 11)

4.3.7.2. Male multilinear regression model

The first male MLRM used height, shoulder width, weight, BMI and age. Values for the intercept, individual variables and the model as a whole were all statistically non-significant.

```
Call:
lm(formula = dfM$tracheal_wv2 ~ dfM$height_meas + dfM$shoulder_w +
    dfM$weight + dfM$bmi + dfM$age, data = dfM)

Residuals:
    Min      1Q  Median      3Q     Max
-3.9983 -1.3492 -0.2534  1.3054  4.2098

Coefficients:
               Estimate Std. Error t value Pr(>|t|)
(Intercept)     5.27089   36.91651   0.143   0.8870
dfM$height_meas  0.08021    0.22090   0.363   0.7180
dfM$shoulder_w  -0.04171    0.14923  -0.279   0.7810
dfM$weight      -0.02324    0.23090  -0.101   0.9202
dfM$bmi          0.02760    0.70179   0.039   0.9688
dfM$age          0.03339    0.01855   1.799   0.0778 .
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 1.923 on 52 degrees of freedom
Multiple R-squared:  0.0772,    Adjusted R-squared:  -0.01153
F-statistic: 0.8701 on 5 and 52 DF,  p-value: 0.5076
```

VIFs were again reviewed to investigate collinearity between variables and to help decide which variables to drop from the second male MLRM. As with the first female MLRM, VIFs were high for height, weight and BMI (46.7; 172.6; and 146.0 respectively). A correlation matrix showed strong correlation between weight and BMI (r=0.87) and moderate correlation between shoulder width and height (r=0.52).

```
            height_meas shoulder_w      weight         bmi          age
height_meas   1.0000000  0.5201672  0.41559073 -0.0867622 -0.43982969
shoulder_w    0.5201672  1.0000000  0.45947473  0.2401749 -0.21061245
weight        0.4155907  0.4594747  1.00000000  0.8666463 -0.07616741
bmi          -0.0867622  0.2401749  0.86664628  1.0000000  0.14954733
age          -0.4398297 -0.2106124 -0.07616741  0.1495473  1.00000000
```

BMI was again selected to be excluded from the second male MLRM due to its derivation from height and weight.

```
Call:
lm(formula = dfM$tracheal_wv2 ~ dfM$height_meas + dfM$shoulder_w +
    dfM$weight + dfM$age, data = dfM)

Residuals:
    Min      1Q  Median      3Q     Max
-4.0028 -1.3511 -0.2568  1.3056  4.2125

Coefficients:
               Estimate Std. Error t value Pr(>|t|)
(Intercept)     6.69378    7.28875   0.918   0.3626
dfM$height_meas  0.07168    0.04231   1.694   0.0961 .
dfM$shoulder_w  -0.04005    0.14181  -0.282   0.7787
dfM$weight      -0.01419    0.02032  -0.698   0.4880
dfM$age          0.03334    0.01834   1.818   0.0748 .
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 1.905 on 53 degrees of freedom
Multiple R-squared:  0.07717,   Adjusted R-squared:  0.007527
F-statistic: 1.108 on 4 and 53 DF,  p-value: 0.3625
```

Though p-values were lower, the intercept value and association between independent variables and tracheal width remained non statistically significant without BMI in the model. There was therefore no indication review the VIFs or to trial a third model that excluded further variables.

4.3.8. Inter-rater reliability

Inter-rater reliability was assessed at the end of the training period, prior to data collection. Ten staff volunteers were measured independently by two reviewers: the senior sonographer who supervised my ultrasound training and myself. Measurements were taken by both reviewers during the same appointment. One reviewer obtained images and collected data as per the data collection protocol while the other reviewer stood to the side, unable to view the screen. Once images were annotated with measurements and reviewer number they were saved and the screen was returned to live capture mode. If settings had been adjusted, these were returned to those outlined in the protocol. Once both sets of measurements had been saved, reviewers compared annotations and discussed differences in order to improve inter-rater reliability, for example there were was a notable difference in measurements recorded for volunteer two. On review of the images, one reviewer appeared to have taken measurements anterior to the widest transverse diameter and placed callipers well inside the outer-tracheal wall. This impacted inter-rater reliability. With data for volunteer 2 included, inter-rater reliability based on the value of the inter-class correlation coefficient using a single-rating, absolute agreement, two-way, mixed effects model was 'good' but the confidence interval was wide (0.75, 95% CI 0.28-0.93).

With data for volunteer 2 excluded, the inter-rater reliability was 'excellent' with a narrow confidence interval (0.98, 95% CI 0.92-1).

4.3.9. Process data

Time taken for image capture and measurement in minutes and seconds ranged from 0:44 to 19:01 with a mean of 5:15. Challenges associated with ultrasound image capture and interpretation were discussed in Chapter 3. In older study participants, calcification meant that views were not always possible at every tracheal ring. In an elderly participant, a low-lying larynx meant most of the trachea was hidden by the sternum. The longest time to obtain a measurement was in a male with calcified airway cartilages.

4.3.10. Incidental findings

The protocol and participant information sheet included a statement outlining that the ultrasound imaging undertaken during the research appointment did not include any form

of health screening. Participants were informed that I was not a sonographer or radiologist. As agreed with the ethics committee and local radiology department, they were also advised that if I saw something that appeared unusual to me during the research appointment, that I would inform them and seek review from a consultant radiologist.

Early in recruitment around one in four participants, mostly female, were found to have thyroid nodules. Review of the literature confirmed that incidence of benign thyroid nodules and papillary microcarcinomas that do not require treatment was high and that incidental findings of these have increased with developments in imaging technology [317, 318]. However, due to concerns that identification of a thyroid nodule might cause anxiety to participants, additional emphasis on the nature and purpose of the ultrasound imaging and information on the incidence and significance of benign thyroid nodules was provided to participants during the recruitment and consent processes so they could factor this information into decisions on whether to participate or not.

Images showing nodules were reviewed by a consultant radiologist for suspicious features as described by Hoang et al in a white paper on the management of incidental thyroid nodules [317]. Most were very small with no suspicious features. A small number were advised to seek GP referral for neck ultrasound by a suitably trained professional. Follow-up of participants who underwent formal neck ultrasound was not part of the study protocol. However, one participant provided feedback that the large nodule found during their research appointment was shown to be cancerous and was later surgically removed.

4.4. Discussion

4.4.1. Summary of findings

4.4.1.1. Concordance of recommended TT sizes with best practice recommendations

The results of this study show there was no agreement between TT sizing methods used in ICU and a best practice method based on tracheal dimensions when data were disaggregated by sex. In females, sizing by height, shoulder width or BMI only matched M-BP-Max recommendations in around a third of cases, and led to oversizing more frequently than matches. Sizing by sex achieved the greatest number of exact matches but concordance was still only around 40% and in one case the recommended TT size was out by three sizes. In males, sizing by height, sex or shoulder width matched M-BP-Max for around a third of cases and led to more recommendations for smaller TTs were more

common than matches. Sizing by shoulder width was out by up to 4 sizes in males. Sizing by BMI led to the lowest percentage concordance for both males and females.

4.4.1.2. Association between tracheal width and other biometrics

There was a strong association between participant sex and tracheal diameter. An exploratory/explanatory MLRM of female data showed that when adjusting for other variables, only height and shoulder width were statistically significantly associated with tracheal width, and that the weakness of association and wide confidence intervals meant neither could be used to accurately determine tracheal width. Attempts to build a MLRM of male data showed that no independent variables were statistically significantly associated with tracheal width.

4.4.1.3. Ultrasound of the trachea

Ultrasound measurement of tracheal diameter was found to be quick. However, as highlighted in this study and the work presented in Chapter 3, image capture and interpretation can be difficult, especially in older subjects, those with a higher BMI and in the presence of calcified cartilage.

4.4.2. Comparison with the published literature

There are no known similar studies with which to compare findings directly. However, data and findings can be compared with normative data on tracheal dimensions and incidence rates of complications that may be due to poor TT sizing decisions.

4.4.2.1. Tracheal norms

The average tracheal width for participants in this study was 17.9 (SD 1.9) for males and 14.9 (SD 1.7) for females. Figures for tracheal width found in the literature and the methods used to obtain them were discussed in Chapter 3 and are summarised below in Table 4.9. As with the cadaver study, figures for tracheal width from the observational study sample fit best with Karmakar et al's findings [319].

Table 4.9.: Published figures for tracheal width with details of measurement technique

Study	Tracheal width (mm)	Measurement technique	Comments on methods
Breatnach et al [91]	M: 15-25 F: 10-21	x-ray, patient sample	Did not account for magnification effect. Breath-hold during imaging likely enlarged trachea
Kamel et al [94]	M: 21.4 F: 17.8	calipers, cadaver specimens	Measured outer tracheal diameter. Embalming may have affected tissue
Kamel et al [94]	M: 27.1 F: 22.9	CT, patient sample	Lower resolution of CT and window width may have missed soft tissue. Breath-hold during imaging likely enlarged trachea. Reported largest diameter from full length of trachea
Or et al [96]	15.0	3D ultrasound	Male and female data not separated, data from younger volunteers
Karmakar et al [319]	M: 18 F: 16.14	CT	Excluded low-resolution CT images
Premakumar et al [93]	17.31	digital vernier calipers, cadaver specimens	Male and female data not separated, sample 80% male. Embalming may have affected tissue.

4.4.2.2. Association between tracheal width and other biometrics

The strong association between tracheal width and sex seen in this study has been reported before [90, 91, 94, 319, 320]. This study found weak associations between tracheal width and height and age in the female sample and no associations between the same in the male sample. Breatnach et al [91] found no statistically significant association with height, though it is not clear whether analysis was based on the sample as a whole or male and female sub-groups. Another study investigating size selection of left-sided bronchial tubes found no association between height and tracheal width, with authors concurring with findings of this study that airway tube size should be selected based on airway measurement [321]. Some studies have found low to moderate associations between tracheal width and height [306, 319, 320]. However, such levels of association are insufficient to

accurately determine between sizes of TT, since the degree to which an independent variable explains variance of the dependent variable is calculated as r squared x 100 [322]. Coordes et al [306] reported a correlation between height and tracheal width of r= 0.51, giving r^2 = 26, i.e. in their sample, just 26% of the variance in tracheal width could be explained by height.

BMI has been shown to be associated with the selection of larger size ETTs in clinical practice [323] and my service evaluation of TT sizing methods suggested the same was likely true for TT size selection. However, no association was seen between tracheal width and BMI in females or males. Other studies have found either no association between tracheal width and BMI or even a negative association in both adults [309] and children [324]. Findings from this study did not support Griscom's [90] hypothesis that tracheal and shoulder width might be controlled by the same biological mechanism as no association between the two was found in males or females. Of note, however, the mean shoulder width and upper range in this sample was smaller than previously published data including those on which the M-shoulder width categories were based [312] and the study from which the data collection technique was copied [313]. However, the former data were taken from a US sample and the latter were collected in a study of personal protective equipment for people working at height. The occupations of the sample of people working at height (mostly male), were related to construction, manufacturing, farming, and engineering, which likely biased the sample to larger body sizes and was the reason for not basing the shoulder-width categories on this data.

4.4.2.3. Incidence of stenosis

There is little evidence on the clinical outcomes of TT sizing decisions. However, the findings that oversizing was more common in females fit with the literature on causes and incidence of tracheal stenosis, for example Gelbard et al [19] found that 83% of patients with iatrogenic laryngo-tracheal stenosis and no previous comorbidities were female. Similarly Zias et al [20] found that 75% of patients with tracheal stenosis in their report of 31 cases were female.

Sizing by BMI led to more frequent oversizing than other methods for males and females. This fits with the evidence on endotracheal tube size selection in patients with high BMIs and the increased incidence of tracheal stenosis in this patient group. Schiff [87] highlights the dual risks in obese patients of developing stenosis due to being given larger diameter

airway tubes and being more likely to have comorbidities such as diabetes or cardiovascular disease. The average BMI of the male and female samples in this study was lower than the UK average (male = 26.2 and female = 24.9 verses 27.6 UK average for males and females). Anecdotally, clinicians assisting with recruitment to the study reported a number of potential female recruits declined to participate because they did not want their weight to be recorded. This may partly explain the lower BMI in the female sample, and suggests oversizing would be more common for these patients in the wider population.

4.4.2.4. Respiratory requirements

The fact that males were recommended smaller than M-BP-Max sizes suggests that males might be at more risk of failing to achieve ventilation targets, difficulties with secretion clearance, or of requiring more frequent upsizing of their TTs. However, there is no primary evidence to support this and anecdotal evidence suggests upsizing is much less common than downsizing.

4.4.3. Limitations - Study design, data collection, analysis

The table below outlines identified study limitations with consideration of impact on findings, alternative approaches and mitigations.

Table 4.10.: Limitations of observational study findings

Limitation	Implications	Alternative approaches	Mitigation
Study design			
Sample: largely healthy volunteers; younger than ICU cohort, lower BMI than average	Potentially not representative of ICU population, e.g. mean tracheal width may be larger in female group given association with age; average BMI is higher in ICU population, which would worsen concordance scores for M-BMI, especially for females	Initial proposal was to recruit from outpatient respiratory, cardiology and neurology clinics (see Section 2.1), however, this was adapted due to the COVID-19 pandemic. Alternative: retrospective data collection from patient sample, however, likely to include estimates for height and weight (unreliable) and limited numbers of patients would have had imaging of trachea from which to obtain measurements, impacting recruitment.	Description of sample provided to enable comparisons with other patient groups. Would not change finding that decisions need to be tailored to patients through measurement of the trachea.
Sample: ethnic diversity differed from national figures with greater proportion of Asian male participants and lower proportion of Black participants.	Mean values for tracheal width and independent variables may differ in ICU population. However, ethnic diversity of male sample more closely reflects the local population of the recruitment site [325]	Stricter control of recruitment with closure to recruitment for over-represented groups (as occurred for female recruits age 20 - 40). However, likely to have significantly delayed completion of recruitment.	Note: ethnic diversity of male sample more closely reflects the local population of the recruitment site (REF: commonslibrary.parliament.uk/constituency-statistics-ethnicity). In contrast, recruitment of Black participants further from local population (13.5%). This is in keeping with evidence on barriers to and rates of participation in research among Black people (REF Farooqi et al 2022)

Limitation	Implications	Alternative approaches	Mitigation
Comparator methods: the categories used to determine TT size in M-height; M-shoulder and M-BMI may not reflect clinical practice and no option for ‘smaller than size 6’ since this was not anticipated to be needed (option existed for M-BP-Max by default).	Different category boundaries may have led to higher or lower concordance rates. However, weak/lack of association between tracheal width and other variables suggests comparator methods would remain poorly concordant with M-BP-Max.	-	-
Recommendations were only for standard size tracheostomy tubes, not adjustable flange/other options	In practice, adjustable flange or other alternative profile tubes may have been used. Note, Uniperc adjustable flange tubes are only available in size 7 and above, so may have led to more oversizing in females and less undersizing in males.		
Best practice method: little evidence on which to base method	M-BP-Max may not lead to optimal size TT	No known evidence-based alternative	Expert consensus approval of method in absence of evidence based alternative. This method ensures a gap between outer TT wall and tracheal wall, reducing risk of tissue trauma and enhancing likelihood of supra-glottic airflow whilst maintaining inner diameter.

Data Collection

Limitation	Implications	Alternative approaches	Mitigation
Ultrasound to measure tracheal diameter instead of CT, MRI or endoscopy	Tracheal measurements may have been different on CT/MRI/endoscopy. However, findings from (CADAVERS chapter) and literature comparing tracheal width obtained from ultrasound and MRI support the use of US in this study. Calcification of cartilages and low-lying larynx (e.g. in elderly) can prohibit imaging of trachea.	MRI: however, time and cost implications, may also have deterred participation CT: however, would expose participants to ionising radiation, cost and time implications, Recruiting patients from MRI/CT clinics: recruitment likely to have been slower. Issues for CT regarding correct window width and levels to capture true internal diameter Endoscopy: would require passing scope through vocal folds (risk of laryngospasm, likely poor tolerance); methods described in literature require specialist software +/- anaesthesia.	Additional work undertaken to better understand sonoanatomy and aid image interpretation/collection of tracheal width data. Acknowledge limitations in image capture in presence of low lying larynx and calcification of cartilage if unable to obtain view between tracheal rings.
Data Analysis			
No intra-rater reliability analysis undertaken on tracheal width measurements	Internal validity not fully assessed.	Could have requested that volunteers or sub-group of sample return on a later date for repeat measurement of tracheal width. However, this would have increased participant burden	Inter-rater reliability was excellent after excluding an outlier collected early in the process of inter-rater reliability testing, suggesting that inter-rater reliability would be high. It is assumed that continuous learning through the process combined with new knowledge of airway sonoanatomy gained from the work in chapter (CADAVERS) would support high inter-rater reliability in further ultrasound assisted tracheal measurements.

4.5. Conclusion

The finding of a lack of agreement between TT sizing methods used in practice and TT sizing based on tracheal width is important since it suggests many patients receiving a tracheostomy in ICU do not receive the optimal size TT. Moreover, when sizing by height, shoulder width or BMI, females are more likely to receive tubes that are too large than to receive the correct size, risking trauma to tracheal tissue and inability to use an OWV. Oversized tubes could lead to tracheal stenosis and negative impacts on weaning, speaking, eating and drinking. In contrast, males are more likely to receive a TT that is smaller than M-BP-Max than the right size tube, with potential negative impacts on ventilation, cuff seal and secretion clearance. In the absence of predictive models of tracheal width based on other biometrics (associations were too weak or non-existent), tracheostomy sizing should be based on measurement of tracheal dimensions. Ultrasound offers one means to obtain measurements and is quick to perform. However, as outlined in the previous chapter, interpretation of ultrasound imaging can be challenging and training programs would need to be developed and validated.

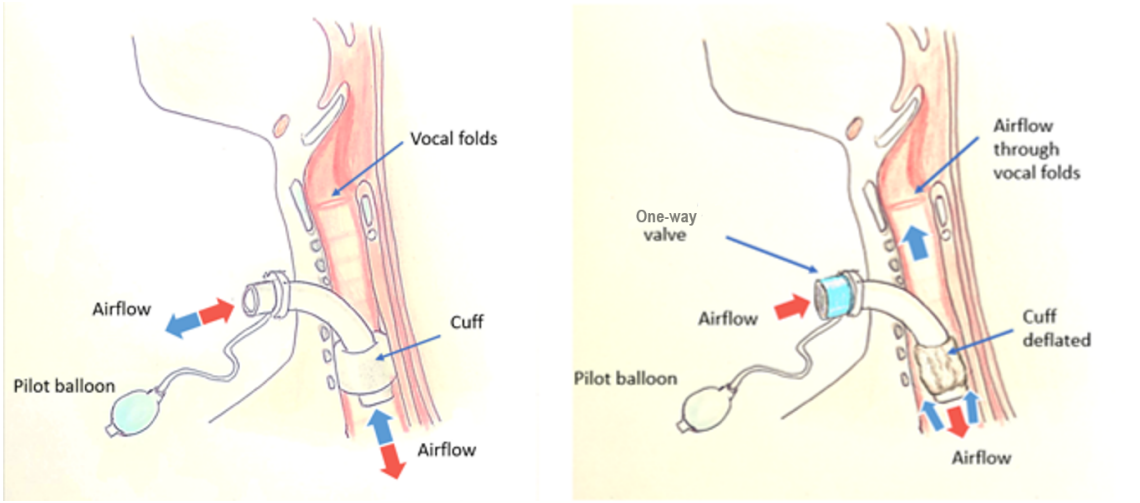
5. Benchtop Study

5.1. Introduction

Resistance to breathing caused by artificial airways is an important consideration in the clinical setting since it can impact delivery of mechanical ventilation and lead to patient exhaustion. Anecdotally, intensivists and anaesthetists tend towards larger size tubes at time of initial insertion with the rationale that 'bigger is better' for ventilation. This view is reflected in the literature with many authors of benchtop studies citing Poiseuille's law that states resistance is inversely proportional to the fourth power of the radius of the tube [99, 101, 102, 326–328], and one recommending to 'select the largest possible TT' [99]. It is acknowledged however in national tracheostomy guidance that the outer diameter of tubes should be limited in order to avoid damage to tracheal mucosa and to allow space for airflow around the tube when the cuff is deflated for weaning and restoration of voice [3]. As outlined in Chapter 1, a substantial body of evidence exists showing that being unable to speak is hugely distressing to patients in ICU [74, 76, 77, 198]. The findings of the systematic review and metasynthesis further indicated voice is of fundamental importance to patients, which requires airflow around the TT and is best achieved through use of a OWV (OWV). Additional benefits of OWVs include helping to restore laryngeal function for swallowing and secretion clearance (oral and pulmonary), and improving respiratory function through restoration of physiologic positive end expiratory pressure (PEEP) [38].

Researchers have investigated tracheostomy-related work of breathing (WOB), using observational studies and benchtop studies. WOB in this context refers to the work required to move air through the upper airway and not elastic work of the lungs or qualitative descriptions of breathing effort used elsewhere [329, 330]. Benchtop studies have focused on the impact of inner tubes, fenestrations, tube placement, cuff design and voice restoration adjuncts (specialised tubes and OWVs), on WOB [99–101, 103]. Some have used steady state flows while others have used sinusoidal flows to more closely mimic physiologic breathing. Only a small number of studies have placed the TT within a model trachea and those that have either used an over-simplified model or only one or two different sizes

of trachea, and none have modelled a small trachea. Most studies have investigated airflow through TTs (the route for inhaled and exhaled airflow when the cuff is inflated), and few have investigated airflow around the tube (the route for exhaled airflow when the cuff is deflated and an OWV is in use, see Figure 5.1). Both scenarios are important clinically - the former is necessary where mechanical ventilation support needs are high or there is risk of gross aspiration of blood, oral secretions or stomach contents [3, 4], and the latter allows restoration of laryngeal function, including voice, with the associated benefits outlined in Chapter 1 and Chapter 2. Interpretation of benchtop findings is further challenged by the lack of clinical data on quantitative values for WOB or even respiratory rate (RR) and tidal volume (TV) seen in tracheostomised ICU populations.



(a) Airflow with an inflated cuff (b) Airflow with a deflated cuff and one-way valve

Figure 5.1.: Differences in tracheal airflow when the tracheostomy cuff is inflated or when the cuff is deflated and one-way valve is in use

Given the value of OWV use, it was important to be able to investigate WOB in this scenario as well as WOB through a TT with an inflated cuff. To provide context and better comparison, it is also necessary to benchmark WOB through the trachea without a TT in situ (i.e. in a plain trachea with tracheostomy inserted), within the same experimental model. There are no known previous benchtop studies that have modelled breathing with an inflated cuff and breathing with a deflated cuff and OWV in a representative range of trachea sizes, or compared these with baseline data. Such quantitative data from TTs in scenarios that better model important clinical conditions would aid understanding of the impact of TT size on WOB and provide valuable evidence to guide clinicians when choosing the size of TT for adults in ICU.

5.1.1. Assumption

There is an optimal size tube for a given size trachea (internal diameter), that balances WOB with an inflated cuff and with a deflated cuff and OWV.

5.1.2. Aim

To determine the impact of size of TT on WOB in scenarios where:

1. the cuff is inflated
2. the cuff is deflated and an OWV is in use

with comparison to baseline WOB (through a plain trachea with no TT inserted).

5.1.3. Objectives

1. to establish a working experimental set up (rig)
2. to establish a trial protocol
3. to undertake trials of all combinations of variables, using clinically relevant variable values

5.2. Methods and materials

5.2.1. Study design

A benchtop experiment consisting of a model of spontaneous breathing in adults and a selection of different size TTs was used to evaluate the effect of size of TT on WOB through and/or around a TT. Flow and pressure differential across the trachea and/or TT were measured under a range of different simulated respiratory conditions. I developed the conceptual plan for the experiment in collaboration with an expert in clinical fluid dynamics at the UCL Department of Mechanical Engineering who co-supervised this workstream. I stipulated the overall purpose, key clinical variables to be modelled and the outcome measure required. My supervisor (a professor of mechanical engineering), provided guidance on the experimental protocol and rig and sourced all components and materials other than TTs and the OWV.

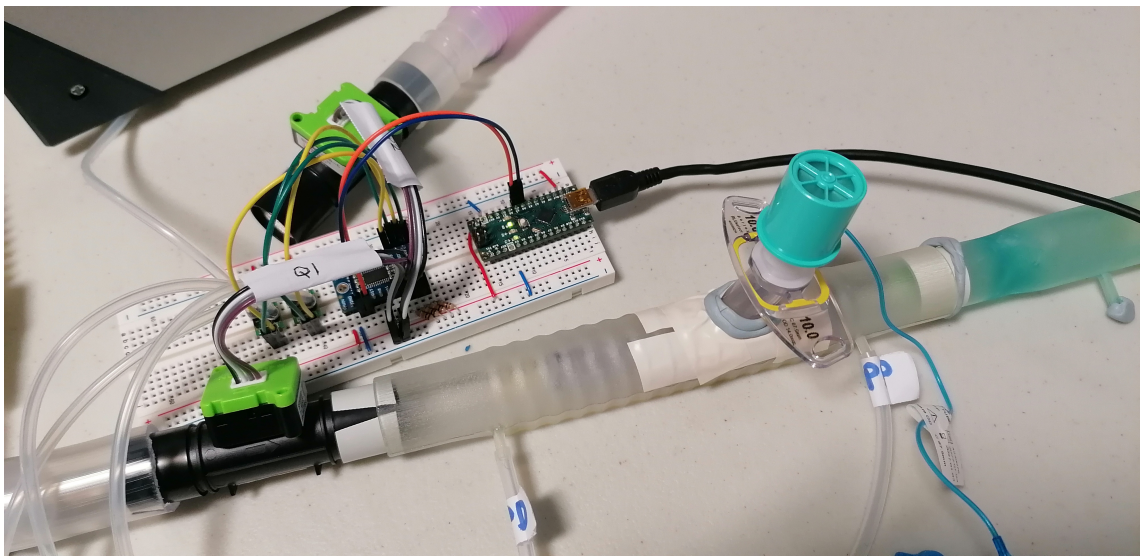


Figure 5.2.: Benchtop flow and electrical circuit

The model of spontaneous breathing consisted of a lung simulator connected to a 3D printed trachea with a hole for a TT to be inserted (see Figure 5.2). Prior to commencement of the benchtop experiment, the set-up and testing of a prototype rig was offered as part of a clinically oriented dissertation project to a Master's level student at the Department of Mechanical Engineering. The objectives were to:

- test the connections between model tracheas and ventilator tubing/pressure sensors
- test the ability of the rig to generate pressure and flow data
- set up an electronic breadboard to allow the download of flow and pressure sensor outputs to an app on a laptop
- confirm the data collection app could record synchronous pressure, flow, and time data that could be saved to file for calculation of the outcome measure

The bespoke data visualisation app was written by my supervisor at the Department of Mechanical Engineering. For the prototype rig, the airflow source was provided by a mechanical ventilator on loan from my clinical site. The intention was for mechanical engineering to build a lung simulator for use in the final experimental rig. However, due to global supply chain issues at the time, this was not possible. Instead, a commercially available lung simulator was loaned from the Royal London Hospital Simulator Centre (see Section 5.2.2). Modifications to the 3D trachea design, pressure sensors, and data collection app were made for the final rig. The original trachea model was printed in a rigid polymer and based on the CT scan of a 50 year old female patient. However, it proved difficult to insert a size 8 TT in this model due to its size, rigid walls, and curved profile. The final trachea models were based on an open-source, straight trachea model with ridges

for tracheal rings and a flat posterior wall representing the trachealis muscle. These are described in more detail in Section 5.2.2. The pressure sensors were exchanged for pressure differential sensors, which reduced data storage and steps in calculating the outcome measure. The data collection app was amended accordingly.

Test runs of the final experimental rig were conducted to ensure it could produce and record the raw data required to calculate the outcome measure which was 'work required to move air through the upper airway under the given set of conditions'. The principle independent variables of interest were: size of TT and cuff/OWV status (whether the cuff was inflated or deflated with a OWV in situ). Three further independent variables were: RR; TV; and trachea model size (see Table 5.1 for a list of variables, levels and data types). The rationales behind the chosen variables are detailed in the following sections.

Table 5.1.: Independent variables

Variable	Data type	Levels
TT size	ordinal	5: Portex size 6, 7, 8, 9, 10
Cuff/OWV	categorical	2: cuff up; deflated cuff + owv
Respiratory rate (RR)	ordinal	3: 12; 24; 36
Tidal volume (TV)	continuous	3: core values were used: 200, 500 and 700 mL. However, target TVs were not achieved in all trials, therefore TV treated as continuous (see Section 5.3) .
Trachea model	categorical	3: small; medium; large

5.2.1.1. Cuff versus one-way valve trials

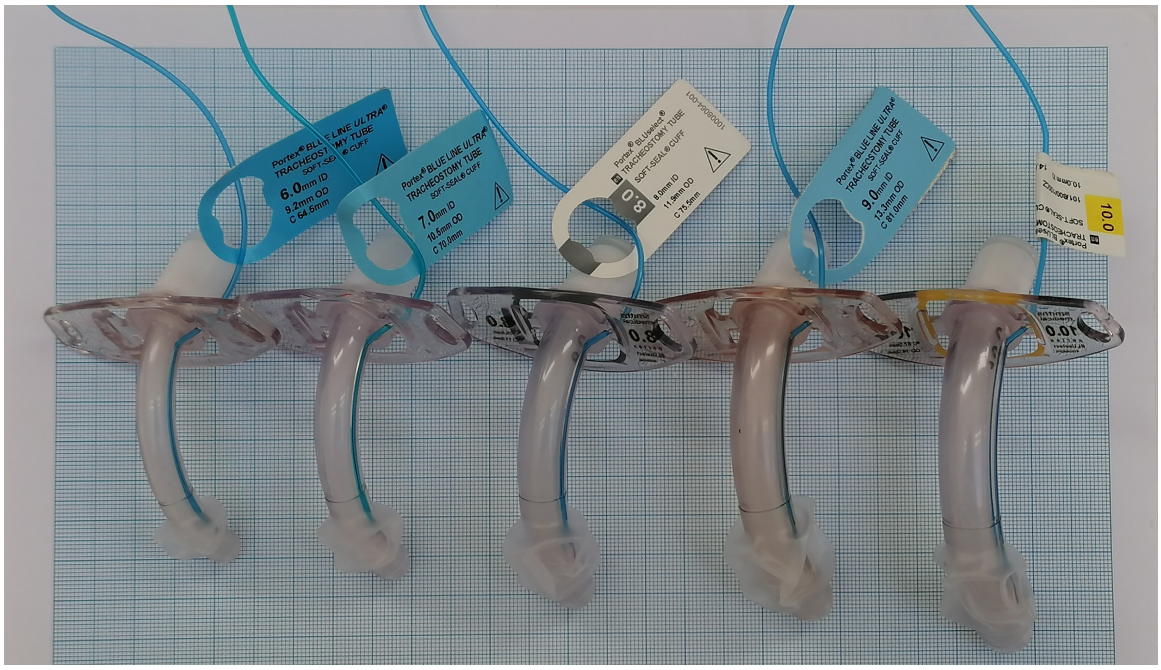
The 'cuff/OWV' variable had two conditions: either the cuff was fully inflated or the cuff was deflated and a OWV placed on the hub of the TT. For brevity, trials are described as 'cuff' or 'OWV' trials from this point on, with the understanding that a deflated cuff was present in all OWV trials unless otherwise stated (i.e. in trials of a cuffless tube). The OWV used was a Passy Muir Speaking Valve^{TM}, as it is the only valve compatible with ventilator circuits and therefore commonly used in UK ICUs. Figure 5.1 illustrates the differences in inhalation and exhalation airflows with an inflated cuff versus a deflated cuff and OWV.

5.2.1.2. Primary tracheostomy tubes and comparator tubes

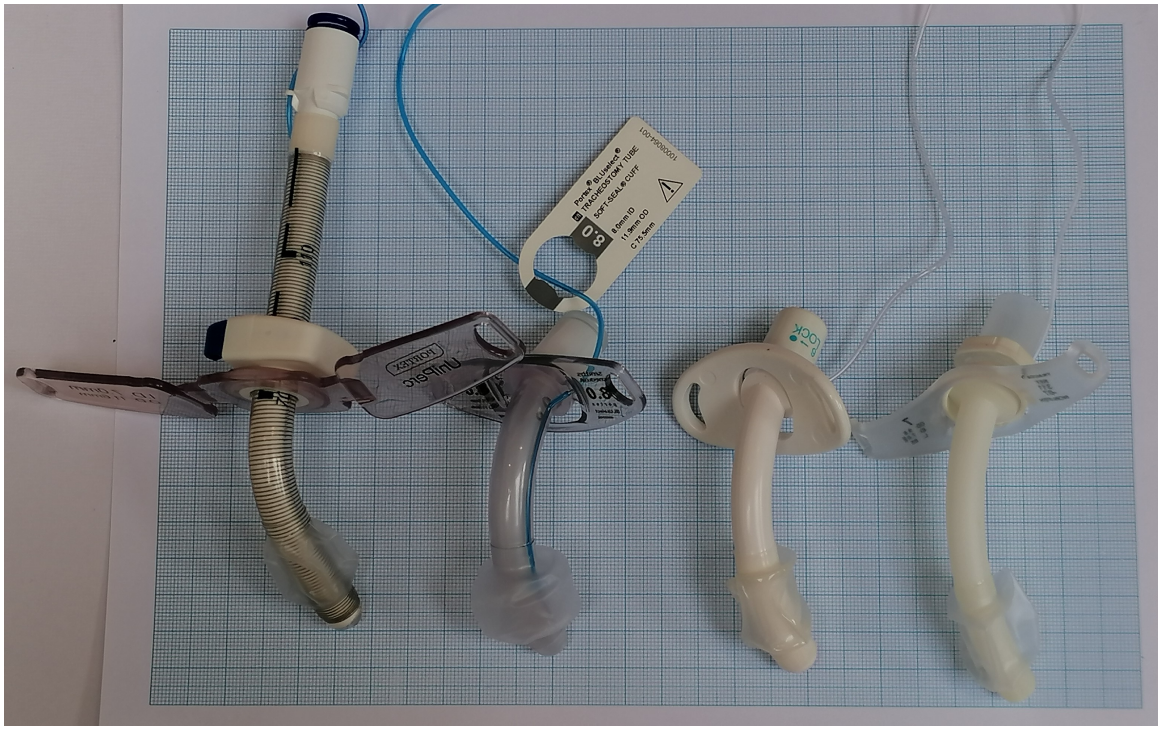
Five sizes of Portex BLU™ TT were tested, representing the most commonly used manufacturer and sizes of TT in UK ICUs. TT profiles, dimensions and sizing conventions differ across manufacturers and models, potentially impacting the resistance to airflow on breathing. The following common alternative tubes were therefore also tested for comparison: Portex Uniperc™ adjustable flange tube, Shiley Low Pressure Cuff™ and Tracoe Twist Plus™. These are subsequently referred to as 'Uniperc', 'Shiley', 'Tracoe Twist+' and the Portex BLU™ as 'Portex'. To rationalise data collection, only one size of comparator tube was used in the study and this was the size whose inner diameter corresponded most closely to the inner diameter of a Portex size 8 (Uniperc: 7; Shiley: 6; Tracoe Twist+: 7). These specific tubes were used as comparators for the following reasons: the Uniperc tube has an adjustable flange that allows clinicians to vary the length of the proximal portion of the tube for use in patients with thicker layers of anterior neck tissue and was in increasing use due to the rise in average BMI of patients; the Shiley tube was commonly used in the UK particularly by ENT and head and neck services but only comes in even sizes making comparison difficult across brands; the selling feature of the Tracoe Twist range was its thinner walls, meaning it offered a larger inner diameter for no increase in outer diameter, potentially reducing trauma to the tracheal wall and improving tolerance of a OWV. The Tracoe Twist+ was also slightly longer, with benefits for the prevention of accidental dislodgement on those with thicker anterior neck tissues. The intention was to include the Bivona 'tight to shaft' (TTS) TT that is sold on the profile of its cuff that deflates be flush with the TT shaft, thereby increasing space for air to circulate around the tube during OWV use. However, due to national supply chain issues around the time of data collection it was not possible to use this tube. Figure 5.3 shows the range of Portex tubes and comparator tubes used in the study.

5.2.1.3. Respiratory rates and tidal volumes

The range of RRs and TVs used in the experiment were selected to reflect those commonly observed in patients on ICUs, ranging from normal breathing to respiratory distress. No data on the range of normal RRs and TVs seen in tracheostomised ICU patients were found, either for spontaneously breathing patients or those fully supported by mechanical ventilation. The values used were therefore determined from a local service evaluation of mechanically ventilated patients and consensus opinion from the project's Clinical Steering Group. The 'core dataset' used RR of 12, 24 and 36 and TVs of 200 mL, 500 mL and



(a) Portex tracheostomy tubes sizes 6 to 10



(b) Size 8 standard experimental tracheostomy tube and equivalent comparator tubes. Left to right: size 7 Portex Uniperc™, size 8 Portex BLU(select)™, size 6 Shiley LPC™, size 7 Tracoe Twist Plus™

Figure 5.3.: Primary and comparator tracheostomy tubes

700 mL.

5.2.2. Equipment

5.2.2.1. Lung simulator

A commercial lung simulator (Laerdal ASL 5000^{TM}, distributed by Ingmar Medical, Pittsburg, US) was loaned from the Royal London Hospital Simulator Centre for the project (see Figure 5.4) . This was a high specification active-servo lung simulator capable of simulating unsupported, spontaneous, negative pressure breathing and came with in-built patient breathing models. For this study the 'normal adult' patient model was selected which produced sinusoidal breathing with lung compliance set at 50 mL/cmH_2O. The inhalation-to-exhalation ratio was modified to 1:2, and tracheal resistance was reduced from the normal adult preset of 5 cmH_2O/L/s to the minimum setting of 3 cmH_2O/L/s, to take into account presence of the model tracheas. The lung simulator was serviced and calibrated by the manufacturer on their site in Germany prior to data collection to ensure accurate delivery of target TVs and RRs.

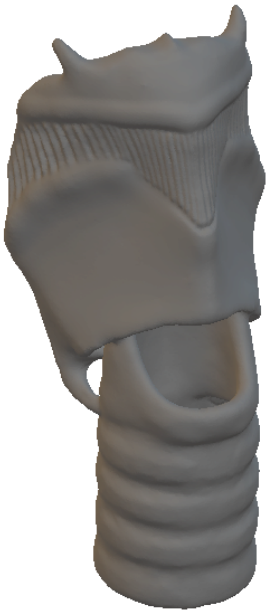
Figure 5.4.: ASL 5000 Lung Simulator used to replicate adult breathing patterns at various physiological parameters

5.2.2.2. Trachea models

Three sizes of trachea model were used. Internal diameters for the small, medium and large models measured 13 mm, 17 mm and 22 mm respectively and were based on the most widely cited published norms [91] and data collected in WS2. The inner diameter

of the largest trachea was set between the values found in the observational study and published data for the mean tracheal width plus two standard deviations in males. The inner diameter of the smallest trachea was intended to be set between the values found in the observational study and published literature for the mean tracheal diameter minus two standard deviations in females (12 mm). However, in testing, it was found to be difficult to insert any TTs in this size model. Therefore, to obtain more data, the inner diameter of the small trachea was set at 13 mm.

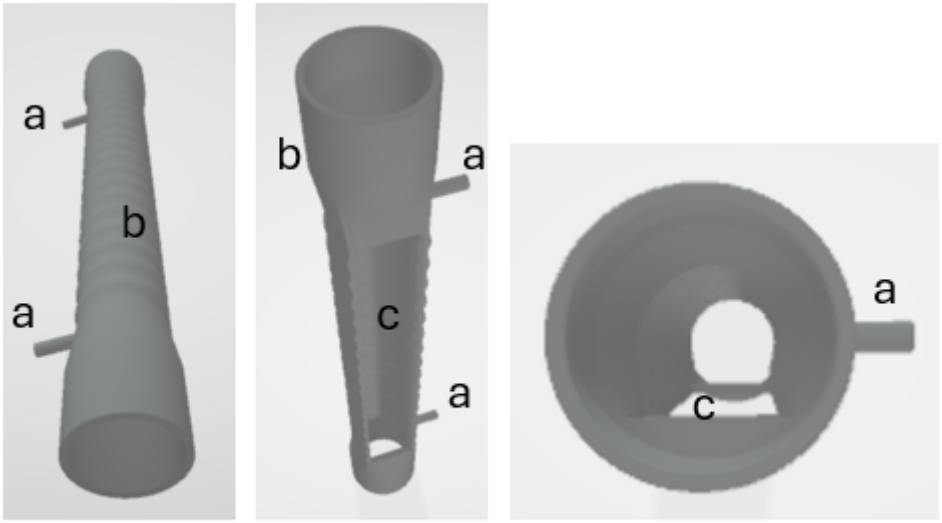
The design of the model trachea was based on an open-source model created for training in emergency tracheostomy [331] and modified to create the required internal diameters and include a stoma for insertion of TTs. The larynx was removed and pressure taps were added to the left lateral wall for connection of pressure monitor tubing: one in the lower third of the trachea and one above the tracheostomy stoma. The cartilaginous anterior and lateral portions of the trachea were 3D-printed on a Stratasys Polyjet printer with Vero clear (rigid resin), at The Bartlett, UCL Faculty of the Built Environment. The posterior smooth-muscle portion of the trachea was 3D-printed with Agilus30 clear (flexible resin). This was to mimic the native trachea and to facilitate insertion of TTs. Figure 5.5a and Figure 5.5b show the original model and the three sizes of trachea model used in experimental trials. A set of three tracheal models that were identical to those in Figure 5.5b except without the hole for TT insertion were used to collect baseline data, i.e. values for WOB at different RR and TVs in a plain trachea with no TT in situ. Figure 5.6 shows the CAD drawings for the final model (plain version with no stoma)



(a) Original Cric-Trainer model [331]

(b) 3D-printed tracheas used in experimental trials

Figure 5.5.: Model tracheas



a = pressure tap, b = rigid polymer for cartilaginous portion, c = space for flexible polymer for trachealis muscle

Figure 5.6.: CAD drawings of final trachea model

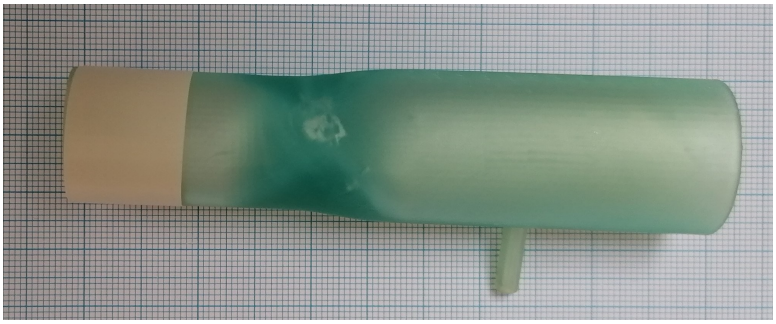
5.2.2.3. Model larynx

A model larynx was placed in the circuit above the model trachea to replicate resistance to airflow created by the vocal folds. Laryngeal-related airway resistance impacts WOB when a patient is breathing in and/or out through the upper airway [332, 333], as is the case with OWV use but has no impact on breathing occurring fully through the TT, i.e. with the cuff up. Inclusion of a larynx was therefore important to give a truer comparison of WOB under cuff versus OWV conditions. In vivo, vocal folds vary in length, thickness and mass between individuals. Abduction and adduction of the vocal folds also varies on inhalation and exhalation and due to respiratory and other factors [334]. For simplicity however, the model larynx was a fixed structure with a circular narrowing representing the glottis, and calibrated to generate 1.75 cmH2O/L/s resistance in a plain medium sized trachea model (with no hole for TT insertion, used for baseline collection), at RR12 and TV500. This resistive value was selected as it is the mid-point of the range quoted in the literature for upper airway resistance. The same larynx was used across all trials.

5.2.2.4. Experimental flow loop

Figure 5.8 shows a simplified diagram of airflow pathways with an inflated cuff or a OWV and the flow and pressure components used in calculations of WOB. Figure 5.9 shows

(a) End view of model larynx



(b) Side view of model larynx

Figure 5.7.: Model larynx

the flow loop from the lung simulator and the electronic connections between sensors, breadboard and laptops used for controlling the lung simulator and in data collection.

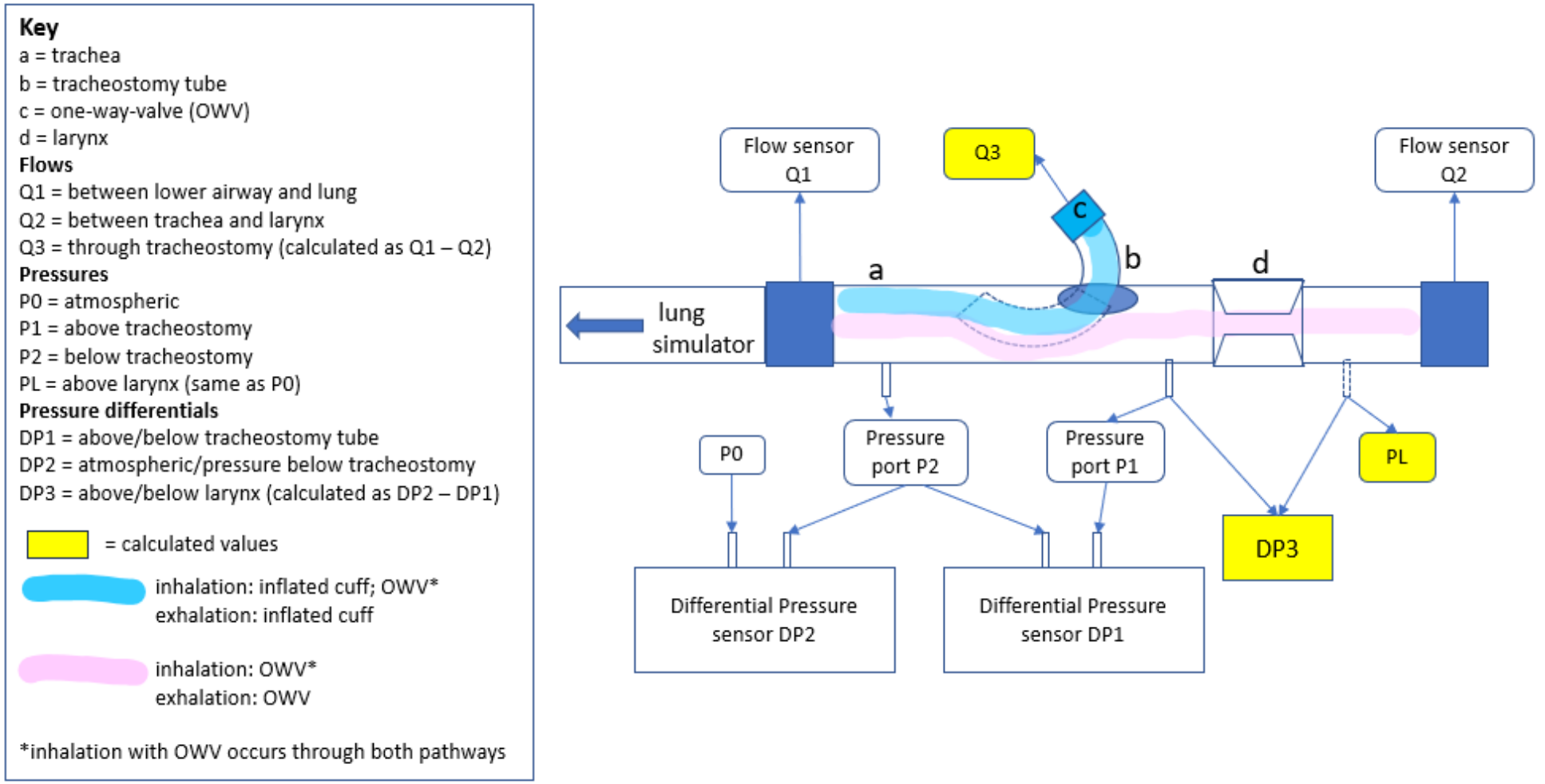


Figure 5.8.: Schematic diagram of rig and components of WOB calculations

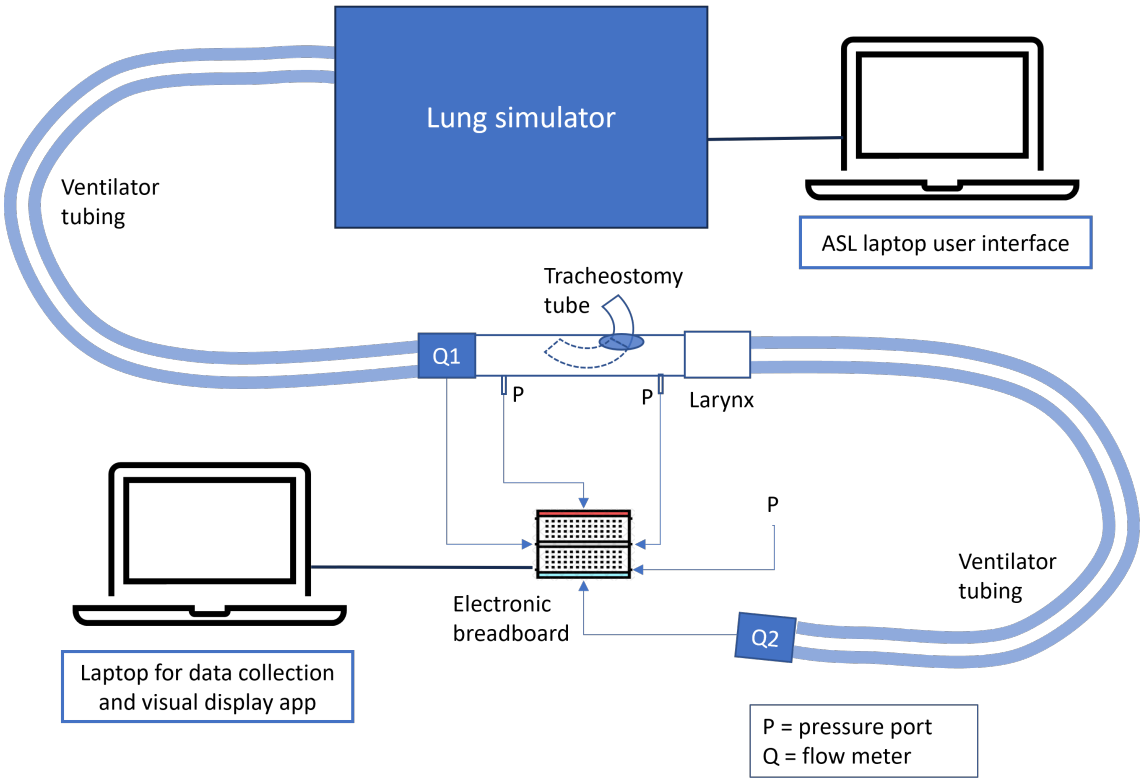


Figure 5.9.: Flow loop showing connections between the lung simulator, trachea, larynx and sensors. Also showing connections between sensors, electronic breadboard, and laptops used in data collection and for controlling the lung simulator

5.2.2.5. Electronic circuit and sensors

Raw data consisted of synchronous flow and pressure differential measurements. Data sampling frequency was set at 20Hz to ensure a spread of points across the waveform of pressure differential over time in trials using a high RR and TV. The flow sensors were Sensiron SFM3000^{TM} models with a maximum flow measure of ± 200 L/min, a sampling rate of 2kHz, 1.5% accuracy and 0.024 L/min resolution. The pressure sensors were Honeywell ABP2^{TM} series with a maximum pressure measure of 6.89 kPa, up to 160Hz sampling rate, 1.5% accuracy and 0.42 Pa resolution. Data were collected using a bespoke Arduino data collection app coded in Python. A visual display of flow and pressure differential provided instant feedback and allowed live gross error checking and troubleshooting, for example disconnection of a sensor was easily seen and could be immediately corrected. The apps were produced by my supervisor Professor Ryo Torii, based in UCL's Department of Mechanical Engineering and trialled during the prototype development. The sampling rate of the app was set at 20Hz to provide a balance between data storage requirements and capturing sufficient data points over a breath cycle at a high RR to generate accurate

measures of WOB.

A flow sensor was positioned at the lower end of the model trachea and measured all flow to and from the lung simulator (Q1, see Figure 5.9). A second was placed at the end of ventilator tubing attached to the upper end of the model trachea and measured flow entering and exiting via the upper airway (Q2). Flow of air inhaled and exhaled via the TT (Q3, see Figure 5.8) was calculated by subtracting Q2 from Q1. Two differential pressure (DP) sensors were used. DP1 was connected to the pressure tap in the distal portion of the model trachea and the pressure tap in the proximal portion of the model trachea, below the larynx. This captured the difference in air pressure above and below the TT (Figure 5.8). DP2 was connected by one tube to the distal trachea pressure tap tube and the other tube was open to the atmosphere. This captured the difference in air pressure below the TT and in the external environment. The pressure differential across the larynx (DP3), was calculated by subtracting DP1 from DP2.

5.2.2.6. Trial protocol

A standard operating procedure (SOP) was created during testing to reduce the risk of error as there were many steps to setting up data collection sessions and individual trials (see Appendix M). The SOP covered setting up the rig (connecting airway model to the lung simulator and sensor circuit board, connecting the circuit board to a laptop for downloading data); lung simulator settings; insertion of correct TT; cuff inflation/deflation and placement of a OWV; and labelling and storage of electronic data files. A standardised format for transparent file naming was adopted to facilitate data management: all files were labelled with letters and digits to indicate trachea model, size or make of tracheostomy, RR, TV and whether it was a cuff or OWV trial. For example, 'me_6_12_700_cuff' was the filename given to the trial of the size 6 Portex tube in a medium trachea with the cuff inflated, a respiratory RR of 12 and TV of 700 mL. Re-test trials had an additional suffix 'retest' for ease of identification in assessment of data validity. For each trial, a photo was taken of the two laptop screens displaying the lung simulator interface and visual data display app plus a Microsoft Word file showing the file label (see Figure 5.10). This was to aid broad post-event comparisons between trials and gross error checking during data analysis.

The position of the TT in the trachea can affect resistance to airflow [101]. A standard approach was therefore agreed on insertion of the TT prior to commencement of data collection. This stipulated that the flange of the TT should be at a distance of approximately

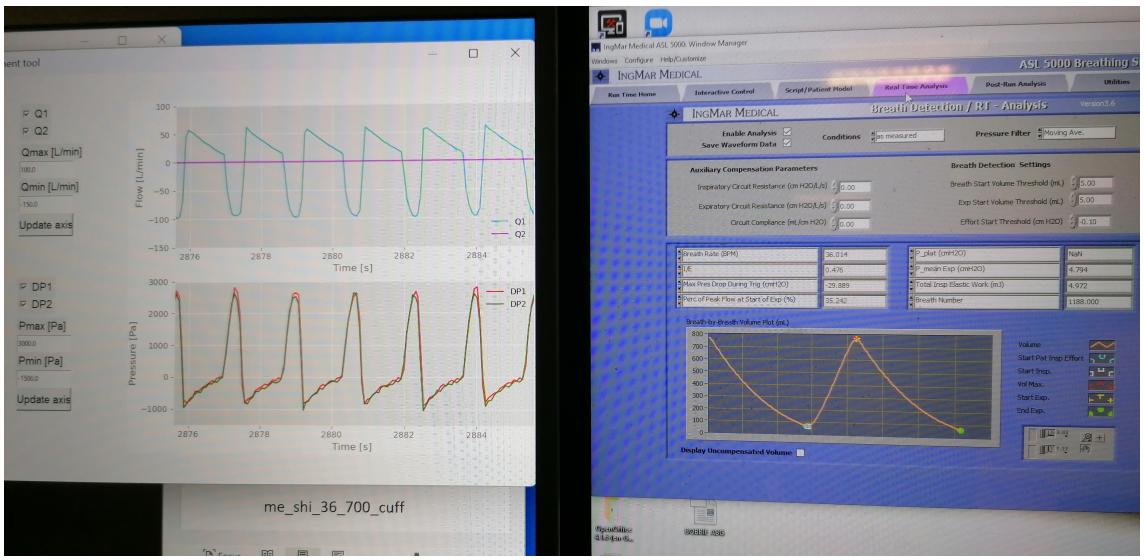


Figure 5.10.: Data visualisation app and file name label (left), and lung simulator software display (right)

1cm from the outer tracheal wall, based on average neck tissue thickness in adults. For all OWV trials the space between the TT and tracheal stoma was sealed using electrical tape and moldable putty.

5.2.3. Analysis

5.2.3.1. Calculation of the outcome measure

The outcome measure was WOB over one minute measured in Joules per minute (J/min). WOB was calculated separately for each section of airflow and then added to give total WOB, i.e. total WOB (WOB_{tot}) equalled work to move air through the TT (WOB_{tt}), plus WOB to move air around the TT (WOB_{around}), plus WOB to move air through the larynx (WOB_{la}). Calculations were based on the following equation:

$$WOB = \int_{t}^{t} Q\Delta P dt \tag{5.1}$$

where Q is airflow in cubic metres per second, ΔP is pressure differential in Pascals and t is time in seconds. This is equal to the area under the graph of flow multiplied by the pressure differential plotted against time. The formulae for individual components of WOB, indicating which pressure and flow data were used in each, were as follows:

$$WOB_{tt} = \int_{t}^{t} Q_3 \Delta P_2 dt \tag{5.2}$$

$$WOB\_around = \int_t^t Q_2 \Delta P_1 dt \tag{5.3}$$

$$WOB\_la = \int_t^t Q_2 \Delta P_3 dt \tag{5.4}$$

No airflow was expected through the larynx with an inflated cuff and no exhaled air was expected through the TT with a deflated cuff and OWV. However, since flows of zero in any component of the composite calculation were expected to return a value of zero for that component, the same three-part calculation (WOB_{tot} = WOB_{tt} + WOB_{around} + WOB_{la}), was used for both cuff-up and OWV trials and for inhalation and exhalation phases of the breath cycle.

This study was an experimental benchtop study not involving biological materials, using standardised equipment and a calibrated lung machine and therefore little variation between trials was expected. However, in order to overcome potential fluctuations in flow and differential pressure recordings over consecutive breath cycles, data were recorded for one minute for each trial and outcome values calculated using the central 30 seconds of each raw data file, meaning outcome values were calculated based on a minimum of 6 full breath cycles per trial (more for trials at higher RR).

5.2.3.2. Validity and reliability testing

Two further steps were taken to address internal validity and repeatability of the study. Firstly, to confirm that the rig generated consistent data and was sensitive enough to detect differences in WOB across TT sizes, raw pressure differential data from an 'average' trial (medium trachea, RR and TV), was reviewed for variation within and between values for different size TTs. Secondly, a series of test-retest trials were conducted and the outcome values compared to see whether equipment settings and set-up produced repeatable results. Retest trials were undertaken on a different day, following trials of different values of independent variables, and/or following disconnection and re-connection of equipment. Different combinations of independent variables were used to ensure a range of outcome values were captured in reliability testing.

5.2.3.3. Descriptive data analysis

The spread of baseline data and experimental core data was visualised by size of trachea model through a series of box plots. Baseline data from the small, medium and large plain trachea models were plotted in a series of line graphs of WOB against TV, stratified by RR. Similar plots were generated of experimental data to explore the effect of size of TT on WOB. Baseline data for each scenario were marked in red on plots of experimental data to allow comparison between experimental and baseline data. Results were analysed systematically, observing the impact of manipulating one independent variable at a time. The effect of size of TT on WOB in different size tracheas and with an inflated cuff or OWV was compared. To allow quantification of the effect of size of TT on WOB where large differences were evident, ratios were calculated of WOB in experimental trials against baseline WOB. This allowed easier comparison between conditions.

5.2.3.4. Data processing

Data was imported into RStudio (PBC, Boston) [280]for data wrangling, exploration and analysis. A data processing script was written and tested on a small number of trials before converting it to an automated loop-script which imported and processed one trial file at a time, outputting a line in a full results database for each trial. Raw data files consisted of 5 columns of data containing time, Q1, Q2, DP1 and DP2 values. The steps involved in processing files and a copy of the code used can be found in Appendix N.

5.2.3.5. Assumptions in data processing

Analysis was based on the assumption that at airflows of below 98.3 m/s (220mph), air can be treated as non-compressible [335].

5.3. Results

5.3.1. Trials

A total of 467 trials were completed, generating over a million data points. This included baseline data collected from the plain 3D printed tracheas.

5.3.1.1. Trials where tidal volume not achievable

The lung simulator was not able to achieve target TVs in trials generating very high or very low WOB. High WOB was generated when simulating the highest RR and TV through a small functional airway. In cuff trials this meant where the TT size was small. In OWV trials this meant where the gap between tracheal wall and TT was small, e.g. all trials in the small trachea. In these cases the resistance to airflow was too great to achieve target TVs. Low WOB was generated when simulating the lowest RR and TV through a large functional airway. In cuff trials this meant where the TT was large and in OWV trials this meant any trial through the large trachea model. With large functional airways, the minimum inspiratory muscle pressure setting on the lung simulator's 'normal adult' profile meant target TVs of 200 mL were exceeded at a RR of 12. As filenames populated the variable columns in the results database, these were written with actual TVs rather than targets. In order to compare WOB with baseline values in trials where the target TV was not achieved, the line of WOB against TV in baseline data was interpolated to give values for every mL of TV.

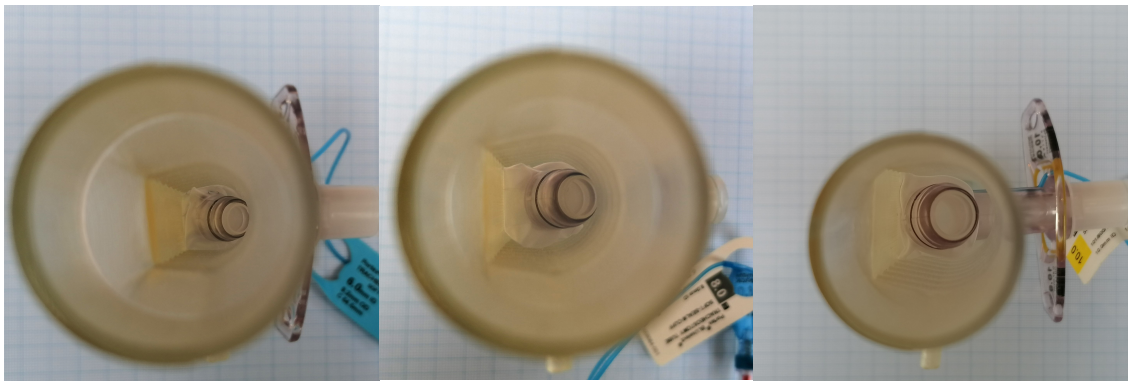
5.3.1.2. Additional trials

It was noted that WOB rose steeply between TVs of 200 mL and 500 mL when RR was high and the functional airway was small. Extra trials were conducted at a TV of 300 mL for these cases to provide an extra data point and better understand the non-linear increase in WOB as TV increased.

5.3.1.3. Fit of TTs within the model tracheas

Not all TTs were compatible with all trachea sizes: only size 6, 7 and 8 Portex tubes and the size 7 Tracoe Twist+ fitted in the small trachea. The Portex size 8 tube required more force and manipulation to insert it in the small trachea than smaller size tubes and insertion caused indentation of the flexible posterior tracheal wall. The documented outer diameter for the size 6 Shiley was smaller than the Portex size 8, however, on examination, the Shiley's cuff was of thicker material than other tubes and increased the functional outer diameter along most of the tube to over the manufacturer reported dimensions. There was little space around deflated cuffs in the small trachea. In contrast, gaps were visible around the size 10 tube in the large trachea. Figure 5.11 shows the space around the deflated cuff of a size 6 Portex in the small trachea, a size 8 in the medium trachea and a

size 10 in the large trachea. The size 10 tube was too large to fit in the small and medium tracheas. Initial trials of the size 10 in the large trachea showed similar performance to the size 9 Portex. Therefore a full dataset was not collected for the size 10 Portex and data for this tube were not included in the 'core dataset'. No cuff trials of the size 6 Portex were conducted in the large trachea as the cuff was too small to reach the inner tracheal wall.



(a) Size 6 Portex in the small trachea (b) Size 8 Portex in the medium trachea (c) Size 10 Portex in the large trachea

Figure 5.11.: Fit of tubes in trachea models showing space around the deflated cuff

5.3.2. Data processing

Data was imported into RStudio as described in Section 5.2.3.4 above. Field notes, the data visualisation app, photographs taken during data collection and preliminary analyses helped identify a number of files with errors that were removed from analysis or corrected as shown in Table 5.2 . These included:

Table 5.2.: Trials with errors identified and action taken

Number of trials	Error	Method of detection	Resolution
9	loss of Q2 data mid-trial	value for one component of WOB was zero; raw data and photos checked	file removed; data recollected
16	data included data from previous trial (not reset between trials)	outliers on preliminary plots of data (4), systematic search of longer length trials (12); raw data time stamps and plots of Q against t showed change in flow/pressure differential	files trimmed in Notepad to only include correct section and results table script re-run in R
2	duplicate files	small deviation of line in plots	re-labelled second file as 'restest' and included in reliability testing
1	mis-labelled as cuff trial	outlier on plot; confirmed by field note and checking photo taken of visual display during trial	re-labelled file as 'owv' and results table script re-run in R

Number of trials	Error	Method of detection	Resolution
1	TT removed prior to saving data	outlier on preliminary plots	removed; data recollected

5.3.3. Validity and reliability

Raw data from trials of the size 6, 7 and 8 Portex under the same conditions were reviewed to look for variability in pressure differentials within trials and a clear distinction in pressure differentials across trials. The waveforms within trials were fairly uniform but with some fluctuation in peaks and troughs. Combining data for three sizes of tube in one plot shows the effect of tracheostomy size on pressure differential and a clear distinction in peak pressure differentials across sizes (see Figure 5.12).

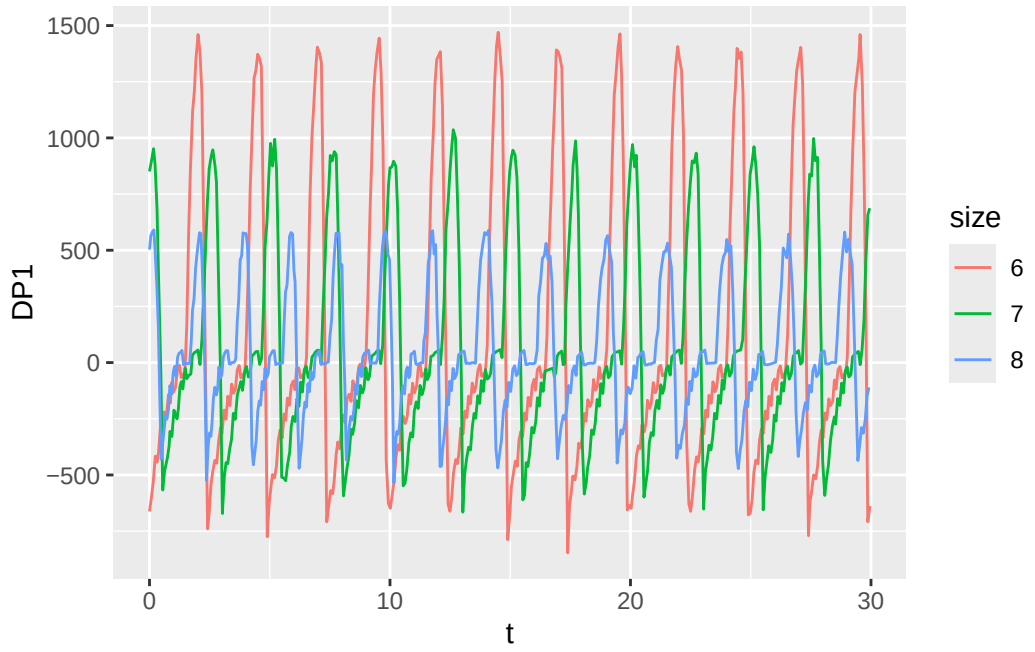
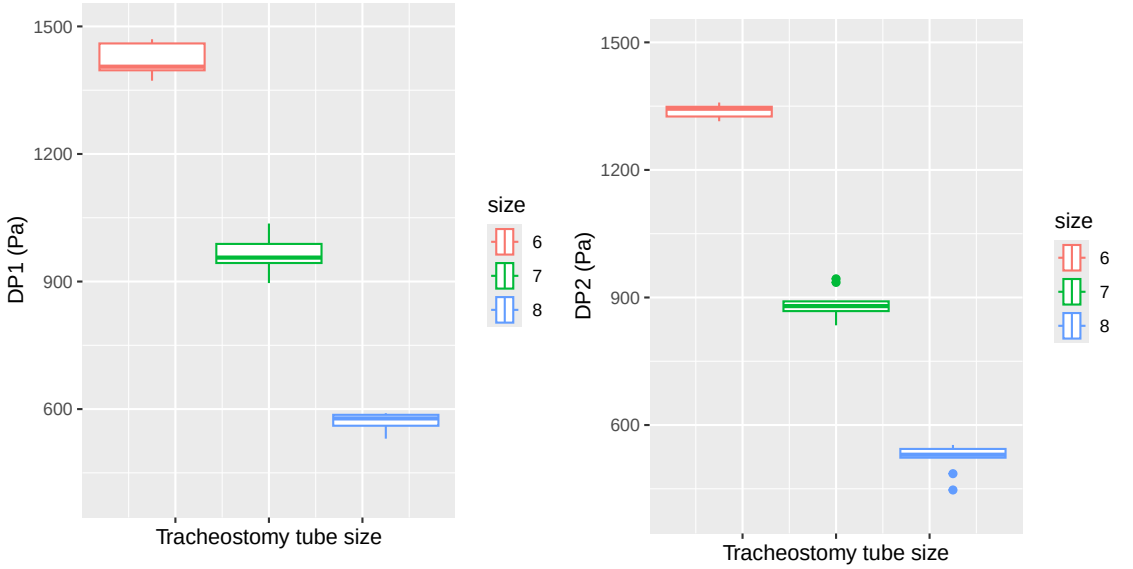


Figure 5.12.: Effect of tracheostomy tube size on pressure differential (above and below tracheostomy tube) in the medium trachea with a respiratory rate of 24 breaths per minute and tidal volume of 500 mL

Boxplots confirmed differences in median peak values for pressure differential between sizes of tube and no overlap in ranges of values (see Figure 5.13), indicating sensitivity of the experimental rig to detect a difference in WOB across different size tracheostomy tubes and low variability in data within tube sizes. The use of 30 seconds of data per trial for calculating WOB further mitigated the effect of any variation across breath cycles by basing WOB values on at least 6 breath cycles (up to 18 breath cycles for RR of 36).



(a) Between upper and lower trachea (above/below the tracheostomy tube), (DP1)

(b) Between lower trachea and external opening of tracheostomy tube (DP2)

Figure 5.13.: Peak values for pressure differentials in a medium trachea at respiratory rate 24, tidal volume 500 mL, by tracheostomy tube size. Boxes represent IQR, points represent observations less than the 1st quartile - 1.5 IQRs or more than the 3rd quartile + 1.5 IQRs, whiskers encompass the minimum and maximum values excluding outliers

Table 5.3.: Table of data for core values of RR and TV

Reproducibility was analysed using 14 pairs of test-retest trials. See Figure 5.14 for comparison of WOB values across test pairs.

Statistical analysis of the closeness of test-pair values was conducted using a two-way mixed effects model intraclass correlation coefficient (ICC) based on single measurement with an absolute agreement definition. This gave an ICC value of 0.997, p<0.0001, CI 0.99-0.999, indicating excellent reproducibility.

5.3.4. Data distribution

Analysis of data distribution was based on a 'core set' of experimental trials, which only included trials of standard Portex tubes at the three core levels of RR and TV. This was to remove the impact on findings of the comparator tubes and additional trials of certain trachea-TT combinations at different TVs (see Section 5.3.1.2). Distribution of data was non-uniform and skewed right for baseline (trials of plain tracheas with no hole for tracheostomy insertion) and experimental trials. Minimum values for WOB were similar in both datasets but the experimental dataset was wider spread and had higher centre and

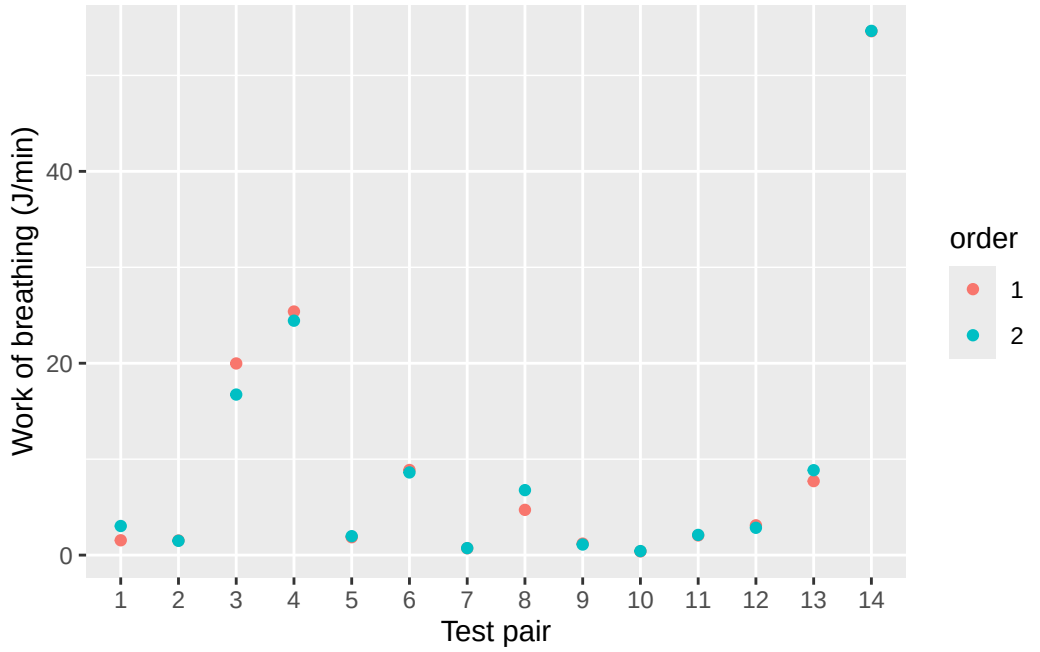


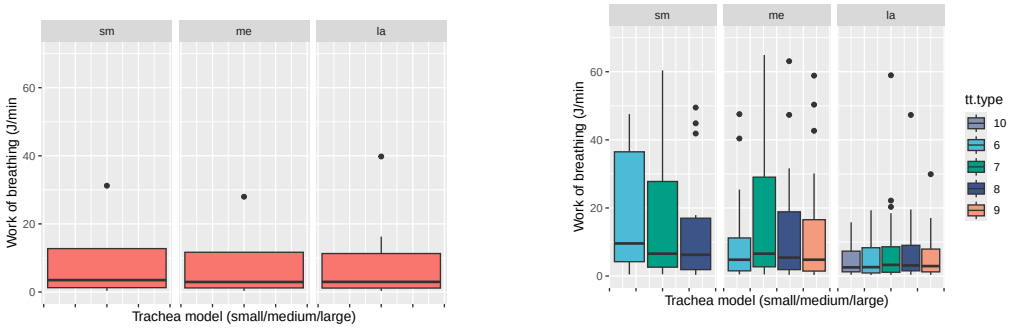
Figure 5.14.: Outcome values for test-retest pairs

Table 5.4.: Summary data for WOB in baseline and experimental trials

	baseline	trial
mean(minute_inex)	7.819621	12.003898
sd(minute_inex)	10.38962	15.82480
median(minute_inex)	2.976358	4.654330
IQR(minute_inex)	10.54643	15.47408
quantile(minute_inex, 0.25)	1.177961	1.517650
quantile(minute_inex, 0.75)	11.72439	16.99173
min(minute_inex)	0.3199393	0.3171212
max(minute_inex)	39.80003	64.90973

maximum values than the baseline dataset. The maximum WOB in experimental trials was almost twice the maximum value for WOB at baseline (see Table 5.4).

Figure 5.15 illustrates the distribution of data by trachea size for baseline and experimental trials respectively. The variation in baseline WOB was relatively stable across size of trachea compared to experimental trials. Figure 5.15 also shows that median and maximum WOB through a small trachea with a TT was higher than in a medium or large trachea with a TT. Figure 5.16 shows distribution of experimental data by trachea size and cuff versus OWV status, and highlights the low WOB in the large trachea with an OWV compared to any other set of trials, including baseline data. Outliers fit with the pattern in the line graphs in Section 5.3.6 of progressively larger increases in WOB as RR and TV increase.



(a) Baseline data

(b) Experimental data by size of tracheostomy tube

Figure 5.15.: Spread of data by trachea size. Boxes represent IQR, points represent observations less than the 1st quartile - 1.5 IQRs or more than the 3rd quartile + 1.5 IQRs, whiskers encompass the minimum and maximum values excluding outliers

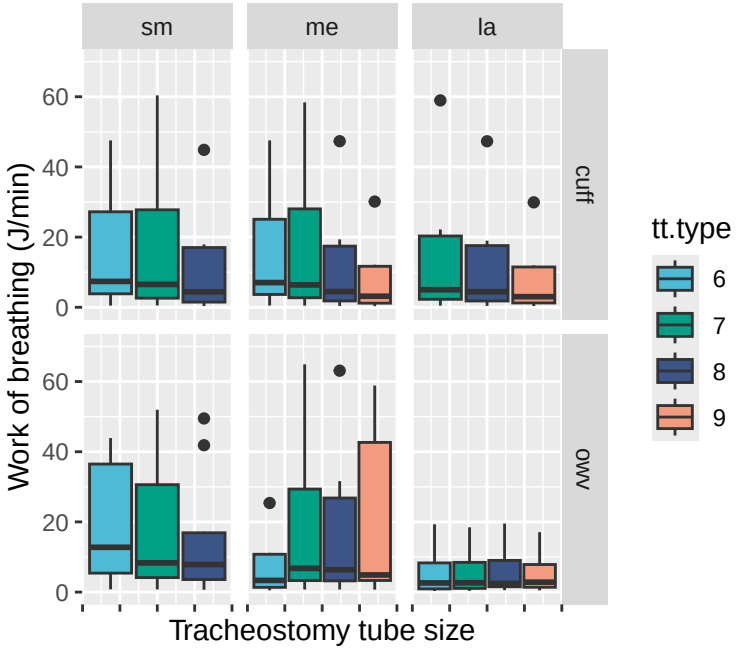


Figure 5.16.: Spread of data by trachea model and inflated cuff versus deflated cuff and one-way valve (OWV). Boxes represent IQR, points represent observations less than the 1st quartile - 1.5 IQRs or more than the 3rd quartile + 1.5 IQRs, whiskers encompass the minimum and maximum values excluding outliers

5.3.5. Baseline data: WOB through a plain trachea

Figure 5.17 shows how WOB changes in a small, medium and large trachea as respiratory rate and tidal volume increase. WOB steadily increased in a non-linear fashion as RR and TV increased. At a normal RR WOB was similar across trachea sizes. At a very high RR, the highest WOB occurred in the large trachea.

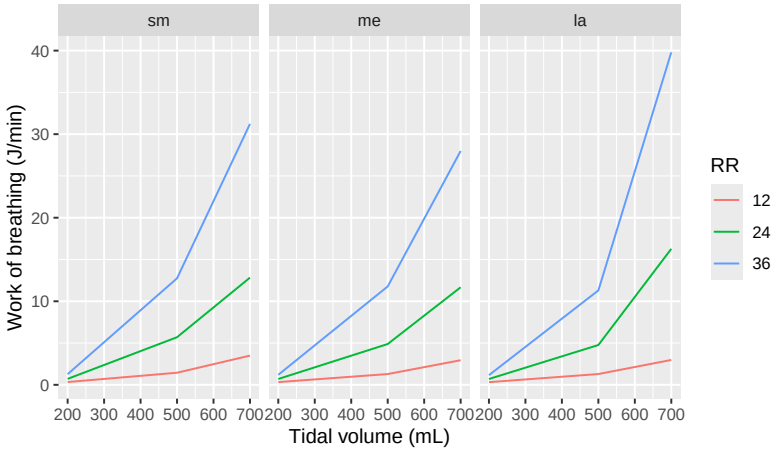


Figure 5.17.: WOB through plain tracheas by TV and RR

5.3.6. Experimental data

The relationship between size of TT and work required to move air through the trachea is described as each of the other independent variables is manipulated. Results for cuffed trials are presented first, broken down by RR, TV and trachea size. Trials of comparator tubes have been presented separately below for ease of viewing plots. Respiratory rates of 12, 24 and 36 are described as ‘normal’, ‘raised’ and ‘very high’. Descriptive terms have not been used for TVs as they are subject dependent, i.e. 300 mL could be a high value for one person and low for another.

5.3.6.1. Work of breathing with an inflated cuff

As above, only the size 6, 7 and 8 Portex fitted the small trachea, and the size 6 TT could not be used in cuff trials in the large trachea as the cuff was too small to reach the tracheal walls. Figure 5.18 shows that the relationship between TT size and WOB with an inflated cuff was similar in the small, medium and large tracheas. At each RR and TV, WOB followed the reverse order of TT size, with the highest levels of WOB generated by the smallest tube and lowest levels by the largest tube.

5.3.6.1.1. Normal RR (12 breaths per minute)

At normal RR and TVs below 350 mL WOB was close in absolute values across tube sizes. At normal RR the maximum WOB in the small and medium tracheas was produced by the size 6 tube at a TV of 700 mL and was three times higher than baseline. At normal RR and a TV of 700 mL the size 7 and 8 tubes generated twice and 1.5 times baseline WOB respectively in all trachea models, whilst WOB in the size 9 was the same as baseline in the medium and large trachea (did not fit in the small trachea).

5.3.6.1.2. Raised RR (24 breaths per minute)

When RR was raised, WOB at TV 200 mL was again comparable across tube sizes. Beyond this, the difference in WOB progressively increased with descending TT size. WOB patterns were slightly different for the size 6 tube in the small and medium tracheas: the maximum TV achieved with a size 6 in the small trachea was 671 mL, generating a WOB four times higher than baseline, whereas in the medium trachea the maximum TV of 700 mL was achieved, generating a WOB 3.5 times higher than baseline. Images captured of the live data visualisation app show small flows through Q2 in the latter trial, suggesting a slight leak around the size 6 cuff in the medium trachea at this combination of RR and TV, which may explain why a higher TV was achieved and WOB was lower. At raised RR the size 7 tube generated the same WOB in the small and medium tracheas at maximum TV, as did the size 8, with trial-to-baseline WOB ratios remaining at just over two and approximately 1.5 respectively. WOB in the size 8 was the same in the large trachea, however, for the size 7, the WOB at TV 700 mL was lower in the large trachea. Again, images captured of the live data visualisation app suggested there was a slight leak around the size 7 cuff in the large trachea at this RR and TV. In the size 9 tube, WOB at raised RR in the medium and large trachea was similar at all TVs, but since the baseline WOB was higher in the large trachea at high RR and TV, WOB in the size 9 at TV of 700 mL was lower than baseline in the large trachea.

5.3.6.1.3. Very high RR (36 breaths per minute)

At very high RR, WOB across tube sizes remained close at TV 200 mL though the gap between the smallest and largest size tubes had widened and there was a steeper increase in WOB as TV increased. The maximum TV achieved with a size 6 tube in the small trachea was 453 mL and this corresponded with a WOB 4.7 times greater than baseline. The size 8 and 9 tubes generated the same WOB at TV 700 mL in all trachea models they

were trialled in (all trachea models for size 8; medium and large for size 9). Again, due to the difference in baseline WOB in the medium and large tracheas, the size 9 produced a WOB slightly higher than baseline in the medium trachea but lower than baseline in the large trachea. A TV of 700 mL could not be achieved in the size 7 tube in the medium trachea but could in the large trachea. This is likely due to a leak around the size 7 cuff in the larger trachea at high combinations of RR and TV.

5.3.6.2. Work of breathing with a deflated cuff and one-way valve

Figure 5.19 shows the effect of size on WOB in the small, medium and large tracheas. As with the cuff trials, there are no data for the size 9 tube in the small trachea as it was too big to fit. There were no trials of the size 6 tube with an inflated cuff in the large trachea, however it was trialled in the large trachea with a deflated cuff and OWV.

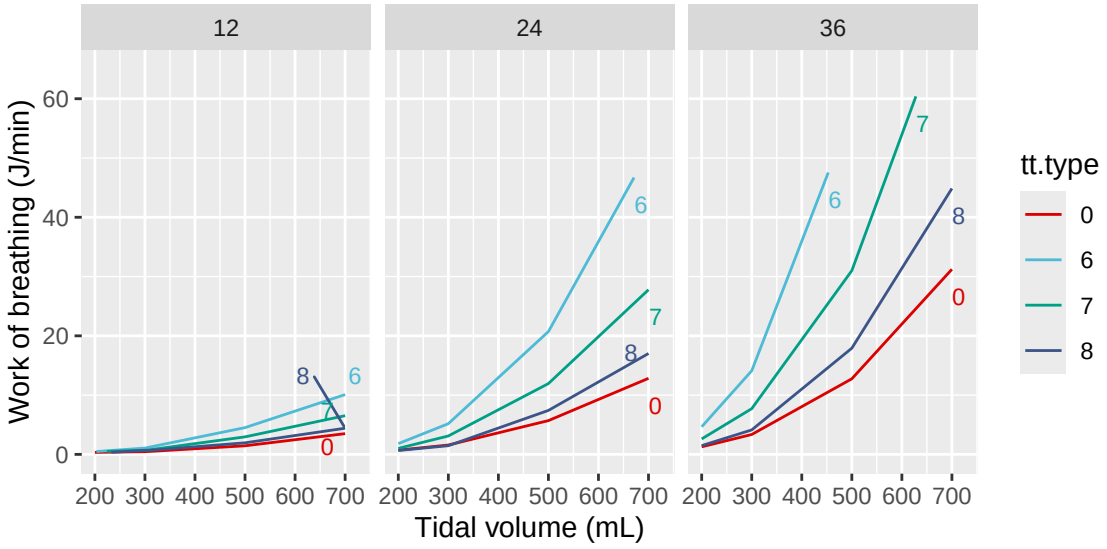
Unlike in cuff trials, trachea size significantly impacted the effect of TT size on WOB. The order of tube size by level of WOB was different in different size tracheas. In the small trachea, WOB increased as size of TT decreased, as seen in cuff trials. In the medium trachea, however, the order of tube size by ascending value of WOB was 6, 8, 7, 9. In the large trachea at normal RR, WOB matched baseline in all TT sizes at all TVs, and at raised and very high RR WOB was lower than baseline (less than half baseline) for all tubes.

5.3.6.2.1. Normal RR (12 breaths per minute)

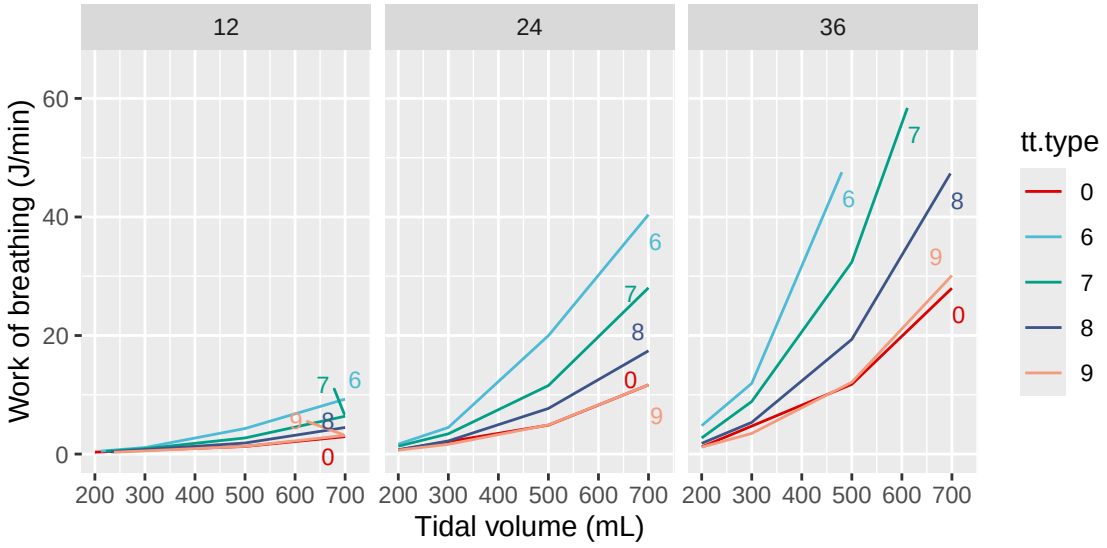
At normal RR and TV of 200 mL, all combinations of TT size and trachea model produced similar WOB to baseline. At a TV of 500 mL the same was true in the large trachea only. In the medium trachea, the size 6 tracheostomy matched baseline WOB but WOB in other tubes was more than twice baseline, whilst in the small trachea, WOB in the size 8, 7 and 6 was just over two, three and four times baseline respectively. In the large trachea at a TV of 700 mL, WOB was lower than baseline in all tube sizes. In the medium trachea at a TV of 700mL WOB was just below 1.5 times baseline in the size 6, just over 1.5 times baseline in the size 9 and over twice baseline in the size 7 and 8.

5.3.6.2.2. Raised RR (24 breaths per minute)

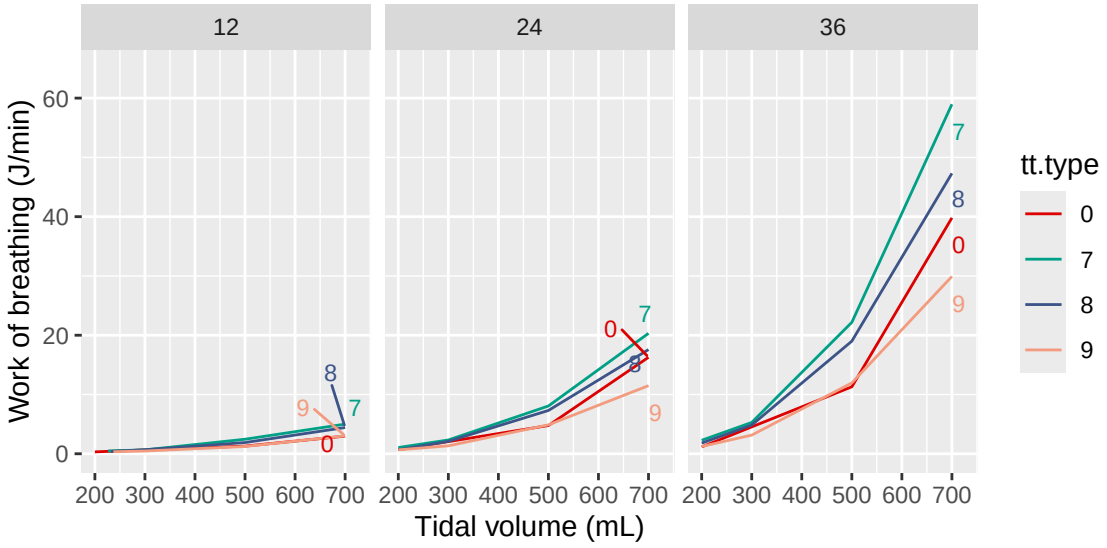
At raised RR and a TV of 200 mL, all tube sizes in the large trachea produced baseline levels of WOB. In the medium and small tracheas WOB was more spread out. In the



(a) Small trachea, inflated cuff



(b) Medium trachea, inflated cuff



(c) Large trachea, inflated cuff

Figure 5.18.: Effect of size of tracheostomy on work of breathing in small, medium and large tracheas with an inflated cuff

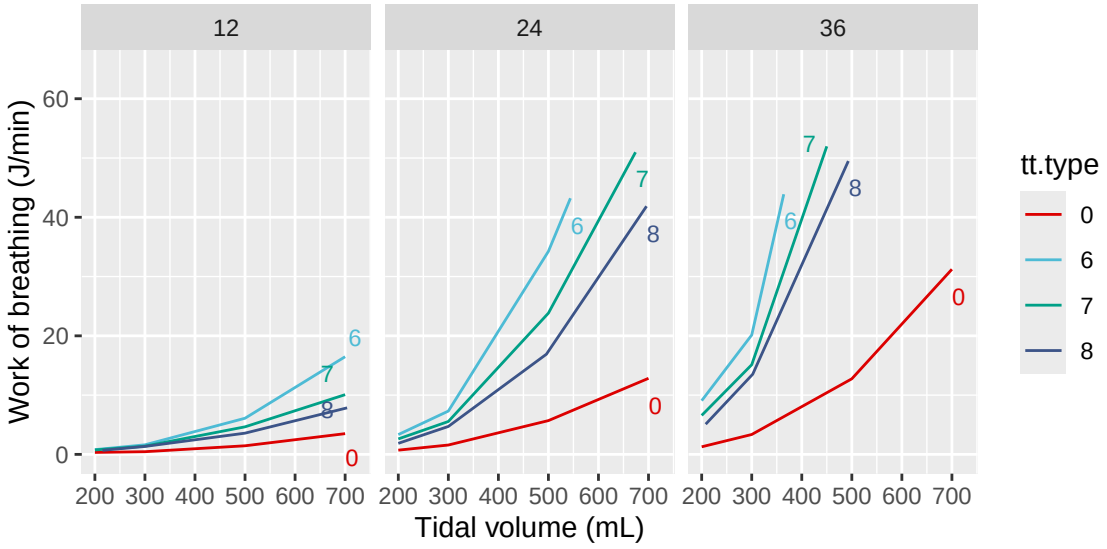
small trachea, the size 6 produced the highest WOB at nearly five times the baseline value, whereas in the medium trachea it produced the lowest WOB at close to the baseline value. At 500 mL, WOB rose sharply in the small trachea to three, four and six times the baseline in the size 8, 7 and 6 TTs respectively. In the medium trachea the size 6 tube produced baseline WOB, the 7 and 8 produced 2.5 times baseline WOB and the size 9 produced over 3.5 times baseline WOB. In the large trachea, WOB was around half the baseline value for all TT sizes. A TV of 700 mL could not be achieved by any size TT in the small trachea. In the medium trachea at TV 700 mL, WOB in the size 6 was lower than baseline but in the size 8, 7 and 9 it was just over 2, 2.5 and 3.5 times baseline WOB. In the large trachea at TV 700 mL, WOB was around half the baseline value in all TT sizes.

5.3.6.2.3. Very high RR (36 breaths per minute)

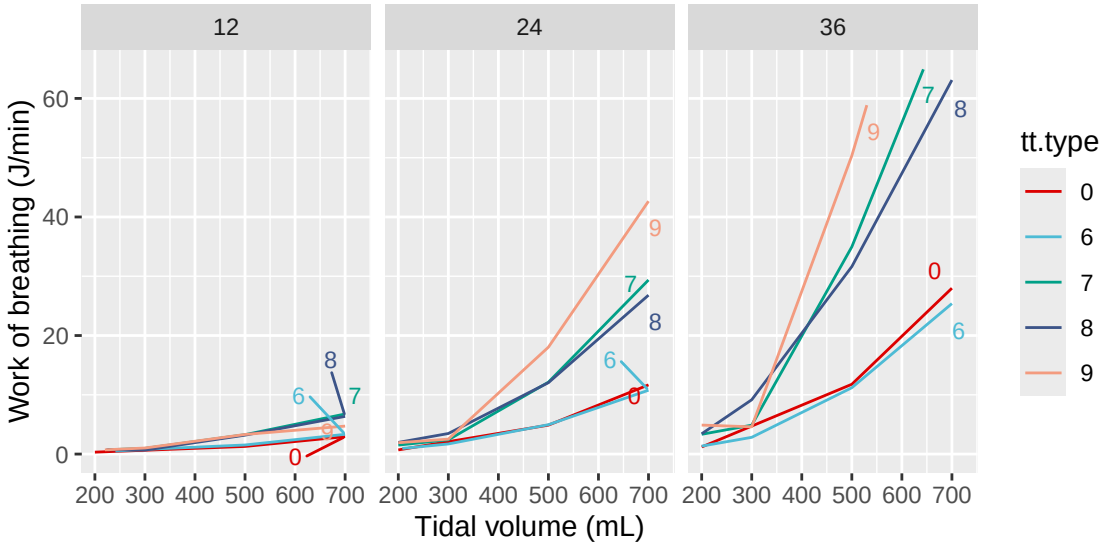
At very high RR and a TV of 200 mL, WOB in the small trachea was the equivalent of baseline values for a TV of 350-450 mL. In the medium trachea, WOB was at or below baseline values for a TV of 300 mL in all tube sizes, and in the large trachea WOB was at baseline values in all tube sizes. A target TV of 500 mL could not be achieved in any tube in the small trachea. The maximum WOB in the size 8, 7 and 6 was four times, just over 5 times and nearly 8 times baseline respectively. In the medium trachea, WOB at TV 500 mL was below baseline in the size 6 tube and over 2.5, 3 and 4 times higher than baseline in the size 8, 7 and 9 respectively. In the large trachea WOB was lower than baseline in all tube sizes. A TV of 700 mL could not be achieved by any size in the small trachea or by the size 7 and 9 tubes in the medium trachea. The WOB in the size 6 tube in the medium trachea at TV 700 mL was below baseline, whilst in the size 8 it was over twice baseline WOB. In the large trachea, WOB was less than half the baseline value in all tube sizes.

5.3.7. Comparison of WOB in size 8 Portex and similar size tracheostomy tubes from other manufacturers

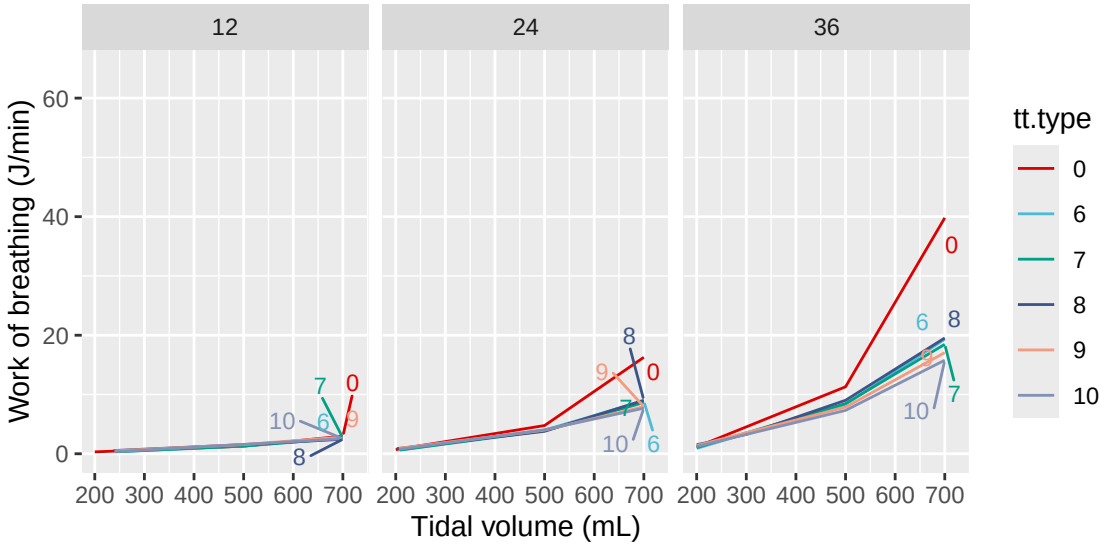
WOB in comparator tubes are presented below against data for the size 8 Portex and baseline data. These were other makes and models of TT, in the size that most closely matched the size 8 Portex (by inner diameter). The comparator tubes were a size 6 Shiley^{TM} LPC; size 7 Tracoe Twist Plus^{TM}; and size 7 Uniperc^{TM} adustable flange. Trials were also conducted in the medium trachea with a size 8 Portex with the cuff removed and an OWV in place. Cuff trials are presented first, broken down by size of trachea.



(a) Small trachea, OWV



(b) Medium trachea, OWV



(c) Large trachea, OWV

Figure 5.19.: Effect of size of tracheostomy on work of breathing in small, medium and large tracheas with a deflated cuff and one-way valve (OWV)

5.3.7.1. Trials of comparator tubes with an inflated cuff

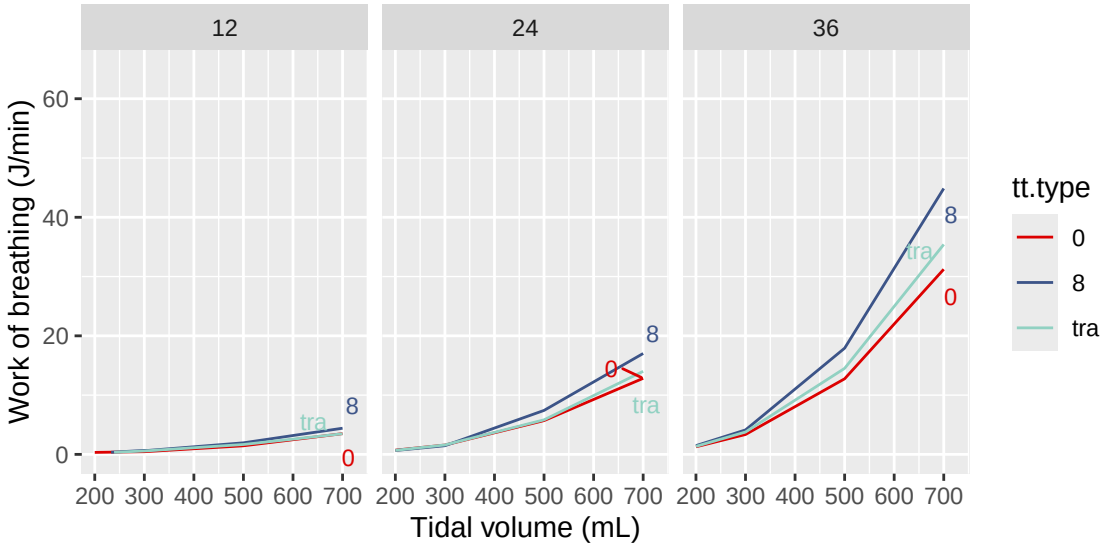
The only comparator tube that fitted the small trachea was the Tracoe Twist+ size 7. This generated slightly lower WOB at all RRs and TVs than the Portex size 8. The Uniperc size 7 and Shiley size 6 were both trialled in the medium and large tracheas. In the medium trachea the Shiley size 6 generated higher WOB than the size 8 Portex at any TV at raised and very high RR, while the Uniperc size 7 generated comparable WOB at raised RR and lower WOB at very high RR than the size 8 Portex. In the large trachea, comparator tubes performed similarly to the size 8 Portex at normal RR. At raised RR and a TV of 700 mL, the Uniperc generated slightly lower WOB than the Portex and Shiley. At a very high RR the Shiley generated the same WOB as the size 8 Portex at TVs of 500 mL and 700 mL, while WOB in the Uniperc was lower and almost equal to baseline.

5.3.7.2. Trials of comparator tube with a one-way valve

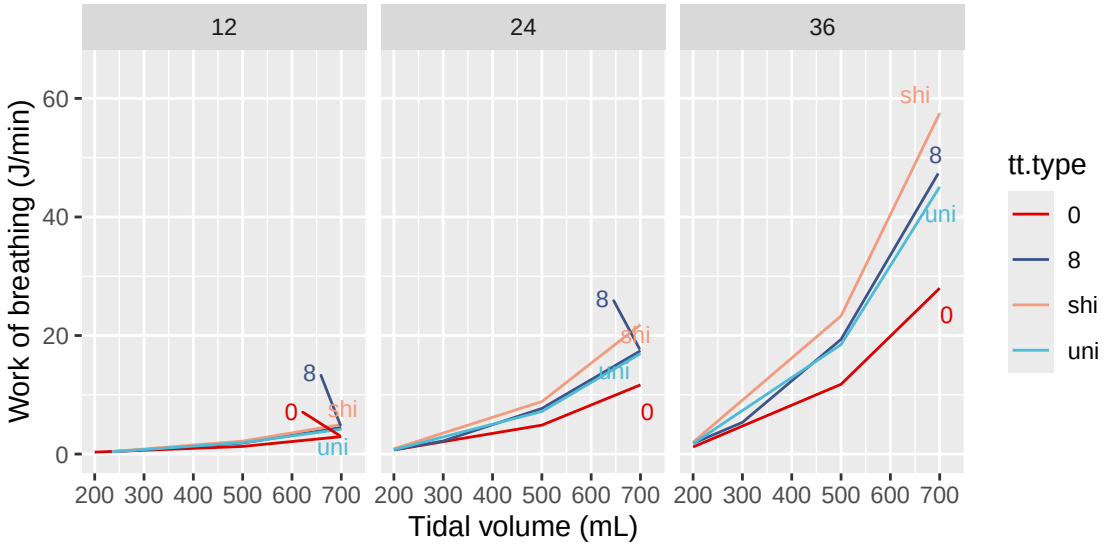
In the small trachea, the Tracoe Twist+ tube generated slightly higher WOB than the size 8 Portex at all combinations of RR and TV except for RR 36 and TV 300 mL.

The greatest difference in performance between the Portex tube and comparator tubes was seen in the medium trachea in OWV trials. At normal RR the Shiley generated three times the baseline WOB which was comparable to the size 8 Portex. The Tracoe Twist+ fell midway between baseline and the size 8 Portex, and the Uniperc generated baseline WOB. At raised RR the Shiley generated similar WOB to the size 8 Portex which was more than double baseline WOB up to TVs of 500 mL and then increasingly higher WOB. The Tracoe Twist+ generated significantly lower WOB than the size 8 Portex (slightly higher than baseline), while the Uniperc and cuffless Portex size 8 generated lower than baseline WOB with the difference widening beyond TV 500 mL. At very high RR the Shiley generated consistently higher WOB than the Portex size 8. The Tracoe Twist+ generated close to baseline WOB; around half that of the Portex size 8. The cuffless Portex size 8 and Uniperc generated increasingly lower than baseline WOB.

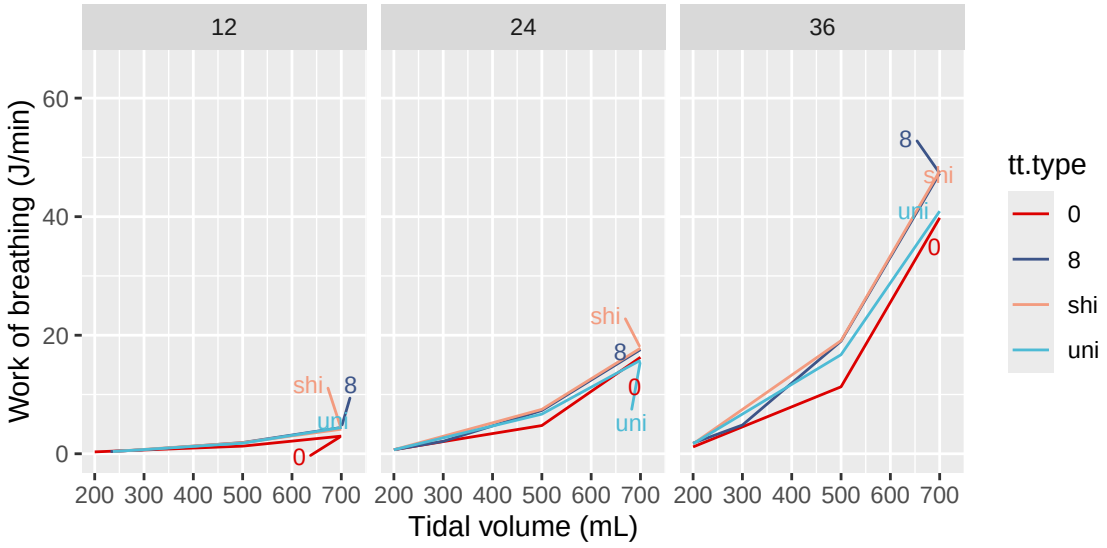
In a large trachea performance across tubes was much closer than in the medium trachea. At normal RR, the size 8 Portex, and the Shiley, Tracoe Twist+ and Uniperc all generated similar WOB to baseline, dipping lower than baseline at TV 700 mL. At raised RR, all comparator tubes generated lower WOB than the Portex size 8 tube, with the lowest value seen in the Uniperc followed by the Shiley then Tracoe Twist+. A similar pattern



(a) Small trachea, inflated cuff



(b) Medium trachea, inflated cuff



(c) Large trachea, inflated cuff

Figure 5.20.: Comparison of work of breathing in trials of Portex size 8 and equivalent sizes from other manufacturers, with an inflated cuff, in small, medium and large tracheas

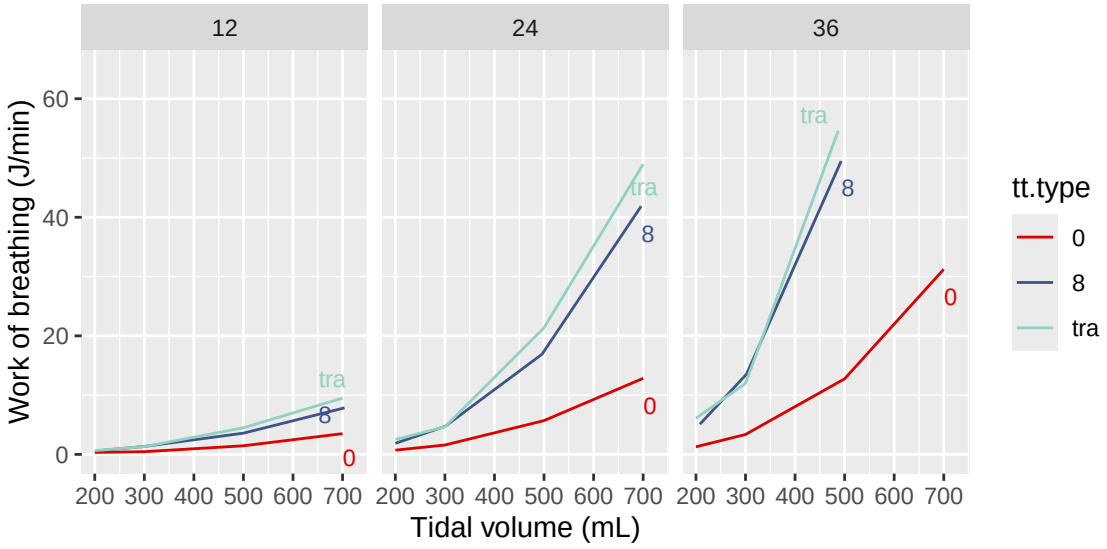
was seen at a very high RR, with all comparator tubes generating lower WOB than the Portex size 8 tube and the Uniperc generating less than half the baseline WOB.

5.4. Discussion

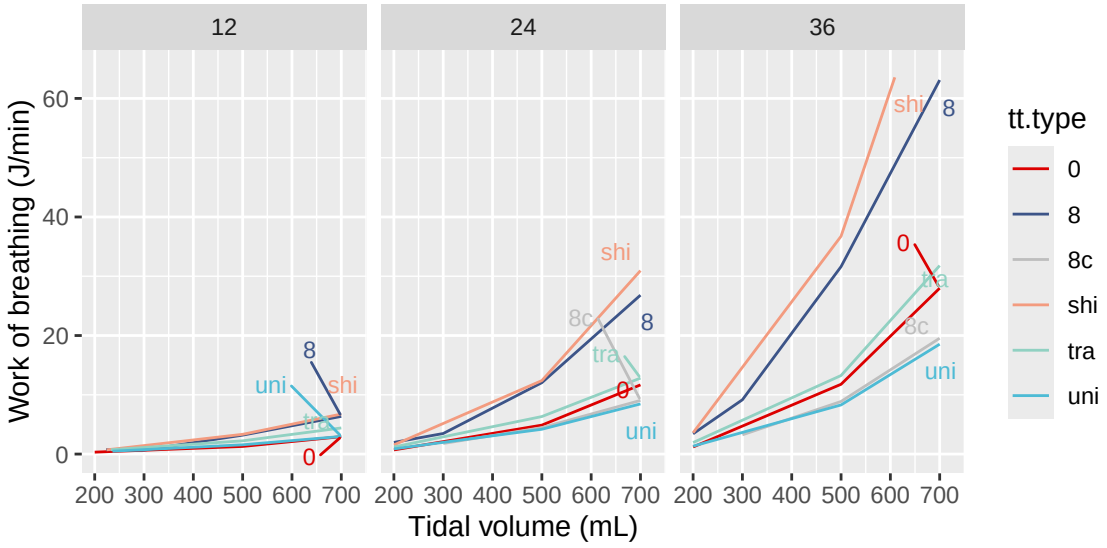
5.4.1. Summary of findings

The aim of this study was to explore the effect of size of TT on WOB, taking into account breathing with a cuff up and with a deflated cuff and OWV in situ. It was hypothesised that different size TTs would provide the 'best fit' for different size tracheas in terms of balancing airflow requirements for breathing through the tube with an inflated cuff, and for breathing through and around the tube with a deflated cuff and OWV. The key findings, however, were that the effect of size of TT on WOB differed greatly dependent on whether the cuff was inflated or deflated with an OWV in situ and on size of trachea. The effect of size of TT on WOB with an inflated cuff was consistent across a small, medium and large trachea. In contrast, trachea size heavily influenced the effect of tube size on WOB in trials with an OWV. In cuff trials, WOB increased with descending order of tube size and absolute values for individual tubes were similar across trachea sizes, except for a slight decrease in maximum WOB in smaller tubes in a large trachea that was likely due to leak around the cuff. This finding that a slight cuff leak lowers WOB at high flows in medium and large tracheas could potentially be used clinically to reduce WOB where flow is high but tube changes are not possible, for example soon after percutaneous TT insertion. In OWV trials the effect of size of TT depended on the size of the trachea. In the small trachea WOB followed the same order of tube size as for cuff trials but with higher values for WOB. In the medium trachea, the smallest tube produced the lowest WOB by a large margin and the largest tube produced the highest WOB. In the large trachea, all tube sizes generated WOB far lower than baseline, though the order did not follow tube size or reverse tube size. This highlights the value of modeling a range of trachea sizes in the experiment. It also makes it difficult to select a 'best fit' tube for patients with small tracheas, though consideration of flow (RR and TV) may be helpful, as discussed later.

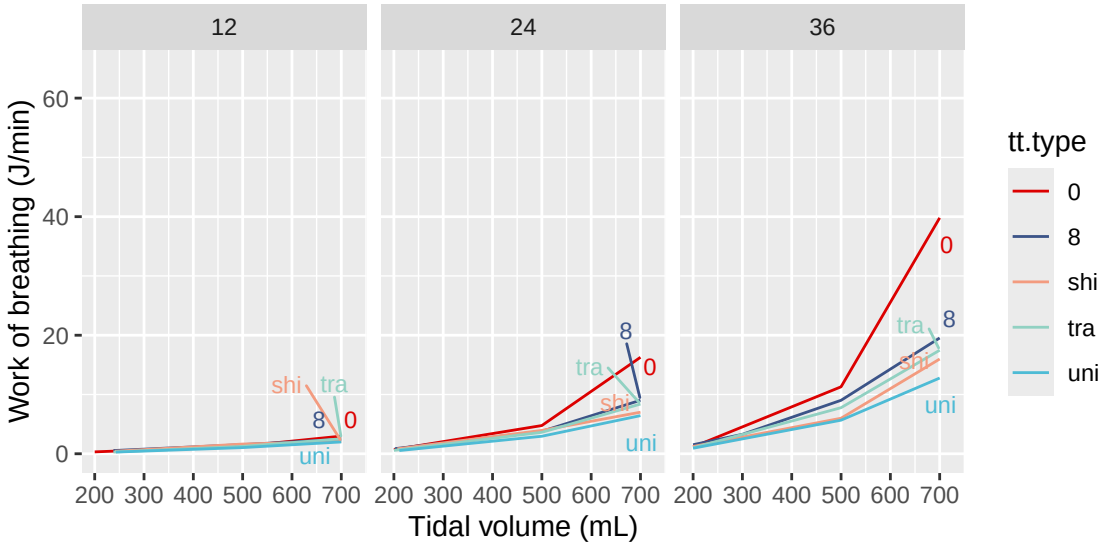
There was a positive, non-linear relationship between WOB and RR and TV. For cuff trials, the rate of increase was similar across the small, medium and large trachea but it differed by trachea size for OWV trials; the greatest rate of increase in WOB on increase in RR and TV occurred in trials in the small trachea, and the lowest rate of increase in WOB



(a) Small trachea, OWV



(b) Medium trachea, OWV



(c) Large trachea, OWV

Figure 5.21.: Comparison of work of breathing in trials of Portex size 8 and equivalent sizes from other manufacturers, with a deflated cuff and one-way valve (OWV)

occurred in trials in the large trachea. In the medium trachea the rate of increase was similar in OWV trials to that in cuff trials, but with different order of tube sizes.

In a large trachea, it was shown that WOB with a size 9 TT was at or below baseline WOB with an inflated cuff or when the cuff was deflated and an OWV was used. The good performance of this tube with an inflated cuff was despite being significantly smaller in outer diameter than the upper recommended limit by the best practice sizing method. In contrast, the size 6 TT was close to the limit for fitting in the small model trachea and generated the highest WOB with an inflated cuff or a deflated cuff and OWV in this model. This suggests that fluid dynamics of TTs are complex and that a linear rule such as keeping the outer diameter of TTs to 3/4 the diameter of the trachea may not suit the full range of trachea sizes.

Finally, differences were found in WOB generated in similar size tubes across different makes and models. In the small trachea, the Tracoe Twist+ performed better than the size 8 Portex in trials where the cuff was inflated. This is likely due to the fact that, despite the size labelling, the Tracoe Twist+ size 7 has a larger inner diameter than the Portex size 8. It also has a smaller outer diameter, however the Tracoe Twist+ performed slightly inferiorly to the Portex size 8 on OWV trials. The largest differences between brands were seen in OWV trials in the medium trachea, where WOB in the Tracoe Twist+ was half that of the size 8 Portex and WOB in the Uniperc and a cuffless size 8 Portex was a third of that in the cuffed size 8 Portex (with the cuff deflated). These findings suggest TT design and the bulk of a deflated cuff might significantly impact WOB. Neither the Uniperc size 7 nor the Shiley size 6 could fit in the small trachea, highlighting the difficulty in comparing sizes across manufacturers. It also indicates there are fewer choices of tube for patients with smaller tracheas in some ranges, since this is the smallest size Uniperc.

5.4.2. Comparison with previous findings

It might not be surprising that the smallest tubes generated the highest WOB in cuff trials since this appears logical and has been shown in previous studies [99, 328, 336, 337]. It was more surprising that smaller tube size was not of benefit in OWV trials in the small trachea, especially since the theoretical airway between outer diameter of the tube and inner wall of the small trachea was greater than the size of airway through a small TT. However, from images in Section 5.2.2 above, it can be seen that little space remained around the deflated cuff of a size 6 TT in the small trachea compared with the space around deflated cuffs in the medium and large tracheas. Therefore, the bulk of the deflated

cuff may have partly negated the theoretical advantage of smaller size TTs to 'peri-tube' airway in the small trachea. It should also be noted that though the exhalation airway with a deflated cuff and OWV use is solely around the tube, there are dual airflow routes on inhalation (through the tube and around it), meaning larger TTs still benefited during the inhalation phase from having a larger inner diameter. Since inhalation flows in trials were double those of exhalation flows due to the i:e ratio of 1:2, pressure differentials would have been greater during inhalation, and larger functional airways on inhalation (i.e. seen in larger tracheas), would have had proportionally greater benefits for WOB. The finding that WOB with a OWV in a large trachea was lower than baseline has clinical implications in terms of potential respiratory muscle deconditioning. Clinicians should consider the impact on WOB post-decannulation and prepare patients accordingly for what to expect.

Similar to findings from other benchtop studies, WOB at low flow (or low combinations of RR and TV), was low across all tubes [99, 100, 102, 103]. Previous studies have also found that WOB increased with decreasing size of tube when breathing through a TT with an inflated cuff [99, 100, 102]. One of these studies did place the TTs in a model trachea [103] but none of them compared the performance of the tubes with a deflated cuff and OWV. Pryor et al [100] tested a tube with a speaking inner cannula, however, they only tested it with all airflow entering through the TT, rather than the dual routes of through the tube and around a deflated cuff, as would be the ideal clinical scenario. Given the findings of the present study, performance with a deflated cuff may have been more favourable than other tubes in a medium trachea and similar to others in a large trachea.

Hussey et al [103] studied WOB when breathing around capped fenestrated and non-fenestrated TTs. Similarly to findings in this study, they found that WOB when breathing around a deflated cuff in a medium-size trachea was much higher than in a large trachea, though findings are not directly comparable as they used a tracheostomy cap rather than OWV, which meant no inhalation via the TT in their model. They also only used two sizes of trachea; at 18 mm, the inner diameter of the smallest was slightly larger than the medium trachea in this study and the larger model was 4mm larger than this study's large trachea. This means Hussey et al's [103] findings cannot be applied to those with a smaller trachea, including most females. The use of a small trachea model in the present study revealed important differences in the effect of size of TT on WOB in different size tracheas under OWV use.

Borg et al [338] found a benefit of smaller TT cuffs on airflow around the deflated cuff. Similarly, trials of an OWV on a cuffless size 8 Portex in this study generated substantially lower WOB compared to the cuffed size 8 Portex. This suggests that the deflated cuff still

has a significant impact on resistance to airflow around the TT and is an area to target in future TT design.

To provide clinical context to their findings, Carter et al [99] compared their findings to physiological values for WOB. However, the value they referenced came from another benchtop experiment. No clinical data on WOB could be found with which to compare with findings in the present study. Instead, baseline data was obtained from plain model tracheas (i.e. with no stoma or tracheostomy inserted). This allowed within-study comparisons to be made of WOB with and without a TT and between sizes of TT. Carter et al [99] found the change up from a size 6 Portex to a size 7 Portex was not as beneficial to WOB as the change up between other sizes due to an unequal stepwise change in inner diameter and length of tube from size 6 to 7 and size 7 to size 8 or 8 to 9. This may explain why, in this study also, the medium trachea the size 7 performed worse than the size 8 in both cuff and OWV trials.

RR and TV both clearly impacted WOB as has been shown in the previously cited benchtop studies. However, there has been little discussion in the literature of how an individual's RR and TV might map onto size of required TT. Poiseuille's law of laminar flow (also known as the Hagen-Poiseuille equation) is often quoted in the literature on airflow through TTs in support of larger tubes. The formula is as follows, where Q is flow, P is pressure differential, r is the radius of the tube, l is the length, and η is the viscosity of the fluid:

$$Q = \frac{\pi P r^4}{8\eta l}$$

Rearranging to make pressure differential (same as the driving force/resistance to airflow) the subject of the equation gives:

$$P = \frac{8Q\eta l}{\pi r^4}$$

While P is inversely proportional to r^4 , it is also directly proportional to RR and TV (flow), and the length of the tube. Given that the length of TTs increase with size and that the difference in inner diameters between one size and the next are small relative to the diameter (around 10-15%), lower values for TT length, RR and TV could partially mitigate the impact of a smaller radius. This could explain why some have argued that its clinical significance may have been overplayed and features such as tube compensation in modern mechanical ventilators could further mitigate the impact of TT inner diameter on resistance

to airflow [87, 339]. On the other hand, in smaller airways and at higher velocity, flow is likely to be turbulent, in which case Poiseuille's law no longer applies and resistance will be higher. The impact of increasing inner diameter on effective airway around the TT required for successful OWV use is largely absent from study designs and discussions.

Borg et al [338] paired small TTs with smaller TVs and large TTs with larger TVs (e.g. 175 mL for a size 4, 500 mL for a size 6 and 800 mL for a size 8), in a benchtop study investigating airflow around deflated cuffs. This appears to be based on the assumption that patients with lower TVs have smaller tracheas, though this is not stated directly and no evidence is given to support this assumption. Moreover, I found no evidence in the literature or anecdotally that TTs are matched to TV in practice. The authors also paired size of model trachea with 'expected' TT for that size, however the study they reference to support this approach does not address TT sizing by trachea size. To overcome the issues of what combinations of trachea size, TV and TT size to replicate, the present study ran trials of all possible combinations of trachea size, TT size, and TV at each RR.

5.4.3. Clinical relevance of flow values in previous studies

Other studies of tracheostomy-related airflow have used wide ranging values of flow per minute, for example 0 - 100 L/min, 5 - 30 L/min, and 0 - 150 L/min [100, 101, 103]. Some of these ranges extend much higher than would be seen clinically. Authors of one study even shaded a 'clinically relevant' section of a plot of differential pressure against flow (40 - 60 L/min), indicating that middle and right half of the plot was not clinically relevant [100]. Given the progressively larger increase in pressure differential as flow increases, presenting data in this way was potentially misleading; even at flows of 40 - 60 L/min a patient would have to maintain the equivalent of a TV of 600 - 800 mL and RR of 36 breaths per minute.

5.4.4. Findings in the context of lung-safe ventilation

As mentioned in Section 5.2.1, no published data on the RRs and TVs seen in ICU patients or normal WOB in relation to RR and TV could be found in the literature. However, viewing the findings of the present study in the context of lung-safe ventilation could aid interpretation of their clinical value. Lung-safe ventilation strategies restrict TV in mechanically ventilated patients in order to prevent barotrauma to the lungs and are now common practice in UK ICUs [340, 341]. Lung-safe TVs are calculated by multiplying a patient's

ideal body weight by 6 mL/kg, where ideal body weight is derived from height, as per the formula below. Lung-safe TV recommendations therefore increase with height.

male:

$$50 + 0.91(height - 152.4) \tag{5.5}$$

female:

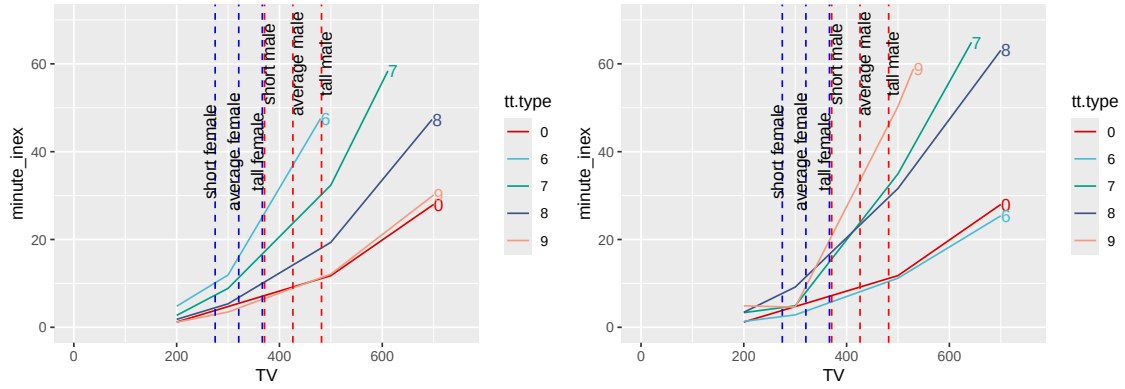
$$45 + 0.91(height - 152.4) \tag{5.6}$$

The following plots show WOB against TV with lines indicating lung-safe TVs for short, average and tall males and females and help illustrate how different tubes might perform for different patients. Heights for each category were based on mean height for adult males and females in the UK +/- 1SD [342] (note: the tall female is taller than the short male, but because safe lung ventilation is based on ideal body weight which is calculated differently for males and females, the safe TV values are lower). As can be seen, the value for TV in safe ventilation for tall males is below 500 mL, yet this is a commonly quoted value for adult TV. The steep rises in WOB in higher TVs are therefore less clinically relevant in the context of lung-safe ventilation (however, they may be relevant in spontaneously breathing patients, whose TVs are not controlled). Figure 5.22a shows that while an average height female with an average size trachea and an inflated cuff might manage with a size 6 or 7, a tall male would require a size 8 or 9 to achieve a similar level of WOB. However, if the cuff was deflated and an OWV placed, WOB would become easier for the female with the size 6 or 7 and harder for the male with the size 8 or 9; WOB would be more than three times harder with the size 9.

Plots for lung-safe TVs in other combinations of trachea size, RR and cuff/OWV use can be found in Appendix O. Figures are not presented for RR 12 since the WOB is low across all sizes of TT with a cuff or an OWV. This may be clinically relevant to patient populations who are less likely to have have raised RR, for example in spinal cord injury.

5.4.5. Limitations

A number of study limitations were identified. These are presented in the table below alongside the potential implications, thoughts on alternative approaches that could have been taken, and mitigating factors or efforts to mitigate the impact of the limitation.



(a) Medium trachea, respiratory rate of 36, inflated cuff

(b) Medium trachea, respiratory rate of 36, deflated cuff and OWV

Figure 5.22.: Work of breathing at lung-safe tidal volumes for short, average and tall males and females

Table 5.5.: Study limitations, implications and mitigation

Limitation	Implications	Alternative approaches	Mitigation
Study design			
Benchtop experiment, not clinical trial	Simplified model of human respiratory function, materials may not closely reflect human tissues	Clinical trial using ICU patients. However unlikely to be able to control for confounders and obtain full range of RR and TV combinations, also risk of tissue trauma if inserted large TTs in small trachea;	Chose tracheal model design and materials to mimic human anatomy, experimental model allows systematic investigation of all combinations of variables.
Position of lower pressure tap in relation to tip of TTs	too close to TT brings risks of capturing effects of turbulent flow, if too far from TT adds resistance caused by that section of trachea	Separate models for each TT with pressure tap at set distance from TT. But costly and time intensive	Pressure tap placed > 1cm below tip of TTs, same trachea models used for all cases. Tips of TTs at slightly different distance from pressure taps due to different lengths, however minimal difference in terms of proportion of tracheal length and therefore minimal difference to results.
i:e ratio of 1:2 not accurate for respiratory distress scenarios	At higher RRs i:e likely to be closer to 1:1. For cuff trials WOB on inhalation would be lower but WOB on exhalation would be higher. For OWV trials WOB on inhalation would be lower but WOB on exhalation would be higher, particularly where gap between outer TT wall and trachea is small (e.g. small trachea, medium trachea with larger TT)	Set variable levels of i:e according to RR. However, not clear what values to use for given RR. Adds another level of complexity to analysis.	Highlight potential impact on findings
Lung simulator upper airway resistance set at 3cmH2O	Airway resistance added to model twice: lung simulator and model tracheas. Would disproportionately affect trials with low WOB values. These are of less importance than trials generating high WOB.	Recalibrate model, however this may have interfered with manufacturer calibration and affected accuracy.	Same upper airway resistance applied to all trials including baseline.
Only 3 levels of RR and TV used in model	Gave limited detail of non-linear change in WOB as TV/RR increases,	Increasing levels by 2 or 3. However this would have greatly increased data collection time	For combinations of TT, trachea and cuff/OWV status where WOB rose sharply with increasing flow, extra trials were run at TV 300 mL to provide an extra data point

Limitation	Implications	Alternative approaches	Mitigation
Use of a fixed larynx model	Did not replicate changes in glottic dimensions across breath cycle/under different respiratory conditions that would be seen in vivo	Use model that abducts and adducts on inhalation/exhalation. However, not clear how much to abduct/adduct and would be complicated to build	Same model used across all trials
Same size larynx used for all tracheas	Larger trachea would be expected to have larger larynx. In OWV trials, current model may have exaggerated WOB values for large trachea trials/underestimated WOB in small trachea trials, i.e. true values for WOB OWV trials in the large trachea would have been even lower and those in the small trachea may have been higher	Use different size larynx to match different tracheas. However, only data available for 'average' upper airway resistance, therefore unclear what size to pair with small/medium/large trachea models	Same larynx used for all tracheas. Potential impact on findings highlighted.
Size of tracheas - smaller than published norms	May have exaggerated impact of size of TT on WOB in trials with a deflated cuff and OWV. However, published values are from x-ray measurements taken at maximal breath hold and therefore likely to exaggerate tracheal width	Use larger tracheas. However, these may have biased findings due to limitations in study producing most frequently quoted norms	Values used were slightly smaller than published norms due to limitations in original data and to reflect sizes seen in the observational study
Use of a simplified trachea model	Airway curvature, surface roughness and changing profile along the length of the model trachea were not included. This may have impacted how closely tracheal airflow matched airflow in vivo and consequently WOB values	Use of more realistic trachea based on CT images. However, this may have limited applicability of findings to the individual trachea. Johari et al (2013) found that a simplified trachea produced more reliable airflow than an 'oversimplified' straight tube model	Tracheal features such as ridges replicating tracheal cartilages and a flat, compliant posterior wall were incorporated. The compliant posterior wall made it possible to insert TTs that would not otherwise have been able to fit in models
Data Collection			
Temperature and humidity not recorded at time of data collection	Pressure is affected by temperature and humidity so change in conditions could have biased results	Measure temperature and humidity	Data collection was conducted in basement of air-conditioned building. Temperature and humidity likely constant. Test-retest trials conducted over separate weeks returned closely matched values.

Limitation	Implications	Alternative approaches	Mitigation
At high flows in larger tubes there was a slight leak around smaller tubes	This would affect cuff trials only, reducing pressure differentials and therefore WOB values	Exclude from analysis or attempt to create seal.	This replicates clinical examples of cuff leak and provides useful data on the effects of cuff leak on WOB
Anterior neck tissue not included in the model	Position of tube in the trachea may not reflect the clinical cases	Addition of layer of artificial neck tissue to model	Tubes were inserted to a standard distance between tracheal wall and TT flange (published value for average thickness of anterior neck tissues). No attempt was made to centralise TT in trachea in order to avoid introducing bias
Distance of TT flange from tracheal wall equal for all size TTs	May be reasonable to expect larger anatomy in patients with larger TTs and larger TTs might sit better with greater distance between TT flange and outer tracheal wall	Increase distance between TT flange and tracheal wall as TT size increases, however no evidence to support this	Insertion depth kept standard across trials
Resolution of senors/spec of circuit board	effect on Q/P readings at different values		
Analysis			
Included WOB on exhalation as well as WOB in inhalation	Exhalation is usually considered passive due to elastic recoil of lungs, some previous benchtops have only analysed WOB on inhalation. Total WOB may be overestimated in this study. However, in higher RR/TV, exhalation is considered active, therefore excluding exhalation could also introduce bias	Exclude exhalation from analysis or only consider at higher RR. However, this may also bias findings	WOB calculated using inhalation and exhalation phases of breath cycle for all RRs
Formula for component approach to calculating WOB in each section of the model assumed Q2 would be zero in cuff trials	Noise in signal generated values for WOB around TT and through the larynx	Use separate formula to calculate WOB in cuff trials based only on Q1. However, this would miss instances of leak around the inflated cuff and add complexity to analysis	Noise values were very low compared to experimental values. Used component system for all trials

Limitation	Implications	Alternative approaches	Mitigation
Interpolation of line of WOB by TV in baseline data	Since target TVs were not achieved in all trials, interpolation was used to obtain baseline values to compare with maximum values achieved in those trials. These values are best-fit values between two observations and may not reflect true values.	Re-run baseline trials with target TV to match maximum values achieved in trials where target not achieved.	Since these values were used for calculating ratios of WOB and not important to primary analysis, interpolation was felt appropriate.

5.5. Conclusions

The effect of size of TT on patient WOB is complex and impacted by route of airflow (i.e. cuff inflated or cuff deflated and OWV in situ); size of trachea; and flow, which in turn depends on RR and TV. Traditional 'big is best' approaches to size decisions should be replaced by ones that consider flows required to meet individual patients' respiratory needs, and the gap between TT and inner tracheal wall, which depends on both TT size and the patient's tracheal width.

Having a large trachea is advantageous for TT size selection since there are more tubes that fit and options that suit both breathing with an inflated cuff and with a deflated cuff and OWV. Conversely, fewer sizes of TT fit in a small trachea, some types of TT are not available in small enough sizes for a small trachea, and no TT options were able to keep WOB low in a small trachea when a OWV was in use, unless flow was kept low (through lower RR and TV). This would appear to disadvantage patients with smaller tracheas, and by default, females.

Further research is required to translate these findings to the clinical setting, for example, observational data is needed on normal RRs and TVs seen in the ICU setting and what associations there may be between these and tracheal width. What constitutes a clinically significant difference in WOB needs to be determined, with sub-group analysis by sex and other demographic variables.

Clinicians need to be aware of the impact of different TT profiles and sizing conventions across manufacturers when choosing or changing patients' TTs. Better TT designs that minimise the ratio of inner to outer diameter, reduce the size of the deflated cuff, and extend ranges to smaller sizes could improve TT performance for all patients.

6. Focus Group Study

6.1. Introduction

As stated in previous chapters, there is currently no clear guidance on how TT size decisions should be made and little evidence on how they are currently made in the UK. A service evaluation I conducted in 2019 suggested practice varies across sites and can be subjective. Objective, evidence-based decision-making could improve the quality of care for patients with a tracheostomy. However, the generation of healthcare evidence alone is not sufficient to improve outcomes for patients or healthcare providers. Various studies and review papers have highlighted a gap between science and practice, with lengthy delays and failures in implementing change in clinical settings [343–345]. The developing field of implementation science seeks to address this through identifying barriers and facilitators to changing practice and using these to inform implementation interventions that improve the uptake of evidence-based practice by clinicians and organisations [346]. National funders of health research (e.g. the National Institute for Health and social care Research, the Medical Research Council, UK Research and Innovation, and the Wellcome Trust), and a government funded review of UK health research funding [347] recognise the importance of expediting the translation of research into practice for patient benefit and financial return, and include this as a research priority. Implementation issues should therefore be considered when seeking to integrate new knowledge into the provision of tracheostomy care such as new methods for TT size decision-making.

The aim of the current study was two-fold: firstly to understand clinician perspectives on the practice of TT size decision-making, and secondly to identify barriers and facilitators to changing practice.

6.2. Methods

A qualitative, mixed inductive-deductive approach to inquiry was adopted in keeping with the project's overarching pragmatist methodology. This approach was taken in order to obtain rich participant data that were relevant to the focused research questions, which were:

1. What are ICU clinicians' perspectives on TT size decision-making?
2. What are the barriers and facilitators to changing practice?

Data were collected through a series of focus groups. Focus groups were chosen over individual interviews to allow interaction and debate between participants and exploration of ideas [348–350]. A semi-structured moderator guide was developed using open questioning to elicit data on the topic without overly restricting or leading participant contributions. Towards the end of the focus groups, a five-minute presentation summarising findings of the broader PhD project was played and participants were invited to give feedback on how the project findings fitted with discussions thus far. In order to capture a range of different perspectives on tracheostomy sizing, the recruitment plan targeted different ICU professions with expertise in tracheostomy management, including intensivists, anaesthetists, ENT surgeons, speech and language therapists, physiotherapists, nurses and advanced critical care practitioners [350]. The inclusion criteria were as follows: UK based healthcare professionals who had experience in tracheostomy management in patients on ICU with a tracheostomy.

Variation in perspectives was anticipated across and within professions and pros and cons of mixed versus single profession focus groups were considered. The decision was left open in order to facilitate recruitment and allow flexibility in scheduling dates and times for focus groups. In the post COVID-19 era, use of synchronous online focus groups has become a viable platform capable of producing valid data [351–353]. Online groups have a number of advantages and disadvantages compared to face-to-face formats such as reduced cost and greater accessibility, versus lack of eye-contact and reduced interaction between participants as sample size increases [351, 352]. A mix of online and face-to-face focus groups was therefore planned in order to ensure accessibility for participants from across the UK whilst allowing for larger group sizes and ease of interaction between participants in the face-to-face setting. Target focus group sample sizes were 6 - 8 participants per online group and 10-12 for the face-to-face group. A strategy of over-recruiting by 30-50% of desired sample size was used due to anticipated non-attendance rates, par-

ticularly with online groups [351, 354]. Recruitment aimed for equal representation from doctors and therapists.

The study was advertised through social media ICU MDT and uni-professional networks. An email was sent to professional bodies for each staff group requesting help with circulating study information and registration links. Recruitment information was also shared through word of mouth via study team members' professional networks. Recruitment material contained links to online copies of the participant information sheet (PIS) and a joint consent/registration form. The consent/registration form was created in a REDcap project stored on a secure university network. The PIS outlined the background and purpose of the study, format of focus groups and details of study supervisors and funders. Potential participants were advised in the PIS and on the consent/registration form of the voluntary nature of participation and their right to withdraw at any point. Ethical approval was granted by the university research ethics committee on the 26th April 2023.

Focus groups were held either online via Microsoft Teams™ or face-to-face at a national intensive care conference. All focus groups were audio recorded using two encrypted digital audio recorders. The online focus groups were also video recorded within Teams. Audio and visual recordings were stored on a secure university network. 'Intelligent verbatim' transcripts were produced by a professional transcript service endorsed by the university. These were fully deidentified and password protected transcriptions with omission of 'ums', 'errs', repetitions and false starts. Additional information such as hesitations, tone pitch or emotion was not included. All transcripts were checked and edited as required by the lead researcher.

Data were analysed using a framework analysis approach, fitting with the overarching pragmatist research paradigm of the broader PhD project and permitting deductive and inductive approaches within the same study. With this methodology, real world practical problems can be investigated in a focussed way whilst remaining flexible enough to capture inductively derived data [144]. This study followed Gale et al's [355] method for framework analysis which lays out 7 stages as follows:

1. good quality recording and verbatim transcription of the focus group (as above).
2. immersion in the data through repeated reviewing of recordings and transcripts and field notes written at the time of focus groups. Field notes consisted of early impressions of key themes or comments on points of particular interest.
3. line-by-line reading of transcripts and coding of important items of information. Open coding was used. i.e. codes were based on the data and not pre-defined in or-

der to remain flexible and reflect the voices of the participants as closely as possible. As recommended by Gale et al [355], second reviewers were recruited to the study team from different participant professions (a speech and language therapist (SLT), a physiotherapist, and a trainee intensivist), with the aim of ensuring different perspectives were adequately reflected in the analysis. Coding was conducted in NVivo™ and Microsoft Word™ documents.

4. creation of a code set with input from all reviewers. All reviewers coded the final focus group transcript. This was selected as it was attended by ICU consultants, SLTs and ENT, providing a broad range of perspectives. The lead researcher and second reviewers met online to compare and discuss coding and initial thoughts on categories of codes and descriptive themes. Code labels and descriptions were developed iteratively through this stage and as the code set was applied to other transcripts.

5. application of the code set as an analytical framework. The remaining two transcripts were coded by the lead researcher in NVivo. Through stages four and five, major descriptive themes evolved and the analytical framework was amended as required.

6. charting the data into the framework. A summary of data coded to each theme and sub-theme was written. Similarities and differences across participants and professional groups or experience level were noted. Key illustrative quotes were identified for themes and sub-themes. Guidance in this process was provided by the senior researcher who has extensive experience in qualitative research methods.

7. interpretation of data. Thoughts on overarching analytic themes were discussed by the research team throughout the data collection and analysis process and recorded by the lead researcher in a reflexive journal. As part of this process, descriptive themes were considered in the context of an a priori selected theoretical framework of behaviour change which helped identify barriers and facilitators to changing practice.

A theoretical framework of behaviour change was used to aid interpretation of findings. The chosen model sits at the centre of the Behaviour Change Wheel developed by Michie et al [356] and is used to identify influences relating to ‘Capability’, ‘Opportunity’ and ‘Motivation’ on a pre-defined Behaviour seen in a person or group of people (the COM-B model). The three categories of influences are divided into sub-categories as follows:

‘Capability’ addresses a person’s intrinsic ability to perform a desired behaviour and includes physical and psychological (including cognitive) influences.

‘Opportunity’ covers social influences and access to physical resources,

‘Motivation’ includes influences on automatic motivation (instinctive) and reflective motivation (motivation after reflecting on the issue).

Behaviour is defined as ‘an intentional action’. The COM-B model leads to a behavioural ‘diagnosis’ that is used to form an intervention plan for the target behaviour. Influences and corresponding interventions are reviewed to identify those likely to have the most efficient impact on behaviour.

6.3. Results

Forty registration and consent forms were completed and 20 participants attended the focus groups including ICU doctors, SLTs, physiotherapists, and an Advanced Critical Care Practitioner (ACCP) (see Table 6.1). Seven non-attendees were unable to make any of the dates and two were based overseas and therefore not eligible to participate. Five participants attended each online group and ten attended the face-to-face group. Each focus group had multidisciplinary attendance. Two participants with backgrounds in SLT and physiotherapy gave their job title as ‘Tracheostomy Practitioner’. Study codes reflect both aspects for transparency (TPSLT and TPPT). The codes for ICU doctor, ENT surgeon, SLT, physiotherapy and advanced critical care practitioner were as follows: ICU, ENT, SLT, PT, ACCP. Codes also indicated which focus group (FG), they attended. In four cases, individual sites were represented in focus groups by multiple participants: one Trust had an SLT at each focus group; another Trust had an SLT at both of the online focus groups; two SLTs from the same Trust attended the face-to-face focus group; and there were three physiotherapists from the same Trust at the face-to-face focus groups.

Table 6.1.: Registration and attendance at focus groups (FG) by profession

Profession	Registered	Online FG	In person-FG	Total attended
ICU doctor	12	2	1	3
SLT	12	5	4	9
Physiotherapist	11	1	4	5
ICU Nurse	1	0	0	0
ACCP	1	0	1	1
ENT surgeon	3	2	0	2
Total	40	10	10	20

The first focus group was online and moderated by the lead researcher's qualitative and mixed methods supervisor, a critical care nurse and Professor of Nursing with experience in running focus group studies, and facilitated by the lead researcher, an SLT and PhD student. The second focus group was face-to-face, moderated by the lead researcher and facilitated by their primary PhD supervisor, an Intensivist and Professor of perioperative and intensive care medicine. This focus group took place in a board meeting room during the lunch break of a national intensive care conference. The final focus group was online and moderated by the lead researcher, facilitated by their qualitative mixed methods supervisor. Members of the project's PPI group were invited to attend as observers but none attended any of the groups. Focus groups 1-3 lasted 83 minutes, 73 minutes and 77 minutes respectively.

6.3.1. Descriptive Themes

Three major themes emerged from the data: 'Real-world sizing practices; 'MDT perspectives and roles in decision making'; and 'Equipment and organizational factors affecting choices'. The themes are presented below with illustrative quotes (indented text). A thematic map was created and iteratively amended during the analysis process to aid identification of themes and sub-themes. Figure 6.1 shows the simplified thematic map indicating links between themes. A more detailed map including the code level can be found in Appendix R. Codes following quotes indicate the profession of the participant and which focus group was attended. A further cross-cutting theme of 'Thoughts on ideal practice in tube sizing' ran through the three major themes.

6.3.2. Theme 1: "Real world" sizing practices

Participants unanimously reported that TT size was almost always chosen by the inserting clinician. Exceptions occurred in sites with Tracheostomy Practitioners who sometimes made the decision, rare occasions where advice was sought from AHPs, and where operators were trainees who deferred to consultants for sizing decisions.

6.3.2.1. How sizes are chosen

There was variation in sizing methods reported across sites. Sizing by sex was frequent; e.g. size 7 for females and 8 for males or in one case 7.0 for females and 7.5 for males (ENT consultant). In some cases a standard size was used for all insertions, mostly size

8 but in one case size 9 (ACCP). BMI and thickness of anterior neck tissues was also used to determine size of tracheostomy and also *type* of tube, i.e. adjustable flange or standard length. Two therapists reported a high incidence of adjustable flange insertions at their place of work that they felt were not always clinically justified. Many reported that decisions followed size of endotracheal tube in place. Height was also mentioned as a factor, sometimes in conjunction with sex. A few participants were unsure of how size decisions were made and felt that size choices often came down to what was in stock.

> 'On a rule of thumb, I think for an average female, we tend to choose size seven. It generally tends to match with the size of the endotracheal tube, size seven and then a size eight for an average adult male.' ICU2FG3

> 'Sometimes, as you say, you end up with a tiny little person who's got a massive size nine tube in and you've no idea why that decision was made in theatre. Sometimes it feels a bit like it was what was on the shelf or what they had to hand at the time. There doesn't seem to be a clinical rationale or if there is, it's never really documented in the op notes or anything like that, that we find.' TPSLT_FG2

6.3.2.2. Experience-based decisions

All groups felt sizing and other insertion decisions were largely experience-led, based on assumptions, 'rules of thumb' and 'eyeballing' patients. A couple of non-operators (staff who did not insert tracheostomies themselves), felt they sometimes knew that the tube was the wrong size just by looking at the patient. Several participants expressed surprise that the correlation between height and tracheal width was found to be very weak in the observational study from this project. Two therapist participants felt size decisions were influenced by historical practices or experience-based beliefs around sizing requirements for ventilation. An ENT consultant added there was an assumption that tubes would be changed a week after insertion and therefore sizing errors could be promptly corrected. All groups felt that evidence-based decision making would be preferable.

> 'But in general, I follow that rule. So I go by height. I don't have a specific, I have to admit, I mostly eyeball the patient. But in general, for an average size female, I would go for a size seven and for an average size male, I would go for a seven and a half.' ENT_FG3

> ‘But sometimes you look at the patient and just think, well, that was probably never going to be the right tube for them.’ TPSLT_FG2

6.3.2.3. Decisions tailored to patients

The concept of ‘one size fits all’ was raised as a poor approach to sizing that nonetheless occurred frequently in ICU practice. Participants felt that the complexity of cases meant more nuanced, multifactorial decision-making was needed. The need to consider ventilatory requirements was acknowledged by all professional groups in the general sense of larger tubes being better for ventilation, but there was no evidence of calibrating an individual’s ventilatory needs to the size of the tube. Some sites had considered measuring tracheal dimensions with CT or ultrasound to guide decisions, but felt the evidence base was not clear. Ultrasound was used occasionally to assess thickness of anterior neck tissue and decide whether to use an adjustable flange TT. No participants reported sizing based on measurements of the tracheal lumen, though some felt that this would be best practice.

Differences were seen in sizing practices across different patient populations and this was felt necessary due to the differing indications for tracheostomy. For example, ENT consultants noted differences in practice across ICU, ENT and maxillo-facial surgeons, highlighting that the latter commonly inserted small tubes as ‘an additional safeguard’ (ENT_FG1), in case of issues breathing around reconstructed tissue. Some felt that ENT were more conservative and protective of the airway than ICU, whereas others felt surgical tracheostomies were less well considered, created large stomas and led to larger tubes to stop stomal air leak.

> ‘I’m definitely not here to defend ENT but I do think that actually that’s a very different cohort of patients. We’re talking a lot about respiratory patients in intensive care … I think ultimately, ENT surgeons do have the interest of the larynx at heart and are quite selective over their tubes … I think it’s probably more the quick nature of ICU, as we all know, heterogeneous population and I think a model would be very useful, particularly from a training point of view but I think there are certain nuances, aren’t there, to each population group that we would have to think about.’ SLT1_FG2

In terms of MDT involvement in decision making at insertion, SLTs were occasionally involved for specific groups such as patients with neurological conditions. However this was the ‘very odd occasion’ (SLT3_FG1) and dependent on the intensivist involved. SLTs

felt that patients' needs relating to communication and laryngeal wean were not given high enough priority at time of insertion.

Standardised practice and consistency in terms of size decisions and range and types of tubes was discussed. Whilst this helped staff training and to ensure staff familiarity with equipment thereby reducing risk, it also meant that there was less flexibility to tailor choices to individual needs. Some sites routinely changed repatriated patients' tubes to the local standard tube for safety reasons while others did not or would consider clinical reasons for not changing tubes.

6.3.2.4. Science, evidence and gaps in knowledge

A lack of evidence behind tracheostomy sizing decisions was a common theme and included evidence on endotracheal sizing - which was reported to underpin many tracheostomy sizing decisions, and on how to measure the trachea. ENT and therapist participants also felt there was a lack of awareness among ICU medics of the evidence that was available, for example on long-term complications and patient experience of tracheostomy, which was perhaps partly due to this research being undertaken by non-ICU researchers. All groups felt further scientific evidence was needed to underpin objective decision making and influence change in practice.

> '…It's only through multidisciplinary research and effort that we've seen that actually when you go and do a flexible nasendoscopy on patients who have been intubated, even for short periods, that these patients have got vocal cord palsy, they've got granulation tissue … patients may have mild dysphonia, may have mild change in their voice or very little difficulty respiratory wise or it's put down to issues that were associated with their underlying chest condition or something else that was blinding or masking.' ENT_FG1

> '… I think if there was some research and some science behind us arguing for smaller traches going in in the first place then I think quite a few of them would be open to that…' SLT2_FG3

6.3.3. Theme 2: MDT perspectives and roles in decision making

6.3.3.1. Attitude to change in practice

There were differences in the degree to which participant groups were open to new methods of sizing. These appeared to be related to the perceived importance of tube size and recognition of the problems arising from sizing decisions. As one participant said, 'if you don't think there's a problem, you're not going to use a different technique' (SLT1_FG3). Therapist participants cited the impact of size on the rehabilitation process, ability to communicate and patients' broader experience of ICU. They specified the importance of 'getting it right first time' to avoid delays to weaning, particularly for percutaneously inserted tubes, and unnecessary tube changes. They saw tube changes as a potential source of both physical and emotional trauma.

> 'On the back of what you were saying, if you have a hairy change as well, you can lose trust in the engagement with that patient, which the whole point of a lot of the therapy that we do is to give them back their independence, give them back their quality of life even under difficult circumstances. The wrong tube can change all of that.' PT_FG2

ENT felt TT sizing was an important topic for research, focussing on the hidden damage to airways and acknowledging their current sizing methods were 'not very scientific' (ENT_FG3). One felt that there was a lack of ownership or awareness in operators of later complications relating to tube size which might limit motivation to change. In contrast to therapists, one ENT participant felt sizing decisions were less important in those with a tracheostomy for a short period of time.

> '.. our approach isn't one of thinking about, and owning, downstream, what ends up happening, at that point … if they had ownership of what happens downstream or they were part of a team that had ownership, combined ownership like we're talking about, then maybe outcomes measuring and determining what is the best option for patients would be on the agenda.' ENT_FG1

ICU doctors of different seniority held different views on the importance of tube size and new methods of tube sizing. The ICU consultants felt their current sizing methods worked well, though one went on to describe fracturing a patient's trachea as a result of inserting a large tube. The same participant felt size was important but should be considered in the context of a patient's recovery, with larger tubes preferred for the early stages or

short cannulations and consideration of smaller tubes if needed later on. Another ICU consultant felt that size mattered mainly for ventilation and that complications and delays to weaning due to large tubes were both rare and not easy to predict. However, an ICU trainee cited cases of complications around insertion arising from poor choice of tube and felt a tool would be helpful in planning for tracheostomy.

> '…at this point in time, I've not had any problems directly with my usual rule of thumb which is seven and eight. So what matters more to a patient in terms of if they had a big fractured trachea because I put in a bigger size tube and then it's causing them paradoxical movement in, which I've seen in a couple of my follow-up patients. Then those probably would sway my views into choosing a better technique.' ICU1_FG3

All groups felt it essential that any new method was evidence-based and practical otherwise implementation would be difficult. ICU consultants added that it would need to be broadly consistent with their current method of sizing or they would doubt its validity. One also highlighted the need for any method to accommodate sizing differences across tube manufacturers.

> 'I mean if it's concordant with my decision making, I will be more willing to accept it. If it's quite discordant to my practice then I would question the long term outcomes and proof of benefit from it.' ICU1_FG3

> 'but I think if it was such a long way from what I would normally do then in all honesty, I would probably question it, regardless of how right it may be because it's so far from what I'm normally doing' ICU2_FG3

6.3.3.2. Making the decision

Participants reported that size decisions were made solely by the intensivist or surgeon inserting the tube unless it was a trainee, who would defer to the requesting consultant. Participants in two groups felt decisions were often based on operator preference. Non-operator participants also expressed personal preferences for particular makes and models of tube. One SLT reported rare occasions where therapist advice was sought prior to tracheostomy insertion for patients who were predicted to have a prolonged wean, for example those with Guillain Barre syndrome. An ICU trainee felt inclusion of the MDT was a positive development in decision making. Two therapist participants reported attempts

to influence choice of tube by placing the preferred tube with the patient prior to insertion, with limited success.

Post-insertion decisions on tube size were different: therapists were often involved in these, sometimes leading on decisions and carrying out tube changes. MDT working relationships were seen as influential in how decisions in tracheostomy management were made and individual relationships underpinned the success of communication, with some intensivists seen as more welcoming of MDT input than others. Recognition by intensivists of MDT members' skills and experience also influenced decision making. A physiotherapist participant reported some of their ICU colleagues were happy to delegate decisions to the physiotherapy team whereas others were not sure of their expertise. Lack of confidence or experience of junior therapy staff was also seen as something that could prevent them engaging in discussions or challenging decisions. Availability of staff and being in the right place to ensure conversations happened early enough was seen as a challenge, particularly for SLTs. Therapists and ENT felt MDT working was essential to ensure decisions reflected the full set of patients' needs and suggested that in the future insertion size should ideally be an MDT decision.

> 'I think as well it's which consultant's on and what sort of relationship you have with that consultant. Luckily now, more of the younger consultants that are coming through, we seem to have a better relationship with, they're not so old school. We have had some old school type consultants where you could say anything you want to and then they just ignore everything. It's a lot to do with your relationship with them as well.' APT1_FG2

> 'I think the biggest restriction that you would have is certainly the availability of speech and language therapy input within the different trusts because we know that there's just such a massive variation of input, whether that's funded input, unfunded input, skill, clinical skill, availability, etc.' SLT1_FG2

Participants reported different experiences working with surgeons versus intensivists. This related to tube size choices, preferences over type of tube, and communication and working relationships as described above. Participants had opposing views over which group provided better care or were easier to work with. A trainee ICU participant saw closer MDT working as a positive development. Consultant ICU participants did not discuss working relationships with other professions. The complexity of care for patients who were under multiple teams was seen as a further challenge to communication and MDT decision making. However, therapists and ENT felt that initial insertion decisions

would benefit from the input and expertise of the full MDT.

> 'The surgeons will say, anybody who has a surgical trache, we can literally have a chat, suggest the right sort of tube, put the right sort of tube on the bed as they're taken up to theatre and they will come down with something completely different.' ACCP_FG2

> 'I've also got that relationship with the maxfax [maxillo-facial] team and the ENT team. So quite often I'm a little bit like a marriage guidance counsellor in between the different specialties, trying to get them to come together for the best decision. But I think it is all about those relationships and that then makes it easier to get those clinical points across.' TPPT_FG2

6.3.3.3. Holistic picture

Perspectives from the different professions combined to create a composite picture of patients' holistic needs and functions that might be impacted by size of TT. These incorporated respiratory and ventilatory needs in the acute phase and during weaning, communication and inclusion in care and rehabilitation, and the avoidance of physical and psychological harm. An ENT participant felt clinicians should consider the reason for insertion and what a patient is 'able to do with that tube' (ENT_FG1) when choosing size.

All professions talked about airflow in relation to size of tube and effect on function. Intensivists predominantly focused on airflow through the tube and problems with tubes that were too small or leaks around an inflated cuff that caused difficulty ventilating patients and failure to progress. Only one participant considered an individual's airflow requirements in relation to size of tube. This was prompted after watching a video summary of a benchtop experiment in which the same airflows had been pushed through a small, medium and large 3D printed trachea. They reflected that this might be an unfair comparison since people with smaller tracheas presumably had smaller lungs and therefore lower flow requirements. An ACCP and an intensivist also commented that if airflow requirements were very high then it may be too soon for tracheostomy insertion.

> '…the size during the early phase of ventilation, a bigger size probably helps in clearing secretions and if the lungs are stiff, then the airway pressures required to ventilate them are going to be much higher, in which case you've got to have a better cuff seal. So that's why we tend to choose- if you choose a smaller

size, you're going to overinflate the cuff and you're going to have more leak…' ICU1_FG3

'it would seem to me that if you've got a smaller trachea, you've probably got, generally, a bit of a smaller respiratory system and therefore the amount of air flow through it is going to be a bit less.' ICU2_FG

Therapists contributed more on airflow around the tube and problems with tubes that were too large to allow sufficient leak around a deflated cuff. They spoke of the knock-on effect of this on OWV use and restoration of laryngeal function, which in turn impacted a patient's ability to speak and engage in rehabilitation, and in turn their mental well-being. Whilst intensivists felt ventilation should be prioritized at insertion, therapists spoke of finding the balance between weaning and ventilation. An SLT commented that voicelessness and tracheal trauma were risks to long-term psychological wellbeing and respiratory function and should be considered alongside the risks to short-term ventilation in any risk assessment of tracheostomy size at insertion.

'I think often the idea of intensivist colleagues would be for ventilation, the bigger the tube the better. Whereas obviously for weaning and again, subsequent complications that we really see very, very commonly, we're trying to get in there early, and often we're then waiting for a downsize prior to weaning which then slows the whole process down.' SLT1_FG3

'It's coming back to hearing what you've been told by patients and their families already, And that communication is key, involvement in their care is key, orientation around delirium and etc, being able to communicate is really important.' APSLT_FG2

'It does sometimes happen that they want to then come off the ventilator entirely because they're, then they can use their valve more readily.' PT_FG2

All professions raised anatomical fit of a TT relating to its size. This was discussed in terms of impact on ventilation, including where sizing meant tubes did not sit parallel with tracheal walls. Length of tube in relation to the depth of a patient's anterior neck tissues as well as diameter was felt to be important by all professions, and some felt this was often the cause of issues that had been wrongly attributed to size. ENT and therapist participants spoke of the impact of fit of tube on tissue trauma and long-term airway complications. Intensivists raised other anatomical considerations such as calcification of tracheal rings, tracheomalacia and lung stiffness. Secretion clearance was also raised by intensivists

and therapists – both groups considering impact of size of tube on clearance of lung secretions and therapists considering saliva management.

> 'I think maybe there's a thought that well actually the risk of inadequate ventilation is a greater risk than the laryngeal trauma which we can sort out down the road. But the initial few days where a patient can't communicate, we know it's very difficult for them and laryngeal trauma can be complicated to work with so if they could make an acknowledgement of both risks.' SLT1_FG2

6.3.3.4. Stage of patient journey

Commentary on early needs versus longer-term needs differed by profession. ENT and therapist professions felt ICU operators' approach was 'big is best', especially initially and this was supported by ICU participant contributions.

> 'It's quite an important decision to make but probably the sizing factor should be put into the stage of their illness as well, probably early in their illness and if its needed for a shorter possible duration then a bigger may be better. But during the later stage, if I've predicted, I anticipate that during the later stage of their illness, smaller may be better… So depending on what stage of their clinical recovery they are and the stage of their illness, I think the choice needs to be made. Size matters at different stage of their illness.' ICU1_FG3

In contrast, several therapist participants described using an early approach to rehabilitation and felt that the wrong size tube at the start could cause delays to weaning and increase patient anxiety. Interestingly, one SLT participant changed their view through the course of the focus group from initially suggesting that ventilation requirements outranked other factors in the early stages, to feeling that therapists equipped with the right knowledge and skills should be involved in decisions early and contribute information on rehabilitation processes and patient experience to inform tube size decisions. The earlier position appeared to be based on the assumption that there was a solid clinical reason for the use of larger tubes at insertion.

> 'my main issues is, so we do an early cuff down weaning strategy here. So the lady that I've literally just come down from seeing for example, has a size eight tube in… But she's not registering any kind of leak [on cuff deflation]… But she's too early really to downsize at the moment because she's not really had long enough for that trache stoma tract to be well-formed …. But she's

> a very anxious lady, she's got a mental health history, so in terms of trying to enable communication for her to try and deal with a whole load of those ITU anxieties, she doesn't appear to be affected with delirium or anything like that at the moment but to try and ward off any of those issues, we're in a sticking point because actually she's got a size eight in…' SLT1_FG1

> 'The more informed we are about that process and how those decisions are made, the more we're able to use our professional judgement in order to fight, you know, make our arguments for something different I suppose, isn't it.' SLT2_FG1

Whilst an intensivist and ACCP participants suggested size requirements might be expected to change over the course of recovery, therapists felt insertion decisions should be influenced by a long-term view of patient function and rehabilitation. As described above, an ENT participant suggested that if operators had more ownership of long-term outcomes then these outcomes would be more likely to inform early decisions.

Downsizing was seen by intensivists and an ACCP as something that could occur later in a patient's recovery. In contrast, therapists felt ideal practice would be getting the size 'right first time', not only to avoid delays in weaning but also because changes could be an unpleasant and risky procedure for patients. Reported frequency of downsizing varied across therapists from 'not that many patients' (PT_FG2) to 'often' (SLT1_FG3). An intensivist reported few patients at their unit required their tube to be downsized prior to decannulation and that those who did were difficult to predict early on. The complexity and heterogeneity of ICU patient populations were cited as potential challenges to the development of a new method of sizing of TTs, though some sub-groups were identified whose recovery was likely to be longer, such as neurological populations.

> 'It's never just a tube change, is it? That's the thing. That's the theme that's coming out from all of us, isn't it? It's never just a tube change.' APSLT_FG2

6.3.4. Theme 3: Equipment and organisational factors affecting choices

6.3.4.1. Hospital systems and governance

Most participants had contributed to locally written MDT tracheostomy guidelines and documentation to support tracheostomy management. However, these did not necessarily cover sizing decisions and a lack of robust evidence meant guidance was based on clinical

experience. An ENT participant described changes in guidance for surgical tracheostomy insertion during the COVID-19 pandemic, where larger tubes were inserted based on a theoretical reduction in air leakage around the tube and staff exposure to virus, but without consideration of the long-term effects on patients. An ICU participant reported drawing on the National Tracheostomy Safety Project guidelines in developing local guidelines. Care pathways were another type of document discussed in two focus groups as a way to ensure continuity through improved communication and additionally ensure multidisciplinary input. Participants highlighted the need to train staff in how to use and where to find the documentation, which was a potential barrier to use.

> 'In Covid for example, we had a change in our approach, significantly. It wasn't based on a lot of evidence base, that we needed to put in bigger tubes in order to save ourselves exposure to, in the circuit to potential virus in the room. So it was the biggest size tube possible… We were responding to the circumstances without necessarily thinking about the impact downstream to what we were going to see.' ENT_FG1

Several participants spoke of rationalizing stock across sites for safety since this ensured staff familiarity with equipment, facilitated training and increased the likelihood of having the right stock throughout the hospital. Financial benefits were also recognised through reduced waste of out of date stock. However, the drawback of limited ranges was reduced ability to tailor choices to patients' needs, since few manufacturers covered all combinations of size or features. In some cases this meant inserting a larger tube or one with an adjustable flange to achieve the desired length. Many sites still reported the use of multiple types of tube and supply chain issues meant in some cases other types of tube had to be purchased, bringing the challenge of comparing models that used different sizing conventions.

> 'We've done a lot of work on this in our trust because we found we were having a lot of incidents because we were using a lot of different tubes. So we had five, six, seven different types of tubes and the problem is different units were using different equipment. We'd have different things in theatres. So then they come out of ITU and we wouldn't have the right kit on ITU. We didn't have the inner tubes. We had lots of single lumen tubes being used where people chucked the inner tubes or didn't have them… we've standardised to one main brand just to try and make it easier for training and everything because again, we found we were doing training and you'd have to talk people through certain different tubes, you might come across this and this is reusable and that's

disposable and you might not have that. We found that has really helped just to make it easier for people.' TPSLT_FG2

All professions spoke of the time required to introduce change in practice, whether this was in documentation or stock choice. Supporting evidence was seen as a facilitator to change. An intensivist indicated that patient experience evidence would be more likely to influence their practice than other types of evidence. In agreement with this, SLT participants cited past examples of using patient experience to introduce use of OWVs with ventilated patients. Some felt surgical teams would be more resistant to change around TT sizing decisions and others felt medical teams would. Coordination of a number of departments or teams with their own preferences and practices was seen as a barrier to change, as was the need to avoid waste through using up existing stock while transitioning to a new type of tube.

'…it took me quite a few years to try and, in my own trust which was changing and merging, there were three different trusts, where they all had slightly different trache tubes and different makes of tubes, there was different quality control around the settings in the different hospitals. We tried to bring a standard and we tried to argue for consistency that we should stick with one manufacturer and that way we'd become familiar with their tubes.' ENT_FG1

6.3.4.2. Staffing for tracheostomy care

This sub-theme incorporated data on skills and experience, workforce and training. Skills and experience of staff were seen as influential in size decisions of operators and in the confidence of other MDT members to contribute to size decisions. An ENT participant felt that junior doctors and those not specialist in tracheostomy insertion and management might be unaware of best practice. Hierarchical practices in ENT and critical care also meant junior doctors might follow consultant advice without challenging it. An SLT participant highlighted the importance of having staff with specialist ICU and tracheostomy skills in order to provide appropriate input. Therapist staff without full understanding of tube size decision-making might not feel they had a role to play or that medical concerns always over-ruled rehabilitation concerns.

'So it's often our juniors who will do tracheostomies and they'll be guided by the influence of a senior intensivist who is asking them to come and do the tracheostomy for them. So they won't necessarily argue about what is an appropriate size.' ENT_FG1

> '..really you need a very competent and a capable speech and language therapist with experience and training regarding these things. So if you've got a speech therapist in a smaller DGH that's covering all of acute care and not necessarily just critical care, it's very hard to get the support and the training around that. So that is quite a challenge within speech and language therapy I guess.' SLT3_FG1

Roles mentioned in relation to tracheostomy care included the ICU medical team, nurses, physiotherapists, SLTs, ACCPs and Tracheostomy Practitioners. The latter were recognised as having expert skills, however not all teams had access to this type of role. Existence and configuration of posts within different professions differed as did funding sources. An ENT participant felt centralisation of funding for and recruitment to tracheostomy MDT roles would help communication and continuity through different hospital departments. Physiotherapists and SLTs noted a shortage of SLTs in ICU, particularly in ring-fence funded specialist posts. This meant less opportunity for building relationships with other members of the ICU team and for highlighting patient needs impacted by sizing decisions, such as swallowing, communication and laryngeal function. Two SLT participants with ring-fenced funding felt this enabled them to provide a better service as they could develop specialist skills and were not called to cover for other areas. One felt the high decannulation rate prior to ICU discharge was due to having a dedicated, funded tracheostomy MDT.

Training in tracheostomy management was raised in all focus groups and by all professions. An ENT participant felt this training was not always accessed by those responsible for inserting TTs. Physiotherapist and SLT participants in one group echoed this and recommended MDT training for junior doctors and surgeons, including raising awareness of long-term tracheostomy outcomes and the implications of sizing decisions. One hoped a new local initiative to provide joint training for surgical and ICU trainees would foster peer understanding of the different considerations in each area. Training was also required for documentation and pathways and any new equipment to ensure they were implemented correctly. All groups felt that to ensure the successful implementation of any new method, it would need to be practical, evidence based and easy to teach and retain.

> 'So that's what we try and teach on the course but the course ends up being delivered to a limited group of professionals. Many of them are probably speech and language therapists, physiotherapists and others who don't meet the patient at that early point in the pathway where the decision is made…' ENT_FG1

> ‘Going back to that training idea as well, one of the things that I’m just starting off in collaboration with all of the teams is some joint training for our trainees in anaesthetics, ITU, head and neck, both maxfax[1] and ENT, is collaborative airway training so that they can all learn from the nuances of their own specialism.’ TPPT_FG2

6.3.4.3. Tube design

The focus groups were intended to elicit information on sizing decisions in terms of diameter of TTs. However all groups raised other sizing considerations such as length and profile, which impacted the way a tube sat in the trachea and resistance to airflow. Many participants mentioned the use of adjustable flange tubes where extra length was needed to traverse anterior neck tissues. Some however, did not like adjustable flange tubes or felt they were used more often than needed, whilst acknowledging their value in the context of the rise in BMI of patients. An ENT consultant expressed a strong preference for one type of tube, but felt that this model was slightly too short, meaning more adjustable flange tubes were used than might otherwise be necessary.

> ‘Most of the cases which just come to my mind, I think it was about the size of trachea but also length of tracheostomy tube because we have a lot of complications after tracheostomy when length of the tube was not enough, so we ended up creating another trauma because we had to put in another tracheostomy on top of the first one.’ ICUSD_FG2

A lack of standardization in tube sizing and other design differences across manufacturers was mentioned in all focus groups and brought with it various challenges in selecting the best size tube. An intensivist highlighted that non-standard sizing in tracheostomy manufacturing meant a size 8 tube from one manufacturer might have different inner and outer diameters to a size 8 from another manufacturer, making transition from one type of tube to another difficult.

> ‘I think the other thing would be how it determines across different sizes of tubes because obviously one of the things, if you look, a size nine is not a size nine, is it? A size nine gives you your internal diameter but the external diameter on different tubes is wildly different.’ ICU2_FG3

[1] Maxillo-facial

Other differences included length, inner and outer diameters, cuff profile, fixed versus moveable flanges, re-usable versus single-use inner cannulae, materials, method of connection to a ventilator and special features such as sub-glottic suction ports and fenestrations. Some features were associated with particular patient groups, such as sub-glottic suction for ICU and neuro populations. An SLT participant raised the problem of not having all combinations of features available in insertion kits and another raised the conflict between restricting the range of tubes for training and safety, versus maintaining enough of a range to allow tailored decisions.

> 'With our longer term patients like the Guillain Barres that we get through, there's been a big issue with the adjustable flanges not having a subglottic port in the main, being able to get them with a subglottic port but they don't come with an insertion kid so you can't put that in as a primary insertion, etc.' SLT1_FG1

Participants felt safety was compromised when staff were presented with unfamiliar kit and that training was more difficult if staff needed to become familiar with different types of equipment, however, most described using at least two types of tube to allow flexibility to tailor choices to individuals, since few manufactures offered the full range of features in all sizes. One participant reported their site had changed to a single type of tube, chosen as it was slightly longer than the previous brand. The local team felt it fitted the majority of their patients, eliminating the need for adjustable flange tubes.

> 'We used to use Portex for exactly the same [comfort reasons] but lots of adjustable flanges, which is why we did a trial with the Tracoe twist and have found- I totally agree about the comfort factor but I think on the whole, that kind of one tube that seems to fit more people has been super useful.' SLT1_FG3

An intensivist who used the same tube reported a reduction in incidents since its introduction on their unit. In contrast, an ENT participant reported the ICU team at their site refused to use the same type of tube as they felt the method of attachment to a ventilator was unsafe, illustrating the influence of operator preference on tube choice.

Following the summary video of the broader PhD findings, participants of all backgrounds expressed surprise that the correlation between height and tracheal width was not closer. An ICU consultant felt that the benchtop trials of a small trachea with large tidal volumes (700 mL) were an unfair test, arguing that patients with small tracheas would presumably have smaller lungs and therefore lower flow through the trachea, and likened the situation to a race horse breathing through a human trachea.

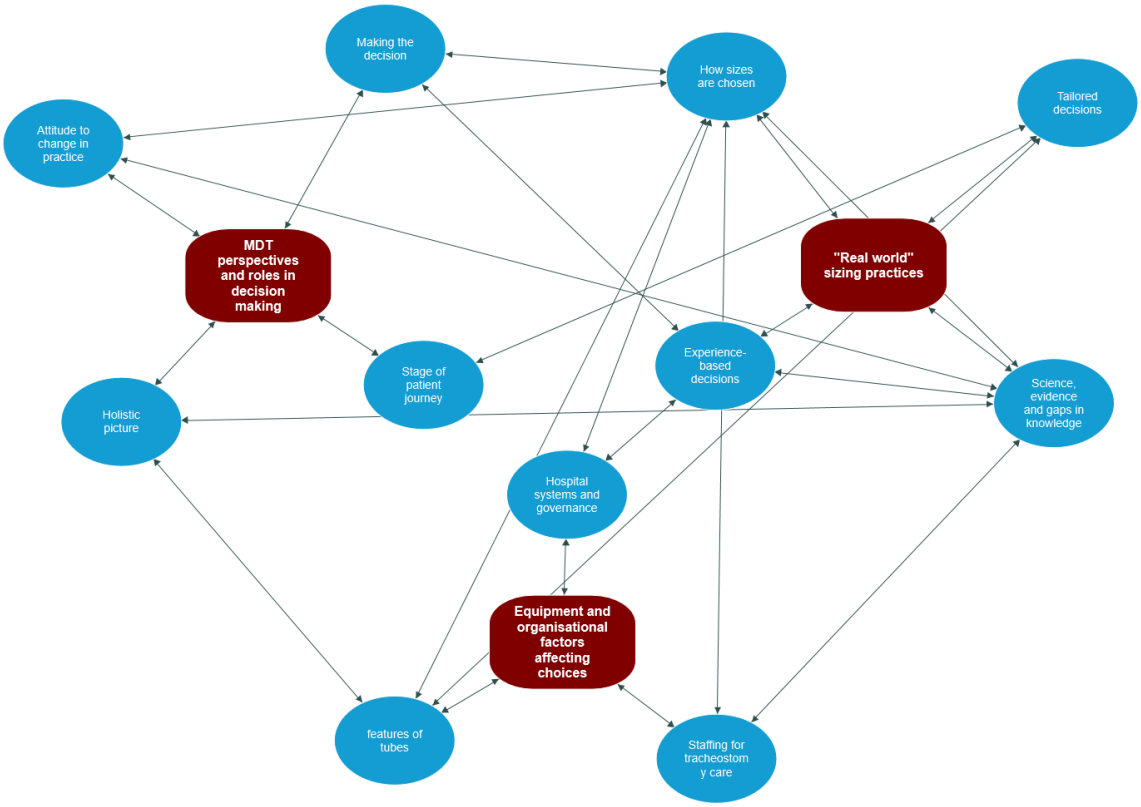


Figure 6.1.: Thematic map of descriptive themes and sub-themes

6.3.5. Interpretation using the COM-B model

The COM-B model of behaviour was designed to identify influences on a behaviour to inform behavioural change intervention (see Section 6.2). For the purposes of this study, the target behaviour was defined as 'method of TT sizing at initial insertion on ICU'. The target group of people was 'MDT members involved in the management of tracheostomy on ICU'. The COM-B model was used to review descriptive themes and sub-themes from the focus groups and interpret key barriers and facilitators to changing practice (see Table 6.2; Table 6.3; Table 6.4). The columns corresponding to dimensions of the COM-B model are populated with codes relating to the descriptive themes and sub-themes in the row headers. Barriers and facilitators were found in each of the three main dimensions of the model: capability; opportunity; and motivation.

6.3.5.1. Capability

No physical barriers were identified to changing practice (i.e. strength, dexterity). There were many psychological barriers including the wide range of existing approaches, mostly to sizing but also to rehabilitation, for example early versus later trials of cuff deflation (see Section 6.3.2.1, Section 6.3.3.4). The dependence of decisions on operator pref-

erences, historic practices and firmly held beliefs were seen as barriers to change, as were operator knowledge of long-term complications related to tracheostomy, therapist roles, and approaches to weaning (see Section 6.3.2.2, Section 6.3.2.4, Section 6.3.3.2). The arbitrary nature of some decisions was also seen as a barrier since it suggested little thought was applied to decisions. The MDT itself was seen as a potential barrier or facilitator, depending on membership, skills, communication and working relationships. A poorly functioning MDT was identified as a barrier to decision-making based on the holistic needs of patients (see Section 6.3.3.2, Section 6.3.4.2, Section 6.3.3.3). Heterogeneity of ICU patient populations was seen as a barrier to developing a universal method of sizing decisions and therefore to changing clinicians' practice. Variability in tube sizing and design across manufacturers was seen as a barrier to training in new methods (see Section 6.3.4.3, Section 6.3.4.1).

Table 6.2.: Capability related barriers and facilitators to changing practice

Themes	Capability: Physical	Capability: Psychological	Barrier	Facilitator
“Real world” sizing practices				
How sizes are chosen	n/a	male vs female; BMI and anterior neck thickness; ETT; height; what’s available;	Various approaches and applications of methods used in practice, not a simple conversion from one method to another. Sometimes appears there is no thought going into decisions. Measurement of the trachea prior to trache insertion is not normal practice. There is no evidence of matching respiratory requirements to ventilation needs within ICU, only an approach in the direction of ‘bigger is better’. The basis for decisions can be ambiguous, e.g. what does ‘patient size’ refer to - height? BMI? skeletal frame? Not overtly clear if ‘fit in trachea’ is a consideration.	All professions recognise the benefits of standardisation and consistency on quality of care which may help implementation of a new sizing method.
Experience-based decisions	n/a	assumptions in sizing; going by experience; eye-balling and rules of thumb; historical practices and beliefs	Heuristic decision making based on assumptions and subjective experiences may be hard to change.	Robust evidence may help correct erroneous assumptions. An evidence-based method would provide an alternative to relying on experience

Themes	Capability: Physical	Capability: Psychological	Barrier	Facilitator
Decisions tailored to patients	n/a	different for different patient populations; one size fits all; balancing ventilation and weaning; measurement and imaging; getting it right first time	If different patient populations have different requirements this adds a level of complexity to any method. Therapists and ICU medics hold contrasting beliefs regarding the concept of ‘one tube for the duration/getting it right first time’ vs ‘changing tubes can happen later’. Weaning is seen by some as ‘something that happens later’. There are no practical, validated methods of measuring the trachea	Clinicians recognise that one size does not fit all and could be receptive to a method that tailors recommendations to the individual. Education on weaning interventions and processes could highlight early application of these and emphasise the importance of initial tube size. Clinicians would likely be receptive to a validated method of measuring the trachea to facilitate TT size decisions, provided the method was practical.

Themes	Capability: Physical	Capability: Psychological	Barrier	Facilitator
Science, evidence and gaps in knowledge	n/a	lack of evidence; knowing about trache related complications; a need for science-backed methods; consistency and standardisation	There is a lack of knowledge on longterm impacts of tracheostomy on the airway among ICU doctors and and non-expert ENT surgeons. There is a lack of knowledge on how to measure the airway. There is a lack of knowledge on how to decide size of ETT (which influences many trache size decisions). There is a lack of knowledge on tracheostomy related airflow in the context of an inflated cuff vs deflated cuff + OWV and patients' respiratory requirements.	All professions value scientific approaches and research evidence. All professions value consistency and standardisation. Research evidence on the longterm impacts of tracheostomy on the airway and how to measure the airway could influence new methods of sizing. Dissemination of research findings +/- new methods of sizing through training and education could lead to change in practice/adoption of new methods. Greater understanding of airflow in the context of an inflated cuff vs deflated cuff + OWV and the patient's specific requirements could facilitate changing practice. Identification of risk factors for likely longer weaning from a trache might help incorporation of longer-term needs in size decisions. Consideration of respiratory requirements in relation to timing of tracheostomy may reduce the likelihood of having to meet very high respiratory needs through a trache, and therefore impact size decisions
MDT perspectives and roles in decision making				

Themes	Capability: Physical	Capability: Psychological	Barrier	Facilitator
Attitude to change in practice	n/a	recognising the problem; practicality of sizing method; perceived importance of tube size	Not all operators are aware of problems with current practice and therefore see a reason to change. Few operators currently perceive a role for the MDT/SLT in TT size decision making.	Some members from all professions feel current sizing methods are not good enough and change is needed. Therapists supporting patient rehabilitation and weaning from tracheostomy report a big impact of tube size decisions, as do ENT surgeons working in airway reconstruction. These groups are already motivated to change practice. Further research and dissemination of evidence could support the argument for change.
Making the decision	n/a	ENT vs ICU, decision makers, communication and working relationships	There are differences in practice between ICU and ENT that may be difficult to resolve. Therapists are not often involved in initial size decisions. Those making the decisions may not have information on or awareness of patient experience, weaning and long-term outcome factors to consider. Poor communication or working relationships between members of the MDT may may mean that operators do not have access to all information required to make sizing decisions	ICU and ENT have complimentary knowledge on tracheostomy function for ventilation and impact on airway that could contribute to holistic approach to tube sizing. SLTs and Physiotherapists knowledge of rehabilitation and patient experience of TTs that could contribute to TT size decisions. Adequate staffing (ensuring presence of a skilled SLT in the MDT) could contribute to better working relationships within the MDT and sharing of professional knowledge.

Themes	Capability: Physical	Capability: Psychological	Barrier	Facilitator
Holistic picture	n/a	airflow; anatomy; complications and long-term impact; size in relation to function and patient experience	ICU operators often view airflow from a ventilation perspective only and take the approach of 'big is best'. The specific requirements of the patient may not be considered. Therapists focus on airflow passed the TT for OWV use in restoration of laryngeal function for voice, airway protection, independent secretion clearance and weaning. They may not be aware of the subjectivity of size decisions or feel confident to challenge them. Different members of the MDT are more involved at different stages of a patient's journey, focus on different functions affected by tracheostomy, and have a different perspective on sizing. Patient experience is not usually a consideration at insertion. The experience of a tube change and impact on patients may be underestimated. It is not known if there is a 'right' tube size for patients' that could suit their needs throughout their hospital stay, or if in some cases initial insertion of a larger tube is unavoidable due to respiratory requirements.	Inclusion of the full trache MDT in size decisions would incorporate a broad range of expertise and perspectives, contributing to holistic patient-centred decisions. More research is needed on sizing decisions and outcomes (respiratory, voice, weaning, tissue trauma, patient experience etc).

Themes	Capability: Physical	Capability: Psychological	Barrier	Facilitator
Stage of the patient's journey	n/a	weaning and downsizing tubes; accounting for complexity and changing needs; around insertion	There may be lack of awareness among ICU doctors of TT related outcomes post-ICU, what rehabilitation entails, and how early rehabilitation interventions can be started. This is compounded by local variation in practice of SLTs and physiotherapists in rehabilitation approaches. The heterogeneity in ICU populations may be difficult to account for in one method of TT size selection It is unusual to involve the MDT in TT sizing decisions at time of insertion.	Dissemination of research knowledge in the ENT, nursing and therapy literature on patient experience and outcomes within ICU doctor audiences Experienced SLTs, physiotherapists and ENT could provide valuable input at time of insertion. More research is needed on outcomes of sizing decisions in different populations.
Equipment and organisational factors affecting choices	n/a			
Hospital systems and governance	n/a	guidance and guidelines; stock and safety vs breadth of range	Guidelines are limited by the lack of robust evidence and are often experience-based. Knowledge and familiarity with equipment depends on local stock choices and training. Ensuring all combinations of features exist for all sizes would lead to a large range and stock/storage issues for hospitals/wards	Organisations usually have a guideline/local guidance on tracheostomy management. These could be used as a platform for introducing/supporting change in practice. Improved TT designs could lead to simplified stock choices and training and better decisions for patients.

Themes	Capability: Physical	Capability: Psychological	Barrier	Facilitator
Staffing for tracheostomy care	n/a	skills and experience of staff; training; having the workforce	Junior operators and therapists may not be aware of all factors to consider in TT sizing. Training may not reach all members of the MDT/different professions may receive training on different aspects of tracheostomy care. Absence of key professions in tracheostomy management could mean reduced MDT understanding of the impact of tracheostomy to patient's holistic experience.	Integrated MDT training (surgeons, doctors, SLTs, physiotherapists, ACCPs, nurses etc) could allow cross-pollination of knowledge and skills and support change in practice through better mutual understanding of roles and perspectives. Adequate funding of ICU therapy staff including SLTs could facilitate MDT knowledge of the impact of TT on laryngeal function and related patient activities/outcomes
Tube design	n/a	differences across manufacturers; length, diameter and profile; special features	Staff may not be aware of differences across models and manufacturers or implications (e.g. changing from a 7 in one brand to a 7 in another may be an upsize/downsize). Any method of sizing would have to take the differences into account or provide recommendations for different tubes	Improving design of tubes to incorporate the best of each brand/model could simplify stock choice, storage and training and make TT size decisions easier for clinicians. Standardised sizing system across manufacturers and models would reduce the risk of inadvertently upsizing/downsizing when switching between brands.

Many positive influences for change were identified, including agreement across all professions that standardisation in care benefited patients. Scientific evidence was identified as a facilitator for implementing new methods (see Section 6.3.2.4). MDT education was identified as a facilitator through providing a forum for sharing knowledge on the long-term impact of sizing decisions and current weaning practices whilst improving mutual recognition of MDT roles and knowledge (see Section 6.3.4.2). The general openness to a validated, practical method of tracheal measurement and overarching sizing method was identified as a facilitator to implementation of change. Multidisciplinary research was identified as a facilitator for investigating issues from multiple perspectives and MDT ownership of holistic patient outcomes (see Section 6.3.2.4, Section 6.3.3.3). Improved design of TTs to meet clinicians' preferences and standardisation of sizing across manufacturers were also identified as facilitators (see Section 6.3.4.3).

6.3.5.2. Opportunity

Fewer influences were identified relating to physical and social opportunity. Physical opportunity usually refers to access to physical resources, however here it was taken to include access to knowledge, for example where participants felt knowledge of tracheal damage caused by tracheostomy was not widely known or disseminated to ICU audiences (see Section 6.3.2.4, Section 6.3.3.3, Section 6.3.3.4). The absence of evidence on various aspects of tracheostomy sizing was identified as a major barrier to changing practice, such as methods for measuring the trachea. A further key barrier was availability of or access to the right tubes. This might be due to purposefully restricting stock for safety and/or cost reasons, unit policy, or gaps in the ranges offered by manufacturers (see Section 6.3.4.1, Section 6.3.4.3). The main barrier to change identified in terms of social opportunity was lack of inclusion of the full tracheostomy MDT in decision making at insertion. This was either due to lack of recognition of potential input from different members (including therapist awareness of own potential role), working relationships, or that certain professions were not represented within the local team (see Section 6.3.3.2, Section 6.3.3.3, Section 6.3.4.2). Other barriers included historical practices and culture around TT sizing (see Section 6.3.2.1, Section 6.3.3.2).

Table 6.3.: Opportunity related barriers and facilitators to changing practice

Themes	Opportunity: Physical	Opportunity: Social	Barrier	Facilitator
Real world sizing practices				
How sizes are chosen	whats available; who chooses	who chooses	The right tubes are not always available or not permitted. Personal choices may dictate range and type of tubes, impacting ability to make tailored decisions.	MDT input to decisions prior to or at insertion of a tracheostomy could ensure decisions reflect a patients holistic needs
			Therapists are rarely present when decisions are made or invited to input to decisions	
Experience-based decisions		experience based approach; historical practices and beliefs; rules of thumb; assumptions	Decisions depend on the local setting, clinician experience and assumptions and past practices	Robust evidence could provide clinicians with more scientific methods
			The potential contribution of AHPs to size decisions may not be recognised if they have not historically been part of the ICU MDT	Research demonstrating the value of AHP roles and their impact could lead to greater involvement in decisions and change in practice
Decisions tailored to patients	measurement and imaging	balancing ventilation and weaning; getting it right first time	Measurement and imaging of the trachea believed best practice, but here is no readily available method or evidence to support this	Clinicians would welcome future validated, practical methods of measuring tracheal diameter
			Those making TT size decisions may be more focused on ventilation and feel TT size changes can happen later, those focusing on weaning and getting the best size at initial insertion may not have a voice in decisions	MDT decision making could encourage broader consideration of factors involved at time of insertion

Themes	Opportunity: Physical	Opportunity: Social	Barrier	Facilitator
Science, evidence and gaps in knowledge	a need for science-backed methods; lack of evidence; knowing about tracheostomy-related complications	knowing about tracheostomy-related complications	Little evidence exists to guide decisions; pockets of evidence generated by professional groups may not be disseminated to whole MDT (e.g. ENT evidence on stenosis not known to ICU physicians)	Clinicians would welcome further research evidence to support decision making. Closer MDT working within ICU and externally with ENT could help dissemination of relevant evidence to the whole tracheostomy team
MDT perspectives and roles in decision making				
attitude to changing practice		openness to new method for sizing; perceived importance of tube size; recognition of the consequences	Without good MDT working and mutual recognition of roles, information around incidence and impact of sizing-related problems may not be shared/known by all team members which in turn may affect attitude to changing practice	Closer MDT working and involvement in sizing decisions could promote recognition of the problem and broader consideration of factors involved at time of insertion
Making the decision	communication and working relationships; decision makers	communication and working relationships; the decision makers; ENT vs ICU	Currently decisions are uni-professional. MDT decision making requires good working relationships and presence of suitably skilled staff.	Adequate funding of skilled therapist and tracheostomy specialist staff would facilitate proper MDT integration and influence in size decisions.
			There are differences in the approaches of ENT and ICU operators.	Better cross-specialty working may help align practices. Joint training would provide opportunity for sharing and understanding professional perspectives and improve decision making.

Themes	Opportunity: Physical	Opportunity: Social	Barrier	Facilitator
holistic picture	airflow; complications and long-term impact; size in relation to function, patient experience and wellbeing	complications and long-term impact; size in relation to function, patient experience and wellbeing	There is insufficient evidence on impact of sizing decisions on airflow under different TT conditions (cuff inflated/deflated + OWV). Decision makers may not be focused on all functions affected by size decisions at time of insertion. Dissemination of the evidence on patient experience relating to TT may not be targeted at decision makers who may therefore not be aware of the patient perspective.	More evidence on airflow with an inflated cuff/deflated cuff + OWV and the clinical implications may support better decision making. Closer MDT working and sharing of knowledge on impact of sizing decisions on function and patient experience may improve decision making.
stage of the patients journey	around insertion; weaning and downsizing	accounting for complexity and changing needs; around insertion; weaning and downsizing	The nature of different professional roles means some staff may be present more at insertion whilst others more during weaning and rehabilitation. This may impact perspectives on TT size decisions, which may not reflect the whole picture. The complexity of ICU patients means needs may change, which makes sizing decisions more difficult	Closer MDT working could facilitate a shared, holistic view of patients needs and improve TT size decision making. More evidence on outcomes of TT sizing may help identify patterns and inform future methods of deciding TT size.
Equipment and organisational factors affecting choices				

Themes	Opportunity: Physical	Opportunity: Social	Barrier	Facilitator
Hospital systems and governance	stock availability and safety vs breadth of range; continuity through the hospital; guidance and guidelines	change takes time; continuity through the hospital; stock and safety vs breadth of range	The right balance of holding a wide enough range for flexibility whilst maintaining safety through staff familiarity with kit is subjective and may be influenced by individual beliefs and perspectives. Continuity through the hospital depends on hospital systems and inter-specialty working relationships. Change requires collaboration between departments which may be influenced by working relationships There is a lack of evidence to support guidance and guidelines, which are therefore based on experience.	Stock decisions should be made by the MDT tracheostomy team to ensure all factors are considered. Better design of TTs could make them suitable for a wider range of patients (e.g. longer, better cuff design), increasing safety through simpler training for staff. Integrated training for different specialties could improve working relationships between departments. Further research could support development of evidence based guidance and guidelines.
staffing for tracheostomy care	having the workforce	having the workforce; skills and experience	MDTs may not have the right staff, may not have any SLTs. Absence of ring-fenced funding may mean therapy staff have little availability on ICU. Lack of specialist skills and experience of therapy staff may impact knowledge of factors involved, own confidence to challenge decisions, and confidence of others in their input.	Adequate funding and training of specialist therapy staffincluding SLTs would facilitate availability and integration within the ICU MDT. In turn this could promote inclusion of broader factors involved in TT size decisions.

Themes	Opportunity: Physical	Opportunity: Social	Barrier	Facilitator
tube design	differences across manufacturers; length, diameter and profile; special features	differences across manufacturers	The right TT may not exist for a patient. Moving between manufacturers to find the best TT is difficult due to inconsistent sizing conventions and profiles of tubes.	Development of new tubes that gave better performance in terms of profile and features could improve patient outcomes, allow smaller ranges for safety, and make decisions easier for clinicians
			Combining all features and sizes might lead to large stock range which complicates staff training and stock -keeping/storage.	If manufacturers supplied ranges that met the requirements of most patients, TT size decisions and staff training could be facilitated.
			Personal preference of operators may influence stock decisions.	Inclusion of TT design differences in training would improve clinician knowledge and reduce the risk of errors when switching between brands of TT.

Facilitators to changing practice within the physical opportunity category included further evidence on topics relevant to tracheostomy sizing such as the long-term impacts of tracheostomy, tracheal measurement techniques, the impact of AHP roles on tracheostomy weaning, and dissemination of findings to all relevant audiences (see Section 6.3.2.4, Section 6.3.3.3, Section 6.3.4.1, Section 6.3.4.2). This in turn could facilitate increased presence of AHPs in critical care and their inclusion in initial sizing decisions and guidelines on TT size decision-making.

6.3.5.3. Motivation

Automatic and reflective motivation can be viewed as unconscious and conscious influences on motivation to perform a behaviour. There were many automatic motivation barriers to changing practice such as historical beliefs, operator preferences, operator experience and assumptions (see Section 6.3.2.1, Section 6.3.2.2, Section 6.3.3.1). The data suggested these might be difficult to change even with scientific evidence. A major barrier identified was lack of recognition by operators of the problems caused by size of tube (see Section 6.3.3.1, Section 6.3.3.3, Section 6.3.3.4 . This was in part due to the lack of evidence as mentioned above and in part due to the perspectives of operators being influenced by the timing of their input in relation to the patient's journey. Barriers to change relating to reflective motivation include preferences for particular design features in tubes, views on appropriate size of ranges of tube for safety and flexibility, or firm confidence in existing methods. Barriers relating to organisational change were also identified, such as the effort required in coordinating and communicating within and between teams (see Section 6.3.4.1).

Table 6.4.: Motivation related barriers and facilitators to changing practice

Theme	Motivation: Automatic	Motivation: Reflective	Barrier	Facilitator
“Real world” sizing practices				
How sizes are chosen	BMI/anterior neck thickness; ETT size; height; male vs female; unsure or other; what’s available; who chooses	BMI/anterior neck thickness; ETT size; height; unsure or other	Heuristic decision making, established ‘go to’ methods, may be difficult to change. TT design and stock decisions may limit the ability of clinicians to provide tailored decisions. Traditionally choices have been made solely by operators and this may be difficult to change.	Awareness among some MDT members that these methods do not work for all patients may provide impetus for change. Evidence highlighting the problems with current methods and supporting new methods could facilitate changing practice. Better tube design could improve stock options and facilitate decision making for clinicians. Adequate staffing and integrated MDT training could improve MDT working, mutual understanding of roles and inclusion of wider MDT in size decisions at insertion.
Experience-based decisions	assumptions; experience-based approach; historical practices and beliefs; eye-balling and rules of thumb	assumptions; experience-based approach; historical practices and beliefs; rules of thumb	Unchallenged assumptions, historical practices and beliefs are a barrier to change. However there there are gaps in the literature that mean clinicians have no evidence based alternative methods to use. Deeply held beliefs may be hard to shift even with evidence	Most clinicians agree on reflection that methods are subjective and that more robust, scientific methods would be preferable.

Theme	Motivation: Automatic	Motivation: Reflective	Barrier	Facilitator
Decisions tailored to patients	getting it right first time; different for different populations; one size fits all; getting it right first time	different choices for different patient populations; balancing ventilation and weaning; measurement and imaging; getting it right first time	Perception of therapists that you should aim for the right tube first time not shared with whole MDT. Current practices include giving the same size TT to all males/all females without reflecting on individual requirements. Assumptions based on one patient population may be applied to others (e.g. vent requirements in respiratory failure vs neurology, head & neck cancer vs respiratory failure)	Motivation from therapists to get the right tube in from insertion, assumption that this is possible. Feeling from all groups that measurement and imaging would be beneficial and add objectivity to decisions Evidence on factors involved in TT size decisions across different patient populations could help guide tailored decisions.
Science, evidence and gaps in knowledge	knowing about trache related complications; lack of evidence; consistency and standardisation	lack of evidence; knowing about trache related complications; a need for science-backed methods; consistency and standardisation;	There is little evidence/no national guidelines to guide trache size decisions. There is limited evidence on long-term consequences of tracheostomy size, and those conducting and/or aware of the research are not necessarily those inserting on ICU There is no validated method of measuring the internal diameter of the trachea.	All groups and professions felt that consistency and standarisation was important for patient safety, Science and evidence was valued by all groups and could be used to challenge assumptions and historical practices and beliefs. Research and dissemination of knowledge on factors to consider in sizing decisions and impact on outcomes could be used to create guidance and promote change in practice.
MDT perspectives and roles in decision making				

Theme	Motivation: Automatic	Motivation: Reflective	Barrier	Facilitator
attitude to change in practice	perceived importance of size of tube; openness to a new method for sizing; recognition of the consequences; practicality of sizing method	perceived importance of size of tube; openness to a new method for sizing; recognition of the consequences; practicality of sizing method	Deeply held beliefs may be hard to shift even with evidence.	Operators may be receptive to patient experience data which may influence automatic and reflective motivation
			A lack of awareness or understanding of consequences of TT size decisions on rehabilitation and long-term outcomes means they may not be seen as important	Evidence on frequency and severity of adverse outcomes in trache may influence reflective motivation.
			Operators may be over confident in their current practice.	Inclusion of the wider MDT in decision making may promote consideration of impacts on rehabilitation and longer-term outcomes.
Making the decision	communication and working relationships; decision makers; ENT vs ICU	communication and working relationships; decision makers; ENT vs ICU	Poor communication and working relationships between teams may prevent knowledge transfer on impact of size decisions	Good communication and working relationships between teams could facilitate knowledge transfer on impact of size decisions
			Those inserting tubes may not be those to see evidence of patient centred outcomes	MDT input at time of insertion and/or in guidelines around insertion decisions could facilitate consideration of size at insertion
			Variation in working relationships between ICU and ENT may make implementation of change difficult	Specialist airway ENT input could provide valuable input to size decisions.

Theme	Motivation: Automatic	Motivation: Reflective	Barrier	Facilitator
holistic picture	airflow; anatomy; complications and longterm impact; size in relation to function, patient experience and wellbeing	airflow; anatomy; complications and longterm impact; size in relation to function, patient experience and wellbeing	Decisions based on the assumption that ‘big is best’ for ventilation. Voice, independence in secretion clearance, swallowing, and the importance of these to patient outcomes may be ignored at time of insertion. Over focus on larger sizes for ventilation or smaller sizes for owv use may impact sizing decisions. SLT knowledge not considered/consulted at point of DM (lost opportunity). Lack of consideration for differences in individual’s anatomy.	Greater undestanding (more evidence) of airflow through and around the TT, and consideration of the patient’s specific respiratory requirements could influence change in sizing methods Inclusion of the full MDT could lead to better awareness among MDT members of the full range of functions affected by tracheostomy and the impact of this on patients, which could encourage consideration of these functions at time of insertion

Theme	Motivation: Automatic	Motivation: Reflective	Barrier	Facilitator
stage of the patient's journey	accounting for complexity and changing needs; around insertion; weaning and downsizing	accounting for complexity and changing needs; around insertion; weaning and downsizing	Patients with a trache on ICU can have complex and changing needs and it may be difficult to predict course of recovery or determine best size tube;	Identification of risk factors for likely longer weaning from a trache might help incorporation of longer term needs in size decisions.
			At the point of insertion the focus might be on the patient's acute medical condition, without necessarily looking at the impacts of intervention on later progress.	Consideration of respiratory requirements in relation to timing of tracheostomy may reduce the likelihood of having to meet very high respiratory needs through a trache, and therefore impact size decisions.
			Weaning may be seen as 'something that can happen later'	Education around the longterm impacts, MDT discussion at the point of insertion and MDT input to guidelines and policy could adjust the focus of size decisions at the time of insertion
			Downsizing may be viewed as a normal part of care, with low motivation to avoid it. Operators may be unaware of downstream complications as not always immediately evident in ICU (stenosis/PTSD etc) so only consider delayed wean.	Education on AHP roles and rehabilitation interventions (including use of OWVs) and their impact on patient experience and wellbeing could influence reflective motivation towards changing practice
Equipment and organisational factors affecting choices				

Theme	Motivation: Automatic	Motivation: Reflective	Barrier	Facilitator
Hospital systems and governance	change takes time; continuity through hospital; guidance and guidelines; stock availability and safety vs breadth of range	change takes time; continuity through hospital; guidance and guidelines; stock availability and safety vs breadth of range	Changing systems and guidelines requires time, effort and coordination of multiple teams, especially with complex patients - may hamper efforts to change. Current guidelines and checklists either do not provide guidance on sizing or are not evidence-based. Lack of continuity through the hospital could influence motivation within a unit to changing practice The balance between safety and breadth of range to allow patient-tailored decisions is subjective and open to variation Lack of availability of the right tubes is a barrier to change	Good communication and working relationships across the hospital could facilitate organisational change. Working relationships may be facilitated through integrated training. Having evidence-based guidelines and checklists in place would support decision making and continuity through the hospital. Continuity was viewed positively and could provide motivation to change. Easy access to an adequate range of familiar stock could facilitate change

Theme	Motivation: Automatic	Motivation: Reflective	Barrier	Facilitator
staffing for tracheostomy care	skills and experience; training; having the workforce	skills and experience; training; workforce	Change could be hindered by lack of skills and experience across the MDT Lack of adequate training could be a barrier to automatic and reflective motivation Lack of therapy professions in tracheostomy management could mean reduced understanding of the impact of tracheostomy to patient's holistic experience, thereby reducing motivation to change. Not all ICUs have dedicated SLTs	Having a workforce with the right MDT members and specialist skills and experience would improve motivation to change. This includes funding for ICU specialist SLTs. Access to coordinated, evidence-based MDT training could improve holistic understanding and motivation to change
tube design	differences across manufacturers; length, diameter and profile; special features	tubes are not 'like for like' across manufacturers; length, diameter and profile; special features	Differences across manufacturers may mean that teams need to change their range of tubes which would likely decrease automatic motivation to change due to training needs of staff Team members may have strong preferences for manufacturer or tube design feature which may impact motivation to change. Current ranges of tubes may not provide the required combinations of length, diameter, profile and special features	Improved tube design in terms of length, comfort, cuff, and thickness of tube walls could improve patient outcomes and motivate teams to change practice Having key combinations of dimensions and features within a single manufacturer's range could improve motivation to change (longer tubes desired - lack of available products).

Many facilitators were identified relating to motivation. Some of these overlapped with psychological capability, for example a general agreement that standardisation and objectivity in decisions was desirable (see Section 6.3.2). Motivation for change was high among therapists, particularly SLTs, who wanted to see voice restoration for patients earlier. Scientific evidence and in particular patient stories were flagged as influences on motivation that could facilitate change . Further evidence on frequency and type of tracheostomy-related complications was also identified as a facilitator for changing practice (see Section 6.3.2.4, Section 6.3.3.3, Section 6.3.3.4). Again, good MDT working was seen as a potential facilitator to change through the influence on knowledge sharing and mutual understanding of roles and interventions. Finally, improved tube design could facilitate change in practice by offering tubes that better met the focus of each profession and therefore the holistic needs of patients (see Section 6.3.3.3, Section 6.3.4.3).

Overall, the key influences on behaviour appeared to relate to knowledge and awareness of MDT roles and the impact of sizing decisions; gaps in the evidence; and access to the right resources in terms of staffing and TTs. An overarching theme of 'evidence and resources, insight and over-confidence' was developed to encapsulate the core issues underpinning both current practice and the barriers and facilitators to changing future practice.

6.4. Discussion

6.4.1. Summary of findings

Framework analysis of data from this focus group study identified three major descriptive themes relating to tracheostomy sizing decisions in the UK. These were ' "Real world" sizing practices'; ' MDT perspectives and roles in decision making', and 'Equipment and organisational factors affecting choices'. Current practice in size decisions at insertion appeared to be varied, experience-based and uni-professional. Participants felt there was a lack of evidence to support decisions and that further research was needed. MDT working was generally seen as important in delivering individualised care but was impacted by mutual understanding of roles and workforce issues, such as existence and funding of specialist ICU AHP roles, particularly in speech and language therapy. A hierarchy was seen within operator teams and across operator and therapy professions, where trainees deferred to consultants and therapists either did not see it as their role to make or challenge decisions on size of tube at insertion, or did not feel their views were taken into

account. The complexity and heterogeneity of the tracheostomy patient population was seen to bring challenges associated with coordination of multiple teams. Standardisation of care was recognised as best practice by the whole MDT, though could conflict with attempts to tailor decisions to individual need. Availability of appropriate staffing and TTs provided a further challenge to decision making relating to TT size.

The COM-B model of behaviour diagnosis was used as an analytical tool to help interpretation of descriptive findings. The over-arching analytical theme was 'Insight, evidence and having the right resources'.

6.4.2. Comparison with the published literature

6.4.2.1. Decision-making processes

Very little evidence exists on how tracheostomy size decisions are made at insertion, though like the current study, my previous service evaluation found differences between how clinicians reported decisions were made in practice and how they thought decisions should be made. Gender/sex, stock availability, consultant preference and anterior neck size were all found to be used in practice and patient anatomy, respiratory weaning and secretions were factors that participants in both studies felt should be used but were not. Generic 'patient size' was the primary factor reported in the service evaluation, whereas in the present study, sex was the most common factor. Patient size was also considered by focus group participants but here they specified patient height. A reliance on experience and historical practice fits with heuristic theory, which addresses the use of mental shortcuts used to make decisions in the context of a high volume of information, time constraints and high stress situations [357]. The risks of heuristic decisions include making decisions based on inaccurate information or influenced by personal biases. Confirmation heuristics can lead to discounting evidence that is contrary to ones beliefs, as reflected in quotes from ICU participants in Section 6.3.3 . Heuristic thinking could also lead to therapists or airway reconstruction specialists over-estimating the incidence of problems due to size of tracheostomy and intensivists underestimating the incidence of problems due to the nature of their roles meaning these cases are more or less salient to them. Others have discussed the uses and risks of heuristics in relation to complex, fast-paced decision-making in busy ICUs [358–360], though no literature was found on heuristics in relation to tracheostomy sizing decisions. Participants were clear that, in order to facilitate change in practice, any new method would have to be easy to learn or teach and to apply in clinical situations. This might appear to conflict with the known risks of heuristic

decision-making. However, more recent developments in heuristic theory highlight the benefits of 'short-cut' decision-making on reducing cognitive load and time to make decisions, which, provided they are based on sound research evidence and true 'expert' experience, can lead to positive patient and clinician outcomes [359, 361, 362].

6.4.2.2. MDT working

A number of studies have concluded that MDT working in tracheostomy management is beneficial to patient outcomes [59, 62, 363]. Mitchell et al [364] found that MDT working improved care through interprofessional protocol development and interprofessional decision-making. The findings of this study add to understanding of the benefits of MDT tracheostomy teams by suggesting inclusion of the multiple perspectives from professions whose focus of input may be hyper-acute or longer-term, and physiological, psychological or functional, is a mechanism by which holistic care is promoted, and the full breadth of patient needs are considered. This study also found that the MDT could be a barrier to good care where communication and working relationships were poor. Similarly, Ferlie et al [365] found that MDT working could be responsible for the 'nonspread' of innovation due to cognitive and social boundaries between professions and poor communication between them. This study found that tracheostomy teams could be hierarchical and size decisions at insertion were, with few exceptions, uni-professional. A link between hierarchical teams and poor safety and increased adverse events was first demonstrated within the airline industry and subsequently within healthcare settings [366–368]; evidence showed communication was poorer in hierarchical teams with lower-ranking team members reluctant to challenge decisions, contributing to higher incident rates and less reporting of incidents. Findings around workforce issues in terms of therapy staff numbers, skills and experience, and protected time for ICU work, echo findings in previous studies of therapy services within ICU [369, 370].

6.4.2.3. Equipment

This study noted equipment-related barriers to providing the best size TT to patients, such as non-standardised sizing conventions that made cross-manufacturer comparisons difficult. This has been described before in a narrative review of available TTs [371]. Review authors noted complications can arise where clinicians are unaware of the implications of cross-manufacturer differences, which was also identified as a potential barrier to implementation of a new method of sizing in the focus group study. The present study also

revealed challenges around balancing safety and flexibility in ranges of tubes stocked within sites. No primary data on this could be found in the literature, though others have commented on challenges relating to TT local stock ranges and storage [26].

A behavioural science approach to identifying barriers and facilitators to changing the way tracheostomy tube size decisions were made indicated key barriers were clinician knowledge, gaps in the evidence and availability of the right staff and equipment. Previous studies have also identified barriers to implementing evidence-based healthcare at the organisational and individual level, and specifically highlighted issues in access to evidence and equipment, motivation of individuals, understanding of roles, and a culture of 'routine' patient care [372, 373]. Given the known lag between scientific discovery and translation into clinical practice, the rapidly evolving therapy roles and evidence behind therapy interventions in ICU [37, 374] present a further challenge to mutual understanding of roles within the ICU MDT. Again, Ferlie et al's theory [365] that cognitive and social boundaries between professions are a barrier to change is relevant here given the different knowledge and perspectives of professions and hierarchies involved. Similarly to this study, the authors identified good interprofessional working relationships as a facilitator to changing practice. This is corroborated in the context of tracheostomy teams by Mitchell et al's [364] investigation into the mechanisms of improved care within tracheostomy teams.

Limitations

The role and experiences of the lead researcher as an SLT was what motivated the initiation of the broader project and could be seen as a source of bias. In this case it might be argued that findings overly reflect a therapy perspective. However in qualitative research this acknowledgement of researcher background and perspectives is known as 'reflexivity' and seen as a quality indicator as it allows the reader to incorporate this knowledge into their interpretation of findings [146]. In this way it serves a similar purpose to a 'conflicts of interest' declaration but goes further to provide information on a researcher's *a priori* perspectives on the research topic. The researcher's background in this case brought the benefits of the insights of a clinician working closely alongside patients in ICU. Moreover, to ensure representation of MDT perspectives, second reviewers for transcript coding were sought from other professional backgrounds, as recommended by Gale et al [355], and the overall PhD project and study was supervised by an intensivist and critical care nurse.

A number of limitations were identified in the study sample. The intention was to recruit

equal numbers of each profession, however nine SLTs attended and only three intensivists. However, the focus groups took place during a prolonged period of junior doctors strikes, potentially affecting the recruitment and availability on the day of trainees and their consultant colleagues who provided emergency cover on some strike days. The nine non-attendees included five doctors and an ENT surgeon. There was multi-professional representation in each group, which may have elicited different responses from participants compared to uni-professional groups. However, this enabled inter-professional discussion and views on the same points from multiple professional perspectives, for example, the incidence of problems due to tube size decisions. There were also four examples of multiple representation of SLTs and physiotherapists from the same Trust. This may have amplified views and practices from these sites which may have differed from other sites.

6.5. Conclusion

Current practice in TT size decision making at insertion is not evidence based. Decisions are uni-professional and prioritise immediate physiological factors, in keeping with an acute medical model of health. Inclusion of the wider MDT in decision making could promote consideration of psychosocial factors and longer-term consequences of decisions and better meet patients' holistic needs. Improved TT design for better patient fit and function could improve patient outcomes and make stock decisions and size decisions for individual patients easier for clinicians. Further evidence is needed on how to measure the trachea; outcomes of sizing decisions; incidence of short and long-term tracheostomy-related airway complications (e.g. dislodgement, stenosis); and airflow dynamics relating to mechanical ventilation and OWV use. Future implementation strategies need to ensure that recommendations are simple; evidence-based; practical to deliver in a busy ICU setting; and widely disseminated. The argument for change needs to be clearly communicated to operators, with evidence, to improve motivation to change. New approaches to TT sizing decisions will require collaborative MDT working to ensure all aspects of sizing decisions are considered. Joint training and education for the whole tracheostomy MDT could support closer working, better communication, and mutual understanding of each other's roles.

7. Integration of quantitative and qualitative findings

7.1. Introduction

This project has addressed tracheostomy sizing decisions for adults in ICU. The fundamental research questions related to factors that should be considered in decisions making, and barriers and facilitators to changing practice. The complexity of the project and nature of the factors involved were given in Chapter 1 as justification for using a pragmatist, mixed methods approach to inquiry. Chapter 2 to Chapter 6 presented the individual workstreams that addressed different components of the project. This chapter summarises the findings of each workstream and presents the methods used to integrate quantitative and qualitative findings, the results of integration, and the interpretation of the integrated output. It ends with a series of four vignettes created through applying integrated findings to cases based on participants recruited in the observational study, which serve to illustrate key project findings. For brevity the systematic review and metasynthesis, and observational, benchtop and focus group studies are referred to as WS1, WS2, WS3, and WS4 respectively. The cadaver study was grouped with WS2 during integration.

7.2. Summary of individual workstream findings

7.2.1. Results of the systematic review and metasynthesis

The systematic review and metasynthesis of qualitative literature presented in Chapter 2 sought to answer the question 'What matters most to patients with a tracheostomy in ICU?'. This generated five descriptive themes:

1. Voice and disrupted communication
2. Autonomy and self-determination

3. Cognitive, psychological and emotional needs and experiences
4. Physical needs and experiences
5. Facilitators to wellbeing and recovery

Viewing these themes through the lens of the research question and a framework of humanised healthcare [157] led to a more abstracted understanding of patient priorities that were summarised in three analytical themes:

1. being seen as a whole, unique, autonomous person
2. making sense of it and connections with others
3. patients' voices as a key currency in humanising care

The over-arching theme was described as 'To be seen and heard as a whole person'. Voice was found to be central to patient-centred outcomes, both as a goal in itself and for the intrinsic role it had in achieving other outcomes. In the context of the wider project, this workstream placed having a voice as an important factor to consider when choosing the size of tracheostomy tube for adults in ICU.

7.2.2. Results of the cadaver study

The work presented in Chapter 3 highlighted the challenges associated with ultrasound imaging and measurement of the airway. These included identification of airway anatomy, artefact due to the shape of the trachea and calcified cartilages, and in particular, interpretation of air-related artefact. The air-mucosa interface (AMI) at the inner surface of the tracheal wall was identified as the brightest white line at the anterior tracheal wall in transverse view, with the line above it interpreted as the outer border of the tracheal ring and lines below it interpreted as artefact. The artefactual lines could be reverberation artefact or a mirror image of the outer border of the tracheal ring (closest line below the AMI). Mirror artefact could be deceptive, appearing to represent a solid anatomical landmark. A single white line at the anterior trachea with deep shadow and an absence of artefact below it indicated calcification of the tracheal ring, with the white line interpreted as the outer border of the tracheal ring.

The implications of this workstream were that ultrasound could be used to determine tracheal width through calculating the mean of the diameters of the outer border of the tracheal wall and its reflection within the tracheal air column. However, this depended on skills in anatomical identification and interpretation of artefact.

7.2.3. Results of the observational study

The observational study presented in Chapter 4 was designed to determine how well theoretical size recommendations derived from methods used in practice agreed with a sizing method based on tracheal width. It also investigated the strength of relationship between tracheal width and other biometrics. The results showed that females were more likely to receive an oversized TT than males and males were more likely to receive a smaller TT than the maximum recommended using the best practice sizing method. BMI was the worst predictor of an appropriate size tube and in three (female) cases, predicted TT sizes that had outer diameters larger than the participants' tracheal width. While sizing by sex scored the most exact matches with best practice recommendations, concordance remained poor, and errors were up to 3 sizes out. A weighted Kappa showed that when stratified by sex, there was no statistical agreement between gold standard sizing recommendations and those of comparator methods.

Separate male and female multilinear regression models showed that in females, height and age were statistically significantly related to tracheal width when adjusting for other variables. However, the wide spread of height and age data plotted against tracheal width suggests that neither are good enough to predict tracheal width in individual patients. In males, no variables were found to be statistically significantly associated with tracheal width when adjusting for variables.

The implications of this workstream were that clinicians should not base TT size decisions on surrogates for tracheal width and should base decisions on tracheal width measurement.

7.2.4. Results of the benchtop experiment

The benchtop experiment presented in Chapter 5 sought to determine the effect of size of TT on WOB, including in inflated cuff scenarios and when the cuff is deflated and an OWV is used. This workstream showed that the effect of size of TT on WOB differed in cuff and OWV trials: in cuff trials, WOB increased as size of TT decreased, and this effect was true in all sizes of trachea; in OWV trials, the effect of size of TT depended on size of trachea. In the medium trachea, as expected, the smallest TT generated the lowest WOB when the cuff was deflated and an OWV used, and the largest TT caused the highest WOB. However, in the small trachea, the smallest TT caused the highest WOB. In the large trachea, all TTs generated lower WOB than baseline, i.e. than breathing without a

TT inserted. Rises in respiratory rate and tidal volume were associated with progressively larger increases in WOB.

Only three sizes from the main range of TTs trialled fitted in the small trachea and the size 8 only fitted with force. The size 6 could not be used in cuff trials in the large trachea as the cuff did not reach the tracheal walls. Differences were noted in sizing conventions and TT profiles across brands which impacted WOB. Presence of a deflated cuff was shown to significantly impact WOB in a size 8 TT in the medium trachea.

The implications of this workstream were that TT sizing is easier for patients with large tracheas, where single tubes deliver good outcomes both with the cuff inflated and with the cuff deflated and an OWV inserted. In a medium trachea, the second best performing TT size when the cuff was inflated was also the second best with the cuff deflated and an OWV. In the small trachea, the smallest TT confered no benefit when using an OWV, and the best performing size TT required force to insert, potentially causing trauma in the clinical setting. In patients with a small trachea, low RR and/or TV may mitigate the impact of small TTs on WOB.

7.2.5. Results of the focus group study

The focus group study aimed to explore the perspectives of ICU MDT members involved in caring for patients with a tracheostomy on sizing methods and to identify barriers and facilitators to changing practice. Three main themes were developed:

1. “Real world” sizing practices
2. MDT perspectives and roles in decision making
3. Equipment and organisational factors affecting choices

Participants described current practice as subjective, based on experience and assumptions. Different professions held different perspectives on what was important to consider in sizing decisions, reflecting the nature and timing of their input to care. Size decisions at insertion were solely made by clinicians inserting the TT, who prioritised ventilation and therefore favoured larger TTs, and felt current sizing methods worked well. All groups felt there was a lack of good quality evidence to support clinicians and that more research was needed. Some felt there was little awareness of or access to existing evidence on patient experience of TT and long-term outcomes. TT design and local stock choices were raised as factors that impacted the safety of care and the ability to make bespoke decisions for individual patients. The main barriers and facilitators to changing practice

were found to relate to MDT knowledge and awareness of sizing decisions and outcomes, gaps in the evidence, and access to the right resources in terms of staffing and equipment. The overall theme was ‘evidence and resources, insight and over-confidence’.

The implications of this workstream were that MDT input to sizing decisions at initial insertion could promote a holistic approach and lead to better outcomes. This depended on having appropriately skilled MDT staff with protected time for ICU and mutual understanding of roles between professions. It was inferred that redesign of TTs could lead to TTs that better meet the anatomical and physiological needs of patients and make sizing decisions, training and stock choices simpler for staff.

7.3. Methods

In order to bring together quantitative and qualitative findings and generate meaningful outputs that are ‘greater than the sum of their parts’, integration of mixed data within mixed method projects should adhere to quality criteria specific to mixed methods methodology. This includes transparency over aspects relating to the integration of mixed data [144, 375, 376]. Creswell and Plano Clark (2018) [144] lists four considerations of integration: the intent of integration; integration procedures; representation of integration results; and interpretation of integration results. These are described in relation to this project below.

7.3.1. Intent of integration

The intent of integration in this project was to expand knowledge on the factors that should be considered in TT size decisions for adults in ICU and identify barriers and facilitators to changing practice. This involved incorporating data collected through quantitative and qualitative methods on patient priorities, outcomes of decision-making methods, fluid dynamics relating to tracheostomy, and clinician perspectives to create a more comprehensive picture of the topic and ultimately generate person-centred guidance to help clinicians select the best size TT for adult in ICU. Integration therefore went beyond triangulation of quantitative and qualitative datasets to confirm or increase confidence in findings, and fitted a pragmatist approach where application to real world issues is an important goal of the process [375].

7.3.2. Integration procedures

The first step in integration of quantitative and qualitative elements in this project used joint displays of quantitative and qualitative findings. Joint displays are an established method of integrating mixed data and are applicable at various stages [377–379]. Fetters and Tajima (2022) [379] identified the following three applications of joint displays: to illustrate integration of data collection; as an analytical tool; and to present integrated results. Here they were used as an analytical tool and to present integrated results.

During the analysis process, matrices were made for each possible pairing of workstreams to show how their findings interacted [380]. A separate matrix was created for each possible pairing of workstreams. Main findings of workstreams provided column and row headers respectively. 'Main findings' were counted as major descriptive or analytical themes and interpretations from the qualitative studies and descriptions of primary and secondary findings and interpretations from the quantitative studies. In this way data from the same level of analysis were integrated [377]. The observational and cadaver study findings were combined since they were so closely related. Matrices of workstreams that both used the same type of data (quantitative or qualitative), were included in order to yield maximum results. Cells of the matrices were populated with summaries of how findings of one workstream converged with, diverged from or expanded on findings of the other. Where there appeared to be no overlap in findings the cells were left blank with no attempt to 'force' integration, in line with Uprichard and Dawney [381] who highlight that data arising from complex 'messy' phenomena that are ideally investigated through mixed methods cannot always be integrated and attempting to do so would result in a distorted representation of the phenomena in question. There were therefore a total of six matrices in the first stage of data integration as follows:

- workstreams 1 & 2
- workstreams 1 & 3
- workstreams 1 & 4
- workstreams 2 & 3
- workstreams 2 & 4
- workstreams 3 & 4

This method provided a systematic approach to identifying topics and concepts in the data across the whole project. Similar to the line-by-line coding used in the metasynthesis workstream, it encouraged identification of points of interaction that may not have otherwise been salient to the researchers. Topics and concepts were then used as preliminary themes in a thematic map. The process of creating the thematic map helped identify clusters and patterns of interaction between findings from different workstreams and to develop the key themes. Where questions arose during the process of comparing mixed data, full findings of the relevant workstreams were reviewed again in search for more granular detail that might further illuminate the relationship between datasets (whether the findings of one workstream converged with, diverged from, expanded or were quiet on findings of another). Themes were developed iteratively through this process until it was felt they fully and accurately captured the essence of the integrated findings. Descriptions of the key themes are presented below.

7.3.3. Representation and interpretation of initial integration results

The results of the first stage of integration were summarised in writing and visually presented in a thematic map. Integrated findings were interrogated through the lens of the research aims and questions to develop meta-inferences, and form a conceptual model of both factors to consider in choosing the size of TT for adults in ICU and areas to target in implementation strategies to encourage adoption of guidance in practice. A meta-matrix was created to show which workstreams contributed to each element of the conceptual model, including an indication of strength of contribution. The conceptual model was visualised diagramatically.

7.4. Results

Pairwise matrices of workstream findings were produced in Excel and summaries of these can be found in Appendix T. The thematic map was produced using pen and paper and post-it notes (see Appendix S). The process of mapping themes/concepts helped visualise the full breadth of the project and refine major themes. In some cases, questions arising from the cross-tabulations and mapping process initiated a return to primary data which revealed new details that helped build a more complete picture of TT sizing. For example, whilst considering the joint implications of workstreams two and three, a table was created to show physical fit of TTs in the three 3D-printed tracheas, recommended

Table 7.1.: Table to show fit of tracheostomy tubes in model tracheas following M-BP-Max recommendations and WOB performance with an inflated cuff or deflated cuff and one-way valve

TT size	OD	Cuff diameter	Min trachea size	Small (13 mm)	Medium (17 mm)	Large (22 mm)
6	9.2	20	12.4	yes	yes	yes*
7	10.5	24	14	no	yes	yes
8	11.9	30	15.9	no	yes	yes
9	13.3	30	17.7	no	no	yes
10	14	30	18.7	no	no	yes
			Best fit	6	8	10
		Performance	Cuff	worst	2nd best	joint best
			OWV	worst	2nd best	joint best

*cuff too small to occlude trachea

TT size according to M-BP-Max, and WOB associated with the recommended TT sizes compared to other sizes (reproduced below, see Table 7.1). This revealed that oversizing was not possible in the large trachea since the largest TT's outer diameter was only 64% of the large trachea's diameter, significantly under the maximum 75% recommended by M-BP-Max. In contrast, the smallest TT's diameter was 71% of the small trachea's diameter.

Major themes related to the fit of TTs within the trachea; functions impacted by tube size; patient experience; the MDT; local equipment and resources; evidence relating to TT sizing (and lack of it); and tube design. These are summarised below. Table 7.2 shows which workstream contributed to each theme, including an indication of relative strength of contribution.

7.4.1. Individual fit

Fit and function were distinct but closely related themes. The theme 'fit' covered the physical fit of a TT within the trachea and all workstreams contributed to it. WS2 showed that current sizing methods do not guarantee good fit and tend to oversize in females but lead to smaller than the maximum recommended size in males. It also showed that height could not be used to predict tracheal width, which contradicted the assumptions of participants in WS4. WS3 showed not all TTs fit all tracheas. A size 6 Portex's cuff was too small to use in the large trachea. The small trachea had the fewest options - size 9 and 10 Portex, size 6 Shiley and size 7 Uniperc were too big to fit the small trachea and the size 8 Portex required force to insert it. However WS4 showed that some teams use size 8 TTs as standard for all patients, suggesting a risk of tracheal trauma for those with

smaller tracheas. In contrast, it was not possible to oversize in a large trachea since its diameter was over 50% larger than the outer diameter of the largest TT. WS2 and WS4 both concluded that tracheal measurement should be part of sizing decisions. Ultrasound was identified as a portable imaging technique that could be used to obtain measurements at bedside, however, the work presented in Chapter 3 demonstrated that airway sonography is challenging and requires specific training, contradicting WS4 participants' views that sizing methods should be simple and easy to learn. WS1 showed that large tubes might cause pain and that tube changes (including downsizing) are an unpleasant experience for patients.

7.4.2. Function

All workstreams contributed to the theme around function which represented things patients *do* that are affected by sizing decisions. WS1 highlighted that being able to talk was fundamentally important to patients – in itself and in the way it gave patients an identity and control over events and decisions, and helped them seek information or comfort, communicate their needs and connect with others. WS3's findings were relevant to breathing, delivery of mechanical ventilation and speaking. It indicated that females, by virtue of having smaller tracheas, would be less likely to be able to talk or to achieve the other patient-centred outcomes dependent on upper airway airflow and OWV use. WS4 therapy participants spoke of laryngeal functions beyond voicing, for example in airway protection, eating and drinking and independent secretion clearance/coughing, which were discussed both in terms of respiratory weaning and improved patient experience. Converging with this were findings from WS1 around the return to eating and drinking, the experience of thirst, and removal of tubes being important motivators and indicators of recovery to patients.

WS2 found current methods commonly oversized for females, reinforcing the argument that females might have worse TT size-related patient-centred outcomes. WS4 found differences in perspectives across professions. Those inserting initial TTs and making sizing decisions did not view speaking as a priority and were less aware of functional outcomes related to TT sizing. An unanticipated finding of WS3 was that patients with a large trachea and large TT might experience lower than baseline WOB (with or without an OWV), which could have implications for patient experience and WOB post-decannulation. No other workstream's findings intersected with this.

Unlike in females, WS2 found current sizing methods tended towards smaller than the

maximum recommended size for males. Integrating this with findings from WS3 suggests males might experience higher WOB while the cuff is inflated. WS4 suggested that undersizing of TTs is rare in practice, however. WS3 showed that respiratory parameters heavily influenced WOB, which was low at low respiratory rates and/or tidal volume but increased in progressively larger increments as respiratory parameters increased. This finding interacts with discussions in the focus groups around 'big is best' approaches to sizing on the grounds of ventilation and breathing, and around differing needs in different patient populations. The combined findings suggest that a large tube might not be necessary where airflow is within normal ranges, which could frequently occur in patients with head and neck cancer, spinal cord injury, or brain injury. Even in fully mechanically ventilated patients with respiratory failure, lung safe ventilation practices were shown in WS3's discussion to keep flows and WOB low. However, this is dependent on controlled mandatory breathing, and for spontaneously breathing patients flow may be much higher and larger TTs may be required in those with high respiratory rate and tidal volumes.

WS3 and WS4 both suggested that tube design could affect function. WS3 showed that the bulk of a deflated cuff and TT profile could significantly impact WOB and that sizing across brands did not correlate in terms of fit or profile. The last two points were supported by WS4 participants, who also highlighted the difficulties this presented for clinicians.

7.4.3. Patient experience

The qualitative workstreams contributed most to this theme. Voice was presented in WS1 as being central to humanised care, impacting the whole ICU experience. Therapists reported TT sizing was important since the return of voice improved patient wellbeing and engagement in rehabilitation, and respiratory weaning required restoration of laryngeal function, which was facilitated by the use of an OWV. Eating and drinking was also important to patients (WS1 and WS4) and facilitated by the use of OWVs, providing further reasons for ensuring appropriate TT sizing decisions. Therapists in WS4 discussed delayed weaning and the sequelae of negative experiences during periods of voicelessness due to TT oversizing. Participants in WS1's selected studies did not link experiences to size of TT. However they recalled strongly negative memories relating to being unable to speak and some reported still feeling the effects of this experience long after ICU discharge.

ENT surgeons and therapists in WS4 discussed tracheal stenosis due to tracheostomy-related tracheal trauma, which had the potential to significantly impact patient experi-

ence in the long-term. Integrating WS2, WS3 and WS4 suggested current practices predispose females to higher risk of poorly fitting tubes and therefore higher rates of tracheal stenosis and worse long-term outcomes.

ICU doctors in WS4 viewed voice as important but did not indicate awareness of its impact on experience, seeing it as something that could be resolved through downsizing later. This conflicted with patient quotes in WS1 studies that indicated that patients wanted information early, that time dragged without a voice, and that tube changes were unpleasant and frightening. However, ICU doctors indicated that patient experience was important and influential on practice, indicating this could be an area to target in implementation strategies.

7.4.4. Clinicians and the MDT

This theme covers clinician-patient relationships, professional roles and MDT working. Connections with staff and ability to take control of decisions were important to patients in WS1 and lack of speech was a barrier to this. Similarly, in WS4, therapist roles depended on patient engagement and trust, which was easier when patients could talk, and meant therapists were more likely to observe the impact of sizing decisions than those who inserted the initial TT. ENT and therapist participants proposed that the mismatch between ICU doctors' recognition of things that mattered to patients (talking, eating, drinking) and the importance attributed to patient experience was in part due to research on patient experience being conducted by and disseminated to other professionals, and in part due to the timing and nature of different professionals' roles and interactions with patients. These were seen as reasons to include the full MDT in sizing decisions and provide multidisciplinary training in tracheostomy which could foster mutual understanding of roles and perspectives.

7.4.5. Evidence (and lack of it)

This theme covers gaps in the evidence and access to evidence on sizing decisions and outcomes. WS4 found that the lack of evidence contributed to MDT TT sizing practices and was a barrier to change (though decisions were almost always made by ICU doctors, a lack of evidence was a barrier to other MDT members challenging practice). Chapter 1 sets out the gaps in the evidence that this project sought to help fill, such as knowledge of what matters most to patients with a TT on ICU; the outcomes of current sizing practices; the correlation between tracheal width and other biometrics; the impact of size of

TT on WOB; and MDT perspectives on TT sizing and barriers and facilitators to changing practice. Through the course of the project other gaps and errors in the literature came to light, such as knowledge of the respiratory rates and tidal volumes seen in ICU populations, how RR and TV map onto WOB (WS3), and the evidence on tracheal ultrasound (WS2). In addition to gaps in the evidence a lack of access to the full range of evidence caused by limited cross-disciplinary dissemination of research findings was seen as an influence and barrier to change in MDT practice (WS4).

7.4.6. Local equipment and resources

This theme was drawn mainly from WS3 and WS4 but was felt to have a significant impact on sizing decisions. WS4 participants explained that stock ranges were influenced by clinician preferences, finances, and a desire to balance breadth of range to enable bespoke decisions with safety, restricting ranges to ensure staff familiarity and ease of training. More broadly, equipment could only be chosen from the existing options on the market, which links to the final theme of tube design. WS3 highlighted issues with the profile and sizing of TTs across manufacturers, especially ranges available to suit patients with small tracheas (mostly female) and female patients with high BMI. Resources was also used to describe staffing which was raised in WS4 as a potentially significant barrier or facilitator to MDT input and therefore holistic decision-making.

7.4.7. Tube design

The final theme links to the themes of fit, function and MDT clinicians and brings together findings from WS1, WS3 and WS4. WS1 showed that TTs caused patients discomfort and WS4 participants reported some brands were more comfortable for patients than others. WS4 also highlighted clinician preferences for one brand over another and strong feelings among local teams for or against certain features, such as the way a TT connected to ventilator tubing. This could present a barrier to developing a single range to meet all patients' needs. WS3 showed differences in performance of different brands in terms of WOB with the cuff inflated or the cuff deflated and an OWV in place. It also showed important differences in sizing conventions, as demonstrated by a size 6 from one brand being unable to fit in the small trachea when a size 8 from another brand could. WS3 also highlighted a shortage of TTs suitable for smaller tracheas. Notably, the smallest adjustable flange TT in its range was unable to fit in the small trachea. Only two TTs from the main range could be inserted in the smaller trachea without force. There were even

disparities in the performance of TTs within the same range, where length and internal-to-external diameters did not increase uniformly.

Table 7.2.: Metamatrix of workstream contributions to themes. Number of ticks indicate strength of contribution to theme: 3 is the strongest contribution

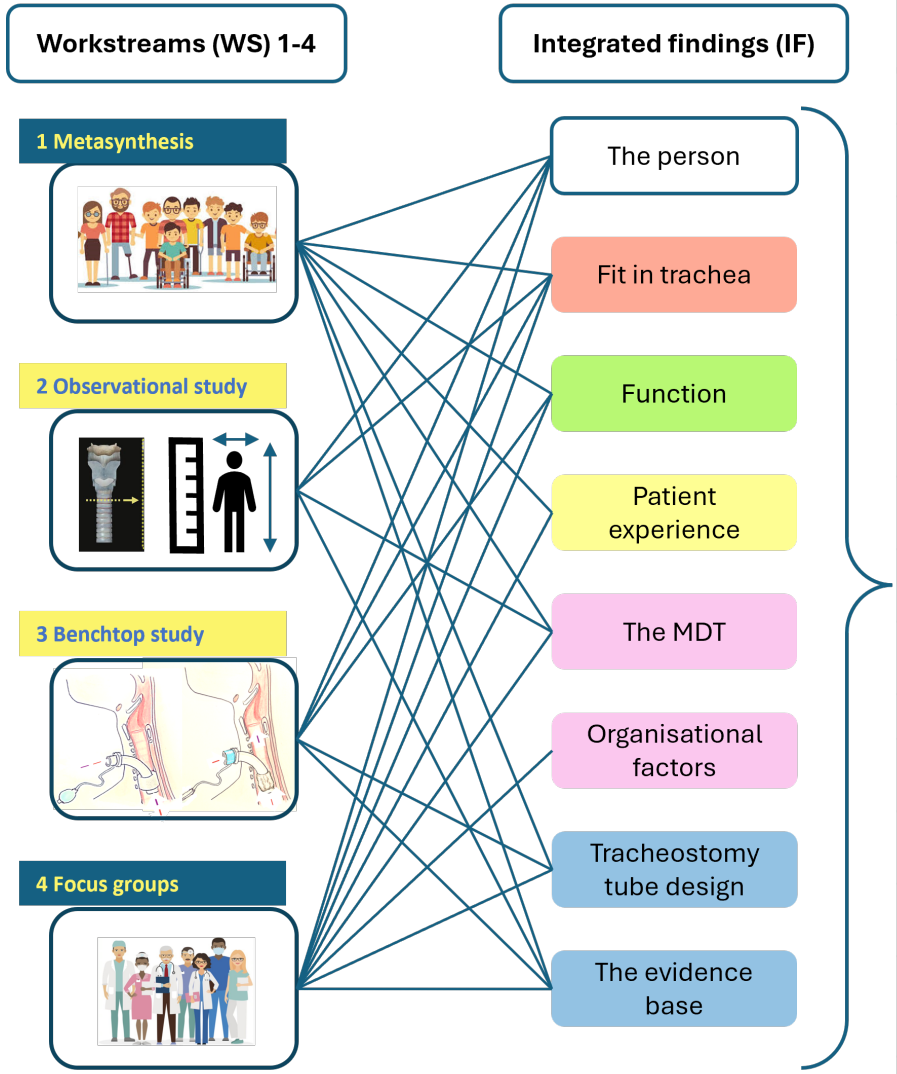
Theme	Metasynthesis	Observational study	Benchtop study	Focus groups
Individual fit	√	√√√	√√√	√√
Function	√√√	√	√√√	√√√
Patient experience	√√√	-	√√	√√√
Clinicians and the MDT	√	√	-	√√√
Local equipment and resources	-	√	√	√√√
Evidence (and lack of it)	√√	√√√	√√	√√√
Tube design	√	-	√√	√√√

7.5. Interpretation

7.5.1. Conceptual model of TT size decision-making and clinical implications

Using the central research questions as a framework within which to view the themes developed during integration of quantitative and qualitative data helped generate a conceptual model of decision making around size of TT and identify clinical implications. A high-level overview of the project components, key themes and clinical implications is presented in Figure 7.1. Different layers of themes were identified corresponding to patient level factors involved in tracheostomy tube sizing decisions and those external to the individual. The two outer layers related to local, organisational factors and broader external factors influencing sizing decisions across all organisations. Figure 7.2 illustrates the conceptual model with the patient at the centre, working outwards to close and more distant external factors. The patient was added to the centre of a modified Venn diagram to represent a cross-cutting theme of individual variation and a need for tailored decision-making. The person represents the patient with their unique demographic data, medico-psycho-social background, values, beliefs and preferences, and nature of current acute illness. The male and female symbols represent discrepancies in outcomes for males and females seen in WS2 and inferred in WS3. Then come overlapping factors

representing the basis of sizing decisions at the bedside: ‘Fit’, ‘Function’ and ‘Patient experience’. These are seen as intrinsically linked to patient factors, but also influenced by external factors. The Venn diagram highlights the cross-over and inter-dependency between factors and outcomes, for example, the size of the TT relative to the trachea affects both the fit of the TT in the trachea and functions such as being able to talk, which in turn affects patient experience. In the next level of the model are the local MDT and organisational contexts. Workforce, knowledge and skills, MDT working relationships and local policy, stock ranges and storage of equipment all influence sizing decisions at the bedside. In the outer layer are factors outside the healthcare organisation: the evidence base and the design of TT ranges available.



Clinical implications	Source: WS	Source: IF (WS)
TT size decision-making should be whole-person centred	1, 4	1, 2, 3, 4
Patients should be given information on tracheostomy and the effects on function (repeated as needed)	1, 4	1, 2, 3, 4
Voice and OWV use should be high priority in sizing decisions	1, 4	1, 3, 4
Where voice is not possible alternative communication should be facilitated to help main social connections and information sharing	1	1, 4
Patients need information on admission events and future care plans	1, 4	1, 4
Decisions should consider the size of a patient's trachea	2, 3	1, 2, 3, 4
Clinicians should be aware that other biometrics are poor indicators of tracheal width or TT size	2	2, 4
Extra care should be taken in size decisions for females due to smaller tracheal width and reduced range of TTs for small tracheas	2, 3	2, 3, 4
Where available, imaging may aid size decisions. Ultrasound imaging should be interpreted with caution	2, 4	1, 2, 3, 4
Smaller TTs may be appropriate where respiratory requirements are low (e.g., low respiratory rate/tidal volume) and vice-versa	3, 4	3, 4
Patients with smaller tracheas may be less able to tolerate an OWV	3, 4	2, 3, 4
MDT input should be included in decision-making around TT size at the individual and organisational level (e.g., stock, policy)	4	1, 2, 3, 4
Patients' experience of post-decannulation work of breathing may depend on size of prior TT, individual tracheal width and OWV use	3	3
Better dissemination of research evidence across professional groups could improve awareness of problems in TT sizing	4	1, 2, 3, 4
Joint MDT training could facilitate holistic decision-making and staff understanding of all factors involved in TT sizing and depends on funding for roles	4	1, 2, 3, 4
Better TT design could improve patient outcomes and aid decision-making	3, 4	2, 3, 4

Figure 7.1.: Clinical implications of integrated data

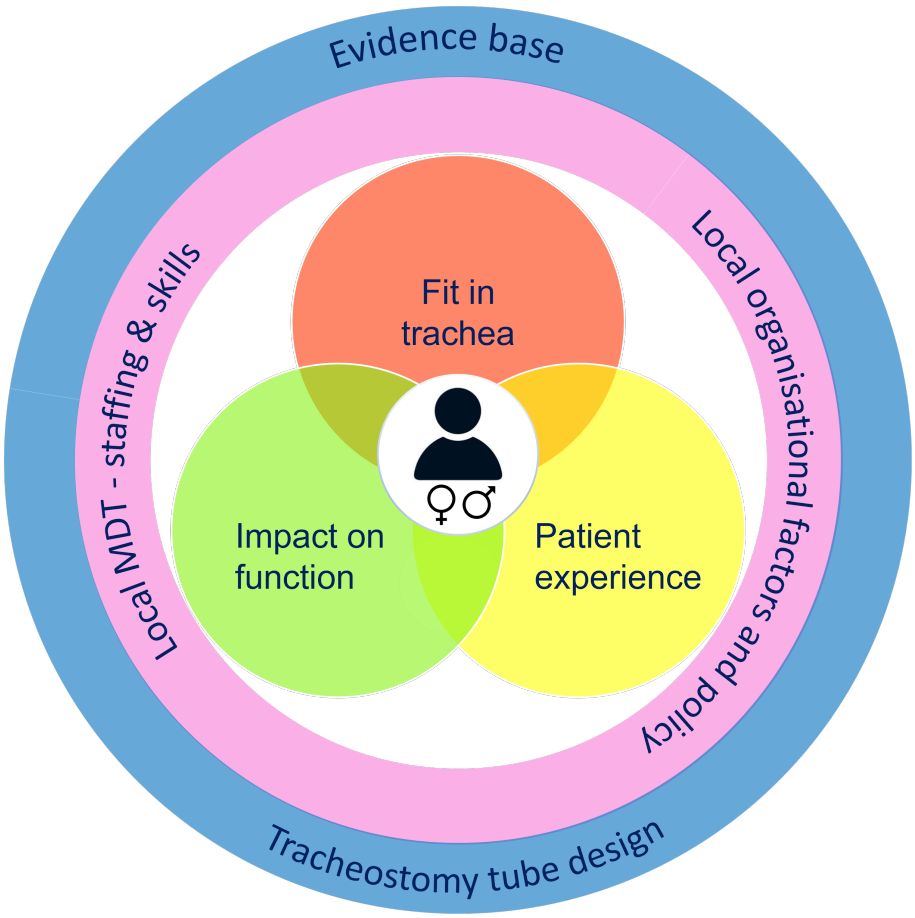


Figure 7.2.: Conceptual map of integrated data

7.5.2. Implementation considerations

Implementation considerations were drawn from the application of behaviour change theory to focus group data and presented in Chapter 6. Here, these are summarised in the context of the broader project findings.

7.5.2.1. Heterogeneity and complexity of patient needs

The patient at the centre of the model reflects the need to consider the needs of individuals, since patients with a TT are heterogeneous in terms of anatomy, physiology and psychology. Variation in tracheal width among male and female groups or among people of the same height as shown in the observational study, for example, means decisions need to be based on an individual's data. However, potential differences in respiratory parameters across diagnostic groups means it may be possible to tailor TT size decision-making to different patient cohorts. The complexity of needs means patients with a TT

may be cared for by several hospital teams, which adds a level of coordination of care and challenges to unifying management approaches.

7.5.2.2. Guidelines and Evidence

Focus groups showed all professions valued standardisation of care and scientific evidence to support decisions, which suggests that national evidence-based guidelines would be welcomed and facilitate changing practice. However, deep-rooted historical practices were seen as a barrier to change, suggesting that the introduction of guidelines would have to be carefully planned. Use of patient stories was seen as an effective way to engage clinicians, indicating these should be used in implementation strategies. All workstreams highlighted gaps in the evidence around the specific workstream focus and these gaps represent barriers to change. Focus group participants also raised access to evidence as a barrier to changing practice, suggesting that those inserting TTs were not those conducting research on patient experience. This is supported by search results in Chapter 2, where only one in fourteen selected articles had an intensivist as lead author. Moreover, nine studies were led by nurses but there were no nursing participants at the focus groups.

Chapter 3 lends support to the use of ultrasound to measure the airway, but further research is needed to validate this method. Additionally, the challenges highlighted by this work, including errors in the published literature, suggest ultrasound measurement of the airway is a difficult skill to learn, thus may be difficult to introduce to practice. If ultrasound is not a feasible method to introduce, other methods will need to be identified.

7.5.2.3. Resources: equipment and workforce

Equipment variability was highlighted as a barrier to change in the focus group study and shown to impact WOB in the benchtop study. For change in practice, there needs to be development of equipment to suit all needs and local purchasing practices to meet local patient population requirements. MDT working was seen as a potential barrier or facilitator to change. MDTs need to communicate well and understand each other's roles. This relies on the existence of posts with protected ICU time for all key professions. Implementation plans should recognise the importance of effective interdisciplinary working and consider mechanisms that might encourage it.

7.5.2.4. Insight and motivation to change

The lack of insight into problems with TT sizing identified through focus groups is indirectly supported by the metasynthesis findings, where patients reported frustration with staff who did not appear to understand the importance of communication to them. However, good insight and attempts to understand patients' needs and wishes made a difference to care. Intensivist focus group participants also indicated that awareness of negative patient experience would influence their practice, indicating knowledge dissemination could facilitate change. The focus group finding that over-confidence was a barrier to change did not overlap with other workstream findings, likely due to specific workstream aims and objectives.

7.6. Vignettes

A series of four vignettes were created through integrating physical data from participants in the observational study with the benchtop study findings (see Appendix U). This gave insight into how TT sizing practices might translate into outcomes for individual patients, both with an inflated cuff or deflated cuff and OWV. Participants whose tracheal diameter was closest to that of the small, medium or large 3D-printed trachea model were selected, in order to be able to integrate observational and benchtop data. Two participants with a small trachea were selected to show the potential difference in outcome for people with the same size trachea but differences in other variables. The cases were as follows:

1. an average-tall female with a small trachea
2. a short-average height female with a small trachea
3. a tall male with a medium size trachea
4. an average height male with a large trachea

The first three cases illustrated the disadvantages of having a small trachea or small relative to height. Sizing by anthropometrics meant the two female participants were recommended TTs that were two sizes larger than recommended by M-BP-Max, putting them at risk of tracheal trauma. The tall male with an average size trachea also had an oversized TT recommended based on height, which combined with expected large TVs, meant WOB was very high with an OWV at up to nearly 50 J/min. In contrast, the fourth case was recommended smaller than M-BP-Max size TTs by other sizing methods but WOB remained relatively low both with an inflated cuff and with an OWV. The four cases also

highlight the importance of respiratory parameters. At normal respiratory rate, WOB remained below 5 J/min for all combinations of variables in all cases, however, where RR was very high, WOB for the first 3 cases rapidly increased at the upper end of TVs used in lung-safe ventilation. These vignettes underline the importance demonstrated by this project of tailoring decisions to patients' individual anatomy and physiology, and potential scenarios where sizing decisions may be more difficult.

In the final chapter I present the integrated findings of the project in the context of the published literature. The Discussion ends with an overview of the clinical implications of this project, considerations for future implementation strategies, and suggestions for further research.

8. Discussion

8.1. Introduction

Chapter 1 highlighted wide-ranging questions around TT size decision-making for adults in ICU that have not been adequately addressed in the literature. The quantitative and qualitative workstreams of this mixed methods project were individually and collectively designed to answer some of these questions and contribute to a better understanding of the holistic factors that should be considered at initial tracheostomy insertion. To my knowledge this is the first time a mixed methods approach has been used to address this topic and that such different aspects of TT size decision-making have been brought together to provide a cohesive view of the topic.

Major project outputs include a conceptual model of TT size decision-making, a list of clinical implications, and pointers to barriers and facilitators to changing practice, as presented in Chapter 7. In this chapter, these outputs are discussed in the context of the extant literature. Points of convergence and divergence are reviewed and significant contributions to the knowledge base on TT size decision-making in ICU are highlighted. In the absence of other comprehensive studies of TT sizing with which to compare findings, the first part of the discussion is organised around the core elements of the conceptual model proposed in the previous chapter, followed by a brief discussion of the model as a whole. Strengths and limitations of the project are then discussed before considering the clinical practice implications and further questions and recommendations for future research arising from this work.

8.2. Conceptual model in relation to the existing evidence base

8.2.1. Fit

As outlined in Chapter 1, few studies have addressed how to select the size of TT for a patient. Most that have are benchtop experiments focusing on the inner diameter of

tubes from the perspective of fluid dynamics and resistance to flow [99, 100, 102], or small scale studies using imaging to improve the fit of selected TTs. This project brings together both essential considerations. It highlighted that basing decisions on sex, height or BMI correlated poorly with decisions based on tracheal width, and that females were at increased risk receiving oversized tubes. It also highlighted the relative lack of TTs to suit smaller tracheas.

8.2.1.1. Imaging to aid artificial airway size decisions

Roldi et al [257] used ultrasound measurement of the trachea to improve the size-selection for left double-lumen tracheal tubes (used to achieve one-lung ventilation). They too cited a lack of guidelines or evidence on which to base decisions and a reliance on clinical experience. The study found that usual practice based on sex and height of participants resulted in appropriate sizing in just 39.2% of cases, with undersizing and oversizing in 22.6% and 38.6% of cases. This rate of concordance with best practice is similar to that seen for TT sizing by height or sex in Section 4.3.4. Moreover, like this project, Roldi et al [257] found oversizing was statistically more frequent in females than males and that sizing by anthropometrics does not work due to the significant anatomical variation between patients. Similarly also, Roldi et al [257] highlight that ultrasound measurement of the trachea requires skill and appropriate training. This was highlighted in Chapter 3 as a potential barrier to widespread use in TT sizing decisions in practice, though continued developments in ultrasound technology including the use of artificial intelligence could make this more feasible in the future [382].

With respect to TTs, authors of a study from the maxillofacial literature conducted during the first wave of the COVID-19 pandemic noted that difficulties in selecting TT size due to a lack of guidelines were compounded by a national shortage of their usual brand of TT [383]. In an attempt to preserve stocks, minimise operative time and reduce trauma to patients, their solution was to use CT imaging to measure the trachea and select an appropriate size TT, which they found reduced the need for tube changes. However, the authors did not clarify how tracheal measurements were converted to TT size. Moreover, most of their patients had CT imaging, which may not be the norm elsewhere or outside the context of the COVID-19 pandemic, and focus group participants indicated CT imaging would not be justifiable purely for determining tracheostomy tube size.

8.2.1.2. Non-standard tubes

Pandian et al [384] used a retrospective case-control study to explore fit in terms of reasons for needing a non-standard TT. They found that males and those requiring an ETT ≥ 8.0 and/or with >4.4 cm of pre-tracheal tissue were more likely to require a non-standard tube, and that tracheal width was not associated with need for tube change. However, non-standard in their study indicated extra length or adjustable flange tubes. Upsizing or downsizing in terms of inner diameter was not addressed. Additionally, data was not collected on clinical reasons given at the time for TT change. The current project has only focused on standard TTs, though the benchtop study and focus group findings indicate that the length of TTs is an important element of TT selection. The benchtop study showed that the Uniperc™ adjustable flange TT did not fit small tracheas. Focus groups indicated that adjustable flange TTs were not popular with all clinicians but were frequently used for patients with deep anterior neck tissues. The reasons for poor popularity were not clear, though one participant cited failure of the flange clip could allow movement of the TT within the trachea. This project's findings indicate those with smaller tracheas might experience trauma from insertion of an adjustable flange or larger size TT and inability to use a OWV. Supporting this, in their study of the effects of oversized endotracheal tubes, Sudhoff et al [385] found a higher risk of tracheal rupture in females (though they reported this was an effect of height rather than sex). Interestingly, participants from two separate sites reported fewer adverse events since they moved to a longer standard tube and stopped using adjustable flange TTs. The risks of poor positioning and dislodgement of short TTs in patients with high BMIs was highlighted in the NCEPOD report on tracheostomy management [1]. This project suggests further work on developing TTs to suit the needs of patients with smaller tracheas who require a longer TT is required.

8.2.1.3. Long-term complications due to poor fit

No direct investigations into the outcomes of TT sizing decisions could be found. However, tracheal stenosis is a recognised complication of artificial airways and has been associated with size of tube. Sarper et al [17] found damaged cartilage at the stoma site was a risk factor for stenosis, and warned against making a large stoma or insertion of TTs by force. Chapter 4 showed oversizing was common in females and the benchtop study highlighted the difficulty inserting a size 8 Portex™ in a small 3D printed trachea. Larger tubes could not be inserted due to the rigid anterolateral walls of the 3D printed tracheas. However, in practice, force may result in insertion and tissue trauma. A retrospective chart

review of artificial airway-related tracheal stenosis found 75% of the patient group were female and 66% were categorised as obese [20]. In keeping with this, the observational study found that TT sizing by BMI in females led to the highest rate of oversizing (49% compared to 19% in males).

8.2.2. Function

8.2.2.1. Humanisation and having a voice

The idea that communication is important to patients is not new and some of the evidence was presented in Chapter 1 and Chapter 2. However, this work definitively highlights the importance of voice to patients with a TT in ICU, emphasising its physical acoustic properties that serve to enable verbal communication and are a part of patients' identities, and the abstract metaphorical properties of 'having a voice' such as giving people agency and control. Happ et al [88] developed the concept of 'voicelessness' a quarter of a century ago. More recently others have noted the importance of voice over other forms of communication [36, 209], and voice was central to one of the selected studies in the metasynthesis [190]. However, the work presented here has developed a broader and deeper understanding of what having a voice means to patients with a TT on ICU, identifying its key role in the humanisation of care. Moreover, it placed it firmly and high on the agenda in the context of TT size decisions.

8.2.2.2. Laryngeal function

The move away from the term 'speaking valves' towards 'one-way valves' acknowledges that they can also help restore other functions. Laryngeal rehabilitation focuses on functions such as airway protection, swallowing, coughing, and restoration of physiological positive end expiratory pressure [36, 38, 386]. As with the early onset of mobilisation, expert consensus is that early cuff-down and OWV trials can can help patient achieve person-centred goals [30, 36, 387–389]. There is also evidence to support the beneficial effect of OWVs on mobility and ventilation [390, 391]. The metasynthesis findings showed that recovery and a return to normal were important to patients. The observational study and benchtop findings suggest that, if rehabilitation is facilitated by the use of OWVs, then size of TT may play an important role in patient-centred outcomes. They also suggest that if oversizing is common in females and OWV use generates higher WOB in smaller tracheas, that female patients are likely to have worse functional outcomes.

8.2.2.3. Respiratory function

Data from the focus groups suggested that clinicians selecting size of TT are primarily focused on reducing resistance to airflow through the TT and therefore tend towards larger sizes. This fits with recommendations of published benchtop studies who have recommended a minimum size TT or removal of the inner cannula to increase functional diameter of TTs [99, 100, 102]. However, there was little discussion in focus groups or in the literature on how RR or TV might map onto TT sizing-decisions. This project highlights the importance of these variables on WOB. This is of particular clinical relevance to the focus group discussions on the differences between diagnostic groups of patients with a TT. For example, those with acute respiratory failure may have different flow profiles to patients with head and neck cancer or spinal cord injury, and therefore require different approaches to TT sizing decisions.

8.2.2.4. In-vivo studies of tube imposed resistance to breathing

The finding that WOB was lower than baseline in the large trachea with a OWV contrasts with an in-vivo study by Villalba et al [392], who found that cuff *inflation* could reduce WOB. They reference other studies of WOB in patients pre- and post-decannulation, with inflated and deflated cuffs and with open and occluded TTs and acknowledge variation in findings [393, 394]. However, though all studies reported the size of TT used, none reported the size of patients' tracheas. The work presented in Chapter 5 suggests that this is very influential on outcomes. It is suggested therefore that size of TT and tracheal width along with information relevant to flow (RR, TV) should be reported in future studies of tracheostomy related interventions as potential confounders. The inability to achieve consensus on optimal timing and technique of tracheostomy may in part be due to ignoring these important factors.

Better understanding of the relationship between TT size, trachea size and patient outcomes could help guide staff and patient expectations around breathing changes post placement of a OWV and post decannulation. It also raises questions regarding the potential for deconditioning in those with larger tracheas and large TTs. Once again, this points towards a more tailored approach to TT size decision-making.

8.2.3. Patient experience

8.2.3.1. Patient-centred care and biopsychosocial models of health

This project has brought rich qualitative data on patient experience of tracheostomy in ICU into the discussion on TT size decisions. This was intentional to ensure findings were patient-centred. No other projects linking patient experience data with TT sizing decisions were found. However, the patient experience component of the model fits with biopsychosocial models of health and person-centred care. The former was developed in response to dissatisfaction with medical models whose focus on purely physical signs and influences on health ignored social, psychological, and behavioural contributors to health [113]. It fits with Merleau-Ponty's theory of embodiment to explain the mind-body connection and embodied health [217, 395]. In this project, following Engel's proposal, physical considerations have been addressed, but not at the expense of psychological and social factors. The triad of components at the heart of the model bring together the physical, functional and patient experience considerations that should be part of TT sizing decisions.

8.2.3.2. Post-intensive care

Forty years after Engel's model was first presented, Wade and Halligan [396] wrote that its reach had yet to take hold in acute care. Intensive care medicine in particular has been accused of being overly medically focused, with patients being hidden behind equipment, new technology or sedation. However, over the last decade a greater focus has been placed on the people in ICU; patients, families, and staff [397, 398]. The Intensive Care Society's report 'Intensive Care 2020 and beyond: Co-developing the future' shifted emphasis from interventions and hospital outcomes to experience and what life is like for survivors post ICU discharge and a large amount of research has been conducted on minimising risks for and developing interventions to treat post intensive care syndrome. This project is in alignment with these aims through its focus on improving patient experience during ICU and reducing long-term harm associated with poor TT size decisions.

8.2.3.3. Stage of life

Wade and Halligan's [396] schematic diagram of the biopsychosocial model includes a temporal context in terms of stage of illness and stage of life (young/old, working/retired).

Stage of life was not directly captured in this project but is an important factor in decision-making and could be seen as part of the 'patient' at the centre of the model. As the work of the HU-CI group [235, 236] noted, humanisation of care is especially important at the end of life. Since a reported 20% of patients with a TT on ICU do not survive to ICU discharge [1, 399–401], this should be considered in tracheostomy related decisions including TT size, or whether or not to insert a tracheostomy. Applied to the 'vignettes' in the previous chapter, decision making might be different for each case if they were a young, previously healthy adult with an acute respiratory infection, or an elderly patient with multiple comorbidities.

8.2.4. The MDT

8.2.4.1. Decision makers and heuristics

There is a substantial body of research and quality improvement literature that suggests MDT involvement improves the care and safety of patients with a TT [57, 61, 62, 64, 402–405]. There is very little literature on how MDTs make TT sizing decisions for adults. Current national guidelines suggest the MDT can be invaluable in size decision-making [4], but in line with the findings of focus groups in this project, there is no evidence that they are involved in decisions at time of insertion and several authors have concurred that in practice it is usually based on operator experience [383]. While heuristic decision-making can have the benefits of speed, lower burden on clinicians and reliable outcomes in some areas [362, 406, 407], Kahneman and Tversky's Nobel-prize winning work on 'fast and slow thinking' [357, 408] highlights the pitfalls of heuristics where decisions are complex, the evidence base is lacking, and where personal biases exist. A review paper compared heuristic versus analytical decision-making in critical care in the context of theories of the cognitive processes involved in each approach [358]. Like this project, it found heuristic decisions risked error due to the inherent complexities of patients in ICU and over confidence and professional biases of operators. Importantly in this project, a fundamental lack of evidence on which to base decisions was also found. However, with the right evidence and equipment, a sizing method that simplified decisions for teams would be more likely to be successfully implemented in practice.

8.2.4.2. Downsizing practices

Some authors cited faster time to downsizing as a positive outcome of tracheostomy MDTs [61, 402], as was noted by Whitmore et al's review [30], suggesting that downsizing is frequently required and that primary insertions are frequently too large. However some therapist participants in focus groups saw 'getting the size right from the start' as the goal, in the belief that the right size TT could suit a patient's respiratory needs from insertion to decannulation. TT changes were also noted to carry risk, especially in the first two weeks after insertion, and be unpleasant for patients. Assumptions among other participants that downsizing was a normal part of weaning fit more with the literature cited above, and were based on the belief that patients might require larger TTs initially but smaller TTs later on to facilitate weaning and decannulation, though as noted by focus group participants, if a patient's respiratory requirements are very high in early acute phase, it may be too soon for tracheostomy. This project was not designed to answer the question of whether it should usually be possible to meet patients' needs with the same size TT from insertion to decannulation, or whether this depends on certain variables. Further research would be useful to determine whether holistic TT size decision-making at the time of insertion could decrease the need for tube changes without adversely impacting respiratory outcomes. A further research question would be whether decisions around timing of tracheostomy should consider TT size required to meet respiratory needs at that time, and whether delaying insertion could lead to successful insertion of a smaller TT. The risks of prolonging intubation duration would have to be considered.

8.2.4.3. Roles and hierarchy within the MDT

Specific roles of the tracheostomy MDT members have been documented [16, 53, 63, 64]. Implicit in the descriptions is the individual contributions to overall care from each profession. This project explicitly highlighted that the differences in contributions relate to focus, timing, and duration of interventions and assessments provided by each profession, identifying these both a source of potential conflict due to differences in perspectives and a strength through providing holistic assessment and management. However, as highlighted above, TT size decision-making in ICU remains uni-professional and based on a bio-medical model. The 'operator-sole-decision-maker' issue speaks to hierarchical models of healthcare that are largely considered outdated and harmful to patients [368, 409, 410].

8.2.4.4. Presence of the full MDT

A further barrier to MDT working identified in this project was the absence of key professionals in some units, notably SLTs, due to funding and access to training. This is supported by several recent surveys [411]. SLTs are not even listed as members of the ICU team in a 2018 review of teamwork in ICU [412]. This project supports the inclusion of ICU doctors, ENT and head and neck surgeons, SLTs, physiotherapists, nurses, tracheostomy practitioners and psychologists in tracheostomy MDTs with the aim of providing holistic care and acknowledging that different patient populations may require different membership of the MDT.

8.2.5. Local organisational factors and policy

The idea that organisational factors can present barriers to implementing evidence-based practice in healthcare is not new. Twenty-five years ago Newman et al [372]found barriers relating dissemination; training and development; and accessing evidence and resources. All of these were highlighted in this project. More recently, barriers have been found relating to workload; lack of support from other staff/management; lack of resources; lack of authority to initiate change; lack of leadership; management; lack of funding; and work place culture of resistance to change [373, 413]. Some of these relate back to the MDT component but again, lack of resources, the difficulties instituting change across an organisation, and workload/workforce issues echo the findings that fed into the organisational factors component of the model.

The conceptual model of TT size decision-making did not identify particular problems with organisational culture, though this may reflect the study designs and data collection methods rather than an absence of barriers or facilitators at this level. Organisational factors in the model centred more around selection, range and location of local stock, workforce (including protected ICU time for therapies staff) and training and education. These were all areas identified and targeted by Twose et al [26] in their quality improvement initiative undertaken in collaboration with the Improving Tracheostomy Care project and the Global Tracheostomy Collaborative [2, 66].

8.2.6. The evidence base

The evidence base and the gaps in evidence relating to each workstream have been covered in the relevant chapters. A strong theme throughout has been a lack of evidence

to guide tracheostomy management generally, but particularly relating to size decisions, and this is supported by national guidelines and audit [1, 3, 4]. The idea of access to the evidence and of professions holding pockets of information that were not readily available to others was raised in focus groups and is supported by a report on the uptake of innovation in healthcare [414]. The authors concluded that multi-professionalism mediated (was a barrier to), uptake of innovation in healthcare and was due to 'social and cognitive boundaries' between professions. On the other hand, focus group data highlighted that MDTs that worked well together facilitated improvement. Further, they proposed that joint MDT training for the whole tracheostomy MDT might aid the establishment of good working relationships between professions and facilitate knowledge sharing and change in practice. This however is dependent on adequate funding of posts. It is also dependent on the creation of new knowledge in each professional area, which is dependent again on ring-fenced time and funding for research, and an argument to support the creation of clinical academic roles for professions where this has not historically been common practice - the allied health professions [415–417].

8.2.7. Tracheostomy tube design

8.2.7.1. Size labelling conventions

The variability in tube design and size labelling highlighted in the benchtop study and focus groups is well noted in the literature [4, 371, 418]. Yet there has been no attempt to address it. Footwear has well established standardisation of sizing, but for life-supporting artificial airway tubes with the potential to impact physical, functional and psychological outcomes in the critically ill, a size 6 in one brand might be very different to a size 6 in another. In the context of this project, design and size labelling of TTs is seen as a significant barrier to change, since new methods in sizing will need to need to account for this variability, and/or healthcare professionals and organisation may need to become familiar with other brands.

8.2.7.2. Effect of tube design on fluid dynamics

The benchtop study showed variation in fluid dynamics through different types of tube, as has been seen in other benchtop studies and computer modelling [100, 337, 419]. It also showed the impact of the deflated cuff on WOB when using a OWV. Most research on cuff design has been around the move to low pressure cuffs to avoid tracheal trauma

[420, 421], though one study focussed on the benefits of different cuff designs in allowing more airflow through the upper airway on cuff deflation [338]. During the benchtop study I intended to trial a Bivona TTS TT, as its main selling point is a cuff that deflates tight to the TT shaft, reducing resistance to airflow around the TT on cuff deflation. However, global shortages of TTs at the time of the study meant none were available. Nevertheless, this project suggests that cuff profile, material and form on deflation, among other aspects of TT design could be key to improving TT performance for patients.

8.2.7.3. Sexism by design

Lastly, a lack of choice in TT size for patients with smaller tracheas means a lack of choice predominantly for females. This is in addition to the systemic female disadvantage seen in TT size decision-making due to the the flawed methods used. Thus tracheostomy sizing and TTs are brought into the discussion on sexism by design. The book 'Invisible Women' brought data gender bias and the consequences for females in a range of areas from car design to recruitment to widespread media attention in 2020 [422]. It also highlighted the disparity in healthcare provision and outcomes for females due to the absence of female data in basic science and primary studies or failure to analyse data from males and females separately. This is reflected in the scientific literature on areas including heart disease, autism and prevalence of disease burden [423–426]. A strength of this project was the separate analysis of male and female data in the observational study, without which, the disparity in outcomes for males and females would have been missed. All future developments in TT design should seek to deliver equity of performance to male and female patients, which means improving design at the smaller ends of ranges and ensuring disaggregation of male and female clinical data in all future research studies.

8.2.8. The conceptual model of tracheostomy tube size decision-making

The model of TT size decision-making presented in Section 7.5.1 was multi-level, incorporating factors involved in decision making at the level of the patient, healthcare organisations, and outside individual organisations. In this respect it is similar to micro, meso and macro level models of healthcare used to evaluate health services [427–430]. Like Vollam's model of patient outcomes related to ICU discharge patterns [430], the micro level in this project represented the patient. Like Vollam's project, the centrality of the individual needs and circumstances of the patient warranted this position in this project's model.

As with other projects, this multi-level model has been used to identify areas to target in implementation strategies with the aim of facilitating adoption of change in practice.

8.3. Strengths and limitations

The use of mixed methods was a particular strength in addressing this complex topic. The mixed method design harnessed the strengths of qualitative methods to gain in depth understanding of the experiences, perspectives and behaviours of patients and clinicians, whilst also drawing on benefits of quantitative methods to generate knowledge of the physical attributes and outcomes related to sizing decisions. Integration of the mixed data allowed a more comprehensive understanding of the topic and theory development on how size decisions should be made and barriers and facilitators to changing practice.

Limitations of the individual workstreams were discussed in the relevant chapters. In addition to these, limitations are acknowledged around the focus on a standard profile TT in the observational and benchtop studies. Adjustable flange and extra length tubes are used by many teams and recommended for patients with high BMIs [1, 4]. However, inclusion of other types of tubes would have greatly added to the complexity and size of this study and limited its scope in other areas. Length and profile of tubes and impact on function should be addressed in future research on TT sizing. Additionally, successful use of OWVs has been presented in this project as an outcome of sizing decisions. It is acknowledged however, that inability to tolerate a OWV may be due to other factors such as upper airway swelling or vocal fold damage due to intubation or poor respiratory drive.

This project has not delivered the definitive guide to TT size decision-making. Much work remains to be done. However, through an innovative approach, it has drawn together important considerations from the patient level through to equipment design and delivered a model to guide decision-making and organisational factors relating to selecting TT size for patients *based on current knowledge and available resources.* Below I outline the clinical implications for practice and recommendations for future work.

8.4. Clinical implications

Clinical implications from individual workstreams and integrated findings have been highlighted in the relevant chapters and in Figure 7.1 in Chapter 7. These are summarised

below in relation to the levels of the conceptual model of TT size decision-making.

8.4.1. Patient level

8.4.1.1. Voice in TT sizing decisions

The metasynthesis found that patients primarily wanted to be seen and treated as a whole person and that having a voice made this easier. This builds on previous evidence documenting the distress caused by not having a voice and further develops the concept of voicelessness by linking it to the concept of humanisation. It places voice as a core consideration in TT sizing decisions and rejects the idea that voice is of secondary importance. This is not to deny that there will be times when it will be appropriate to select a TT that precludes the use of voice, rather it is to state that restoration of voice should always be a core goal from the time the decision is made to insert the tracheostomy. Where voice is not possible, alternative forms of communication that are tailored to patients' physical and cognitive needs should be employed to help meet patients needs for information and involvement in care decisions. This work additionally emphasises the importance to patients of human connections with staff and family and the role that voice plays in facilitating them, again linking to themes around humanisation.

8.4.1.2. Fit and function

Little research has been conducted on TT sizing and most of what has been published looks at either fit or function, not both. This project has brought both elements together and highlighted the impact of one on the other. In doing so it has revealed unexpected knowledge around discrepancies in outcomes for males and females. A major clinical implication is that teams should take extra care to select an appropriate size TT for females, especially those with a high BMI, who are more at risk of trauma from insertion of oversized TTs and not being able to tolerate an OWV.

This project also presents respiratory parameters from a new perspective in TT sizing decisions. Rather than respiratory requirements being raised as a reason to insert a large TT, this project suggests they could equally support insertion of a *small* tube in patients who are not in respiratory distress and do not have large TVs. To paraphrase a focus group participant, if you do not have a race horse's lungs, you do not need a horse's TT. This also has implications for working with different patient populations, for example those with neurological disorders may benefit from different sizing decisions to those with acute

respiratory failure. Also important for clinicians is the new knowledge that decannulation may lead to higher or lower work of breathing depending on a patient's size of trachea, TT, and cuff status.

8.4.1.3. Imaging

This project has generated empirical evidence to support better understanding and interpretation of tracheal sonoanatomy. This has important clinical implications since it suggests that developing ultrasound skills for tracheal assessment and measurement is more challenging than other applications of airway ultrasound, and errors of interpretation are easy to make. However, given the standard use of ultrasound to screen for blood vessels at the time of tracheostomy insertion and its non-invasive nature, it has potential to be used with appropriate training and/or technological advancement in the future.

8.4.2. The MDT

The COM-B model [356] was key in helping identify barriers and facilitators to changing practice in the focus group study, and shaping the conceptual model of TT size decision-making. Usually it is used as a tool to analyse influences on behaviours of patient groups or service users. However, in this project it was used as a framework for analysing influences on sizing decisions within the ICU tracheostomy MDT. The framework domains of capacity, opportunity and motivation automatically led to consideration of staff knowledge, skills and beliefs but also resources and culture. An important clinical implication arising from this was the need for better mutual understanding of roles and interventions undertaken by MDT members and sharing of information around patient needs. Joint training for all team members including doctors, surgeons, therapists and nursing is proposed as a strategy for future implementation interventions to encourage change in practice, since this could allow exchange of knowledge and perspectives and greater holistic awareness of the impact of TT size among team members.

8.4.3. Tube design

Although tube design falls under research and innovation, it is listed here since this project indicates clinicians (from all professions involved in tracheostomy management), should be involved in redesigning TTs to ensure they deliver the best person-centred outcomes. This includes ensuring that TTs are simple for clinicians to understand and manage.

8.5. Recommendations for future research

As stated above, this work has provided a framework for TT size decision making. The clinical implications of this project provide guidance on how some parts of the model can be operationalised, for example, a shift in practice at time of insertion to giving higher priority to voice and OWV use. However, many gaps remain in the evidence. Below are suggested areas for research arising from the findings of this project:

- Observational data collection to test the findings on outcomes of TT size decision-making *in vivo*, for example - are women more likely to receive an oversized TT? Are functional outcomes and rates of tracheostomy-related stenosis worse in those with a smaller trachea? Are psychological outcomes worse in those with a smaller trachea?
- Research to determine how best to obtain tracheal measurements in patients prior to tracheostomy including:
  - suitably powered studies to validate the accuracy of ultrasound measurements of tracheal width (the 'gold standard' measurement with which to compare ultrasound measurements would need to be determined)
  - feasibility studies of training interventions to teach ultrasound measurement of the trachea that address ease of knowledge and skills acquisition, time to obtain measurements, and acceptability of the measurement technique among clinicians
  - exploration of AI applications to facilitate ultrasound measurement of tracheal width (i.e. can AI algorithms aid tracheal landmark identification and interpretation of artefact?)
  - exploration of other imaging options for obtaining tracheal width measurements in patients prior to tracheostomy, such as endoscopic/bronchoscopic measurement
- Data collection on the ranges of RR and TV seen in patients with a TT - to inform future benchtop studies and the testing and development of new TT designs. The simultaneous collection of RR and TV data with tracheal width measurements, demographic data and medical history could be used to investigate possible associations between these variables that could be used to select TT size.

- Up to date normative data on tracheal width in adults, stratified by sex and ethnicity, to help inform decisions about appropriate ranges of TT size in the design of new TTs and in local stock decisions..
- Specific transdisciplinary research and innovation is needed to optimise tracheostomy tube design, including:
  - optimisation of the fluid dynamic performance of TTs whilst considering the technicalities of insertion, and patient comfort and anatomy (through collaboration between clinicians, medical engineers and patients)
  - investigation of thinner materials to give better inner-to-outer diameter ratios in TTs (through collaboration between medical materials experts and clinicians)
  - improved cuff design to reduce the cross-sectional area of deflated cuffs and improve airflow through the upper airway on cuff deflation
  - a focus on the performance of tubes to fit smaller tracheas (informed by findings on possible associations between flow requirements and tracheal width)
- A separate but linked piece of work around the standardisation of size-labelling and TT profile descriptions for TTs across manufacturers. This is a highly challenging task, requiring 1) understanding of what elements of size and profile are important to TT function and how they affect function *in vivo*, and 2) collaboration between clinicians, biomedical engineers, and the different manufacturers.
- Development of a core outcome set for future studies of tracheostomy interventions and outcomes - to assist in comparisons between studies. Given the impact of TT size and size of trachea on function, it is suggested that these should be part of a core outcome set. In order to capture change that is meaningful to patients, voice restoration and ability to eat and drink should also be included.
- Exploration and development of the central ‘person’ element of the conceptual model of TT sizing decisions, for example, what elements of a person’s social, medical and psychological background are relevant to decision-making? How do they impact person-centred outcomes? What weight should they carry in TT size decisions?
- Since complications arising from tracheostomy may be compounded by complications due to prior intubation, and in the absence of robust guidelines around the

sizing of endotracheal tubes, a futher recommendation for future research is a similar piece of work around developing the evidence-base to support endotracheal tube size decision-making for adults in ICU

These suggestions could move the evidence base forward and help translate further specific recommendations, moving towards formal guidelines for clinicians on how to choose the right size TT for adults in ICU. Differences in male and female tracheal anatomy and tracheostomy outcomes mean it is *essential* that all studies include male and female data and analyse it separately. Other demographic variables (such as ethnicity), or medical diagnoses that may have an impact on respiratory profiles or anatomy, should also be considered separately.

Finally, some of the barriers and facilitators to changing practice that should be addressed in implementation work to embed knew knowledge into practice are factored into the suggested work above. Further work is needed to understand the factors and processes behind good MDT working within the ICU tracheostomy team. Joint training might be part of this, and work is needed to identify the elements of tracheostomy training and education that could be delivered jointly to the full MDT - doctors, surgeons, nurses, therapists and tracheostomy practitioners, to promote holistic understanding of patients' needs and mutual understanding of fellow professionals' roles. Underpinning this work, more evidence is required in the fields of speech and language therapy and physiotherapy on the nature and impact of tracheostomy-related interventions employed by these specialities. Targeting support from senior professional and organisational leadership would also help ensure MDTs are formalised, and not reliant on *ad hoc* local staffing and working relationships.

8.6. Conclusion

This project could bring meaninful change to TT sizing decisions for adults in ICU and bring the person and person-centred outcomes to the heart of decision-making. Choosing the right size TT for adults in ICU matters because it impacts things that are important to patients. The wrong size TT can cause voicelessness, which impacts all other aspects of care and risks dehumanisation of patients. Voice should therefore be high priority in TT sizing decisions. Current decision-making practices are subjective, based on flawed assumptions, and lead to high rates of oversizing in females, especially those with higher BMIs. Sex, height, shoulder width and BMI cannot be used to predict tracheal width or select TT size, though in practice, sex and height commonly are.

Equipment ranges and design disproportionately disadvantage females through a lack of provision for patients with smaller tracheas and higher resistance to airflow through and around TTs that do fit smaller tracheas. A hypothetical association between smaller TVs (and lower overall flow), in ICU patients with smaller tracheas may partially mitigate the latter effect, though this hypothetical association needs to be confirmed. RR and TV heavily impact WOB as well as TT tube size, and an individual patient's expected respiratory requirements should be factored into TT size decisions. Better TT design, for example improving the ratio of inner to outer diameter of TTs and designing TT cuffs that deflate to a smaller cross-sectional area could improve TT fit within the trachea and functional outcomes such as WOB, voicing, eating and drinking.

Each profession involved in tracheostomy management on ICU, including medical, nursing, speech and language therapy, physiotherapy and surgical, brings a different perspective, knowledge and skills relevant to TT sizing decisions. Successful MDT working can therefore promote holistic decision-making and person-centred outcomes. Implementation interventions to help embed change in practice should promote good MDT working and mutual understanding of roles and interventions, for example, through joint training in tracheostomy management for all MDT members. Training should include insertion considerations including timing, technique and size decisions; complications, including those associated with TT sizing; weaning strategies and interventions; patient experience of tracheostomy; and patient-centred outcomes, including voice, eating, drinking, and psychosocial wellbeing. Support from senior leadership is also important to ensure the funding of protected time for therapies within ICU, especially speech and language therapy, who are currently under-represented.

In summary, good decision-making should take into account the fit of TTs within the trachea, the impact of TT size on functions important to patients, and patient experience. Better design of TTs could deliver better functional outcomes for patients and make size decision-making easier for clinicians. Creation of new knowledge to fill the identified gaps in the evidence, raising interdisciplinary awareness of the issues around TT sizing, and supporting effective MDT working will be key to the implementation of change in practice and improved person-centred outcomes for patients.

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A. GRIPP2 reporting form

Section and topic	Item	Reported on page No
1: Aim	The aim of involving patients and family was to improve the quality and relevance of the research through confirming the topic was of importance to patients and using insights from the patient and carer perspective to shape study design, data collection, and interpretation of findings. People with lived experience of being in intensive care with a tracheostomy (patients and one spouse of a patient), were involved at different stages of the project.	
2: Methods	Five PPI representatives responded to an advert disseminated through an online peer support network for ICU patients and their relatives and caregivers (ICUsteps). Four were patients and one was a patient's spouse. Input was requested initially to help develop the research proposal prior to applying for funding. Information was collected through phone calls with individual PPI representatives. Phone calls lasted between 30-60 minutes. Extra information was provided by some PPI members via email. Each respondent received a gift voucher funded via the Research Design Service Enabling Involvement Fund in appreciation of their important input. Additional support was sought through the Research Design Service Fast Track Service to write the Plain English summary for the funding application. Amendments were made in response to recommendations by two lay reviewers. Following confirmation of funding, two patients with lived experience of tracheostomy from my local ICU volunteered to join the PPI steering group. Subsequent communication was via email and 1:1 or group online virtual meetings, with the offer of speaking via phone if preferred. Reminders were given in meetings and emails that there was no obligation to continue involvement if at any point and for any reason they no longer wished/were able to participate.	

Section and topic	Item	Reported on page No
3: Study results	Funding application stage: all respondents were supportive of the project and felt it explored an important research question that warranted investment and investigation. Four recalled periods of not being able to talk due to their tracheostomy tube and the resulting impact on levels of fear and anxiety, the ability to request pain relief, participate in treatment decisions, and staff behaviour towards them. Workstream 1: PPI input into methodology - Evidence synthesis chosen over patient interviews. PPI felt that timing of interviews could be difficult due to severity of illness, variation in patients' readiness and ability to talk, variation in understanding of tracheostomy-related outcomes. Comment on findings: PPI members felt the descriptive and analytical themes captured the experience of having a tracheostomy well. One member felt it was important to highlight the deep impact that the experience of tracheostomy had on family members. Due to the specific focus of the research question, this was not highlighted in the review findings. Workstream 2: PPI group consulted on recruitment strategy and data collection procedures and asked to review the Participant Information Sheet (PIS). Not all ideas possible to take forward, for example, recruiting from gyms and GP surgeries. PIS felt to be far too long, but unable to abbreviate significantly due to ethical approval requirements. Workstream 3: No obvious role for PPI group. However, members were invited to observe data collection. One member attended the simulation centre and engaged in discussions around the purpose and theory behind the experiment, providing useful insights into how the experiment might be perceived by lay audiences. Workstream 4: PPI members were consulted on the focus group topic guide and invited to attend a groups (online or face-to-face). None attended a focus group.	
4: Discussion and conclusions	Patient and public involvement was highly valuable in the early stages of developing the research proposal, through endorsement of the project's focus and questions and insights in the the experience of having a tracheostomy in ICU. Following commencement of the project, PPI-researcher meetings were helpful in identifying aspects of the aims, methods and results of different workstreams that required more clarity when presenting to others.	

Section and topic	Item	Reported on page No
5: Reflections/critical perspective	Patient and public involvement was an important part of the study and contributed significantly to a successful application for NIHR funding. However, members of the group were not involved as much as they could have been at all stages of the research. For example, there was no PPI input during the integration of the mixed methods data or in developing the discussion. This was mainly due to the time pressures towards the end of this large project and the amount of complex data to process and summarise. This is a limitation and in retrospect, involvement of PPI group during this stage could have helped shape the outputs of integration and added strength to the project's findings. A further limitation is acknowledged in the lack of diversity of the PPI group. No data was formally collected on age, ethnicity, or socio-economic status. There was a mix of male and female members, however, all members of the group were White, over forty, and most held professional qualifications. One male patient of a minority ethnic background volunteered initially but subsequently withdrew from the project without attending any meetings. The lack of diversity of the patient and public involvement group may be in part due to recruitment to the group being mostly online, preventing those without access to internet-enabled devices or digital skills from knowing about or being able to participate in the project. By default, this may have excluded members of the public on the grounds of age, socio-economic status, disability and geographical region [431]. An advantage of online communication, however, was that people were able to participate from all over the country.	

B. Search strategies by bibliographic source

Table B.1.: Embase Classic + Embase search strategy

Line	Search term
1	exp tracheostomy/ or tracheostomy tube/
2	tracheo?t*.ti,kw.
3	(patient* adj2 (perspective* or attitude* or opinion* of experience* or perception* or view* of feeling* or thought* or priorit* or choice* or decision* or outcome* or satisfaction*)).ab,kw,ti.
4	“quality of life”.kw,ti.
5	phenomenol*.ab,kw,ti.
6	(lived adj3 experience*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
7	1 or 2
8	3 or 4 or 5 or 6
9	7 and 8

Table B.2.: CINAHL search strategy

Line	Search terms
1	(MH “Tracheostomy and Ventilator Swallowing and Speaking Valve”) OR (MH “Tracheostomy Care (Saba CCC)”) OR (MH “Tracheostomy Care”) OR (MH “Tracheostomy Tube”) OR (MH “Tracheostomy”)
2	TI Tracheo?t*
3	(MH “Patient Centered Care”)
4	“patient perspective*” or “patient attitude*” or “patient opinion” or “patient experience*” or patient perception*” or patient view*” or “patient feeling*” or “patient thought*” or “patient priorit*” or “patient choice*” or “patient decision*” or “patient outcome*” “patient satisfaction*”
5	Phenomenol*
6	Lived experience
7	1 or 2
8	3 or 4 or 5 or 6
9	7 and 8

Table B.3.: Web of Science search strategy

Line	Search terms
1	TOPIC: (Tracheo?t*)
2	TOPIC: (lived near/3 experience*)

3	TI=(patient* (perspective* or attitude* or opinion* of experience* or perception* or view* of feeling* or thought* or priorit* or choice* or decision* or outcome* or satisfaction*)) or KP=(patient* (perspective* or attitude* or opinion* of experience* or perception* or view* of feeling* or thought* or priorit* or choice* or decision* or outcome* or satisfaction*))
4	TI="quality of life" or KP="quality of life"
5	ALL=phenomenol*
6	#5 OR #4 OR #3 OR #2
7	#6 AND #1

C. Evaluation of metasynthesis work against ENTREQ criteria

Table C.1.: Evaluation of metasynthesis work against ENTREQ criteria

No.	Item	Guide and description	Evidence
1	Aim	State the research question the synthesis addresses.	Question in title: 'What matters most to patients in terms of key tracheostomy-related needs, experiences and outcomes?'
2	Synthesis methodology	Identify the synthesis methodology or theoretical framework which underpins the synthesis, and describe the rationale for choice of methodology (e.g. meta-ethnography, thematic synthesis, critical interpretive synthesis, grounded theory synthesis, realist synthesis, meta-aggregation, meta-study, framework synthesis).	Thematic synthesis based on Thomas and Harden [156] . This allowed the development of a metasynthesis which resulted in findings that went beyond those which could be read within any one given study manuscript whilst retaining individual voices of participants.
3	Approach to searching	Indicate whether the search was pre-planned (comprehensive search strategies to seek all available studies) or iterative (to seek all available concepts until they theoretical saturation is achieved).	A comprehensive, a priori search strategy was designed with support from an expert librarian to locate research evidence in both peer reviewed academic literature and grey literature. The aim was to capture as many eligible articles as possible, since it was anticipated that there would be relatively little published on the topic. The search was re-run just before the final analyses and no eligible articles were found.
4	Inclusion criteria	Specify the inclusion/exclusion criteria (e.g. in terms of population, language, year limits, type of publication, study type).	Inclusion Criteria: articles that focussed on adult patients with a tracheostomy tube in a critical care setting and reported qualitative data from the patient's or non-professional carer's perspective. Any qualitative or mixed-methods studies were eligible; wholly quantitative studies were excluded. No restrictions on date of publication were applied. Only English language articles were retrieved due to available resources.
6	Electronic Search strategy	Describe the literature search (e.g. provide electronic search strategies with population terms, clinical or health topic terms, experiential or social phenomena related terms, filters for qualitative research, and search limits).	The search strategy used for bibliographic databases can be found in Appendix B

7	Study screening methods	Describe the process of study screening and sifting (e.g. title, abstract and full text review, number of independent reviewers who screened studies).	All titles and abstracts were screened by the primary researcher (PhD student) using a screening tool developed in EPPI-Reviewer [170]. Two reviewers provided a second screening of titles and abstracts, taking half of the eligible articles each. Disagreements between the first author and second and third reviewers were resolved by referring to two further members of the research team. All full texts were reviewed by the primary researcher and three further authors reviewed a third of the full texts each. Any disagreements were resolved by the fifth member of the team. A data extraction tool was developed within EPPI-Reviewer and piloted by two members of the team on 4 articles prior to use. No modifications were made.
8	Study characteristics	Present the characteristics of the included studies (e.g. year of publication, country, population, number of participants, data collection, methodology, analysis, research questions).	See Chapter 2
9	Study selection results	Identify the number of studies screened and provide reasons for study exclusion (e,g, for comprehensive searching, provide numbers of studies screened and reasons for exclusion indicated in a figure/flowchart; for iterative searching describe reasons for study exclusion and inclusion based on modifications to the research question and/or contribution to theory development).	See PRISMA flow chart in Chapter 2
10	Rationale for appraisal	Describe the rationale and approach used to appraise the included studies or selected findings (e.g. assessment of conduct (validity and robustness), assessment of reporting (transparency), assessment of content and utility of the findings).	All included studies were critically appraised by the primary researcher, with support from her academic supervisor, reviewer 6, for methodological rigor and transparency of reporting using a modified version of the CASP for Qualitative Studies. An additional score was given to studies to indicate relevance to the research question. A sensitivity analysis based on these two scores can be found in Supplementary material F.
11	Appraisal items	State the tools, frameworks and criteria used to appraise the studies or selected findings (e.g. Existing tools: CASP, QARI, COREQ, Mays and Pope [25]; reviewer developed tools; describe the domains assessed: research team, study design, data analysis and interpretations, reporting).	Domains covered in the CASP include research design, recruitment strategy, data collection, whether the researcher-participant relationship has been addressed, rigor of the analytical process and value of the research. An additional dimension of 'relevance to patient experience of tracheostomy in the ICU setting' was added during the review process as some included articles were more focussed on the post-ICU experience of patients.
12	Appraisal process	Indicate whether the appraisal was conducted independently by more than one reviewer and if consensus was required.	see 10

13	Appraisal results	Present results of the quality assessment and indicate which articles, if any, were weighted/excluded based on the assessment and give the rationale.	See Section 2.2.6 and Section 2.5.6 . No articles were excluded based on the outcome of the appraisal. A sensitivity analysis was undertaken to see if/how the poorer quality studies affected the overall findings of the metasynthesis.
14	Data extraction	Indicate which sections of the primary studies were analysed and how were the data extracted from the primary studies? (e.g. all text under the headings “results /conclusions” were extracted electronically and entered into a computer software).	Whole texts were uploaded to EPPI-Reviewer software [170] . All text from ‘Results’/‘Finding’ onwards was treated as data.
15	Software	State the computer software used, if any.	EPPI-Reviewer software [170]
16	Number of reviewers	Identify who was involved in coding and analysis.	Reviewers 1 and 6 independently coded all the data inductively, line-by-line, searching for key concepts. Codes were compared midway through the process and a working draft coding framework agreed. The coding framework was refined iteratively with new codes in subsequent texts being applied to earlier texts. Emerging themes were discussed and developed collaboratively by reviewer 1 and 6 who looked for consistent or contrasting patterns across texts. Reviewers 2-5 were involved in discussions of themes.
17	Coding	Describe the process for coding of data (e.g. line by line coding to search for concepts).	see 16
18	Study comparison	Describe how were comparisons made within and across studies (e.g. subsequent studies were coded into pre-existing concepts, and new concepts were created when deemed necessary).	see 16
19	Derivation of themes	Explain whether the process of deriving the themes or constructs was inductive or deductive.	see 16
20	Quotations	Provide quotations from the primary studies to illustrate themes/constructs, and identify whether the quotations were participant quotations of the author’s interpretation.	Quotations are provided in the table of descriptive themes and section on analytical themes. Participant quotations are indicated in italics and author interpretations in plain text.
21	Synthesis output	Present rich, compelling and useful results that go beyond a summary of the primary studies (e.g. new interpretation, models of evidence, conceptual models, analytical framework, development of a new theory or construct).	See Section 2.6 . Inductive and analytical findings are presented and discussed in relation to the Humanisation Value Framework [157] and other relevant literature.

D. Risk of bias assessment in selected studies in Chapter 2

Table D.1.: Risk of bias scores for selected studies including CASP and relevance scores

Study	A	B	C	D	E	F	G	H	I	J	CASP total	Relevance score	Total
Arslanian-Engoren (2003)	2	2	2	1	1	2	1	1	2	2	16	2	18
Donnelly (2006)	2	2	2	1	1	1	2	2	2	2	17	2	19
Segaran (2006)	2	2	2	1	2	0	1	1	2	2	15	3	18
Carroll (2007)	2	2	2	2	2	1	1	2	2	2	18	2	20
Sherlock (2009)	2	2	2	1	2	2	2	1	2	2	18	3	21
Briscoe (2010)	2	2	2	2	2	1	1	2	2	2	18	1	19
Foster (2010)	2	2	2	1	2	1	2	1	1	1	15	3	18
Dyrstad (2013)	2	2	2	1	2	0	2	2	2	2	17	1	18
Flinterud (2015)	1	2	2	1	2	0	1	2	1	2	14	3	17
Tolotti (2018)	2	2	1	2	1	1	1	2	2	2	16	3	19
Freeman-Sanderson (2018)	2	2	2	2	1	1	1	2	2	2	17	3	20
Nelissen (2019)	2	2	2	2	2	1	2	1	2	1	17	2	19
Ng (2019)	2	2	1	1	1	0	1	1	2	2	13	2	15

Key: A = Was there a clear statement of the aims of the research? B = Is a qualitative methodology appropriate? C = Was the research design appropriate to address the aims of the research? D = Was the recruitment strategy appropriate to the aims of the research? E = Were the data collected in a way that addressed the research issue? F = Has the relationship between researcher and participants been adequately considered? G = Have ethical issues been taken into consideration? H = Was the data analysis sufficiently rigorous? I = Is there a clear statement of findings? J = How valuable is the research? K = CASP Total; L = Relevance score

Table D.2.: Comments on risk of bias by study

Study	Comments
Arslanian-Engoren (2003)	More than half potential participants who were contacted and physically able declined to participate; would findings in this group differ? Data was collected 2 years post discharge, potentially affecting recall. Impact of participation on participants was not addressed. A small amount of primary data was presented and authors did not indicate which were from the same participant. Focus is on mechanical ventilation but in ICU via a tracheostomy.
Donnelly (2006)	Small sample size. Almost half approached declined to participate; would findings in these participants differ? Lacks detail of consent process. Did not discuss influence of researcher-participant relationship on data collected.
Segaran (2006)	Process of selecting later participants on basis of initial interviews unclear. Researcher was part of patient's ICU care team: no reflection on potential impact on data collection and findings.
Carroll (2007)	Did not provide information on relationship between researcher and participants, however considered impact of researcher's ability to lip-read on data collection.
Sherlock (2009)	Exclusion criteria and Ethics Committee advice may have biased results to less severely ill. Brief description only of analytical process and unclear how many researchers coded information.
Briscoe (2010)	Relationship between participants and researcher not described. Authors did not discuss potential impacts on patients of taking part in the research but did report steps to protect the identities of participants
Foster (2010)	Small sample size. Author discussed reflexivity but not impact of relationship between researcher and participants. Data collection and analysis was conducted by sole researcher. Provides practice recommendations that are extrapolated from results.
Dyrstad (2013)	Small sample size, acknowledged as limitation by authors. No discussion of relationship between author and participants.
Flinterud (2015)	Unclear if aim is to address changing communication or adapting to being ICU. Excluded patients who were not discharged to their own residence. Did not discuss researcher-participant relationship. No ethical approvals however not deemed research at the time/location study took place. Thorough informed consent procedures are described.

E. Descriptive themes by dimensions of the Humanisation Value Framework

Table E.1.: HVF dimensions 1-4

Theme	Sub-theme	1. Insiderness/ Objectification	2. Agency/ Passivity	3. Uniqueness/ Homogenization	4. Togetherness/ Isolation
Voice and disrupted communication	How it feels to be voiceless in ICU	Not understood, resignation, giving up; mis-guessing	Not understood, resignation, giving up	Mis-guessing	Uncertainty; Frustration; Not understood, resignation and giving up; Sheer relief and happiness on return of voice
	AAC is a poor substitute	Creativity and individual approach; Communication has to be simplified; reliance on the effort and skills of others	Reliance on the effort and skills of others	Creativity and individual approach; Reliance on the effort and skills of others	communicating is effortful, slow and often fails; non-verbal communication is not the same;
	Speech functions: implications of impaired communication	Being overlooked and unable to correct misassumptions;	Voice as a means to achieve a goal; Conveying pain and asking for help; being overlooked and unable to correct misassumptions	Being overlooked and unable to correct misassumptions	Role of communication in building relationships; Being overlooked and unable to correct misassumptions
Autonomy and self-identity	Agency and self-determination	Being involved in decisions about care and rehab	Being involved in decisions about care and rehab; Powerlessness, loss of control and dependence on others;	Being involved in decisions about care and rehabilitation; Families as intermediaries	Being involved in decisions about care and rehabilitation; Family as intermediaries
	The self and connecting with others	Feeling non-human and being treated as an object; Alone, separate from the world; Sense of identity	Feeling non-human and being treated as an object	Feeling non-human and being treated as an object; Sense of identity; Feeling incomplete without a voice	Alone, separate from the rest of the world; Feeling non-human and being treated as an object; Creating connections and building relationships; Praising and defending nurses
Cognitive, psychological and emotional needs and experiences	Fear, anxiety and mental well-being	Tube changes are significant events to patients	Vulnerable and helpless	Tube changes are significant events; Feelings towards the tracheostomy and stoma; Failed communication causes suffering and leads to withdrawal	Fear and anxiety; Failed communication causes suffering and leads to withdrawal; Vulnerable and helpless
	Information needs and situational awareness	Awareness of the significance of events to patients		Information needs: prep, explanation, reassurance and planning; Awareness of significance of events to patients	Not understanding what is happening
	The experience of time	Boredom, passing the time and thinking things over		Changing and adapting over time	Boredom, passing the time and thinking things over
Physical needs and experiences	Physical sensations related to tracheostomy	Thirst, dry mouth, cravings	Eating and drinking with a tracheostomy		

Theme	Sub-theme	1. Insiderness/ Objectification	2. Agency/ Passivity	3. Uniqueness/ Homogenization	4. Togetherness/ Isolation
	Meeting physical needs	Voicelessness means needs are not always met; Anticipation of needs is easier when people know patients better		Anticipation of needs is easier when people know patients better; Voicelessness means needs are not always met	Coordinated care by competent staff
Facilitators to feeling better and recovery	Improving communication	Communication is helped by having a voice, people being able to lipread, AAC, and people knowing patients better; Body language, physical presence, eye contact and touch communicate sense of caring and safety to patients	Return of voice is wonderful and lets you do things again	Communication is helped by having a voice, people being able to lip read AAC and people knowing patients better	Body language, physical presence, eye contact and touch communicate sense of caring and safety to patients
	Coping strategies and character traits	Spiritual comfort	Determination and regaining control	Coping and passing the time; Spiritual comfort; Determination and regaining control	Determination and regaining control; Spiritual comfort
	Signs that indicate recovery to patients		Removal of tubes and technology and setting own goals; eating and drinking signifies getting better	Return to normality as goal and indicator of recovery	Returning to normality as goal and indicator of recovery; Return of voice associated with sense of getting better
	Making sense of the situation	Preparation, information and ability to ask questions	Preparation, information and ability to ask questions	Preparation, information and ability to ask questions	
	The essentialness of relationships with others	Importance of staff-patient relationships; Importance of family	Importance of caring staff-patient relationships	Importance of caring staff-patient relationships; Importance of family	Importance of caring staff-patient relationships; Importance of family

Table E.2.: HVF dimensions 5-8

Theme	Sub-theme	5. Sense-making/ Loss of meaning	6. Personal Journey/ Loss of same	7. Sense of place/Dislocation	8. Embodiment/ Reductionist body
Voice and disrupted communication	How it feels to be voiceless in ICU	Uncertainty;	Uncertainty; Not understood, resignation and giving up; Sheer relief and happiness on return of voice		
	AAC is a poor substitute	communicating is effortful, slow and often fails; communication has to be simplified		reliance on the effort and skills of others	lip reading

Theme	Sub-theme	5. Sense-making/ Loss of meaning	6. Personal Journey/ Loss of same	7. Sense of place/Dislocation	8. Embodiment/ Reductionist body
	Speech functions: implications of impaired communication	Voice as a means to achieve a goal/get info; Processing admission to ICU; Being voiceless means you are given less information	Role of communication in building relationships; Fundamental importance of communication [losing reference points and usual ways of coping]	Processing an admission to ICU; Being overlooked and unable to correct misassumptions	Being overlooked and unable to correct misassumptions; the fundamental importance of being able to speak
Autonomy and self-identity	Agency and self-determination		Being involved in decisions about care and rehabilitation; Powerlessness, loss of control and dependence on others; Families as intermediaries; self-determination vs giving up	Families as intermediaries	Physical restriction and loss of freedom
	The self and connecting with others	Sense of identity	Feeling incomplete without voice; Alone, separate from the rest of the world; Sense of identity; Creating connections and building relationships	Praising and defending nurses	Feeling incomplete without voice; Feeling non-human and being treated as an object; Praising and defending nurses
Cognitive, psychological and emotional needs and experiences	Fear, anxiety and mental well-being	Shock; feelings towards the tracheostomy and stoma	Shock; Vulnerable and helpless	Fear and anxiety; Failed communication causes suffering and leads to anger and withdrawal	Tube changes are significant events; Feelings towards the tracheostomy and stoma
	Information needs and situational awareness	Life vs death; Information needs of patients: prep, explanation, reassurance and planning; Not understanding what is happening; Memory and confusion	Life vs death; Information needs of patients: preparation, explanation, reassurance and planning	Not understanding what is happening; Memory and confusion	Awareness of the significance of events to patients
	The experience of time	Boredom, passing the time and thinking things over; Changing and adapting over time	Time slows with no voice; Boredom, passing the time and thinking things over; Changing and adapting over time		
Physical needs and experiences	Physical sensations related to tracheostomy			Eating and drinking with a tracheostomy	Eating and drinking with a tracheostomy; Thirst, dry mouth and cravings; Desire to have trache removed; Difficulty breathing; physical discomfort and pain
	Meeting physical needs				Voicelessness means care needs are not always met; Issues post decannulation
Facilitators to feeling better and recovery	Improving communication	Return of voice is wonderful and lets you do things again	Return of voice is wonderful and lets you do things again		Body language, physical presence, eye contact and touch communicate sense of caring and safety to patients; Return of voice is wonderful and lets you do things again

Theme	Sub-theme	5. Sense-making/ Loss of meaning	6. Personal Journey/ Loss of same	7. Sense of place/Dislocation	8. Embodiment/ Reductionist body
	Coping strategies and character traits	Coping and passing the time, Spiritual comfort	Coping and passing the time; Spiritual comfort	Coping and passing the time	Spiritual comfort; Determination and regaining control
	Signs that indicate recovery to patients	Removal of tubes and technology and setting own goals	Removal of tubes and tech is a goal and signifies to patients they are getting better; Return to normality as a goal and indicator of recovery; Eating and drinking signifies getting better; Return of voice is associated with sense of getting better	Return to normality as goal and indicator of recovery	Removal of tubes and tech is a goal and signifies to patients that they are getting better; Eating and drinking signifies getting better; Return of voice associated with sense of getting better
	Making sense of the situation	Preparation, information and ability to ask questions	Preparation, information and ability to ask questions		
	The essen-tialness of relationships with others	Helpful behaviours or attitudes of staff	Importance of caring staff-patient relationships; Helpful attitudes of staff; Importance of family	Importance of trust in staff and feeling safe	Importance of caring staff-patient relationships; Helpful behaviours or attitudes of staff; Importance of family; Importance of trust in staff and feeling safe

F. Protocol for obtaining ultrasound measurements of the trachea

Yellow dots mark the outer tracheal wall and its reflection* around the air-mucosa interface. The air-mucosa interface is the brightest white line.

- Measure width at level of widest point of trachea (9 o'clock and 3 o'clock)
- Take measurements from same level as direct measurements (aim for clear black bands of cartilage + reflected cartilage**). You will hopefully be able to see Nur's measurement needle/gauge as indicator of where to measure.
- If possible, record in comments what number tracheal ring you are level with (count rings as you descend in transverse view from the cricoid, or count in longitudinal view and swivel to transverse view of same ring)
- Depth: 4.5 (adjust if nec., may need 3.0)
- Focus: at level of widest point of trachea
- dB – 5 (adjust as needed)
- Labelling, measurement and image storage

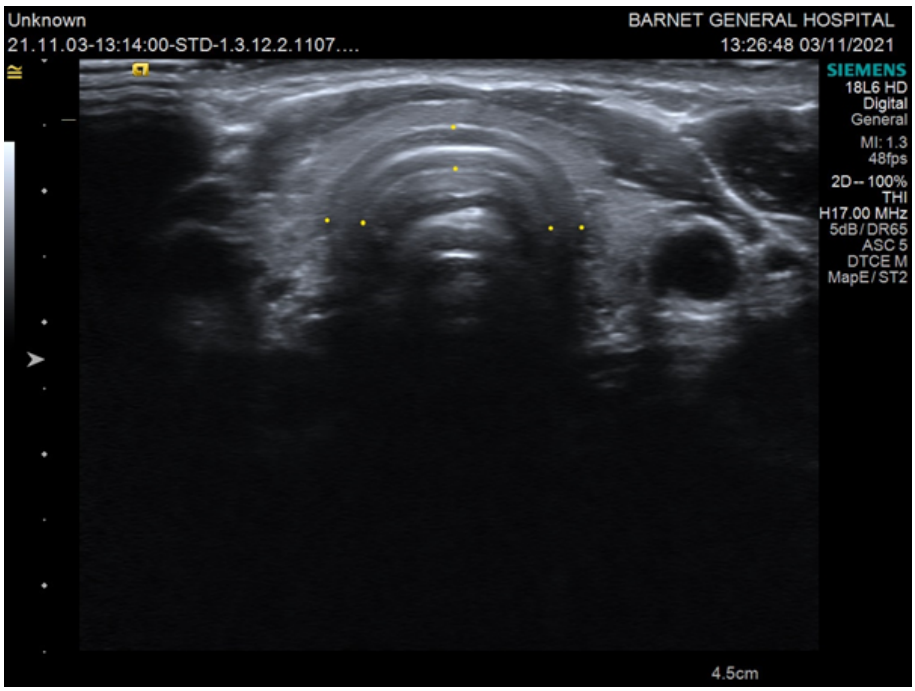

Figure F.1.

  - Once suitable image is captured, label to describe time/specimen/measurement site/rater, e.g.: T1S3Mb2R2 would be the first round of measurement, specimen 3, measurement site B, second image, by rater 2.
  - Save a blank (no measurements marked on it) labelled image – to be used later in static measurement reliability testing
  - Record:
    - Outer wall diameter
    - Reflected outer wall diameter
    - Inner wall diameter (where you think it is from extrapolating air-mucosa interface line seen at top of image) at same level as previous measurements
  - Repeat if you feel you can get a better image

- THI on
- 14MHz – adjust as needed
- If image is small, zoom in to make measurement area take up 1/2 - 2/3 of screen

*currently understand this to be the reflected outer tracheal wall.

**may find that only able to take measurements through inter-tracheal ring space, e.g. if using needle and cannot puncture through cartilage. To document as comment.

G. Service evaluation: tracheostomy tube sizing

Choosing the size of tracheostomy tube for adults in UK intensive care units: how do we do it?

Helen Newman[1], Anna-Lisa Sutt[2, 3, 4], Sarah Wallace[5, 6]
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Background

Each year 12000 people in the UK receive a tracheostomy tube (TT) (1). TTs bring lifesaving benefits to patients, such as facilitating mechanical ventilation (MV), weaning from MV, providing a patent airway, and allowing access to remove pulmonary secretions (2). There are important risks associated with their use, however. The wrong size TT can lead to difficulty ventilating patients, accidental dislodgement, tracheal stenosis, tracheomalacia and the inability to communicate with concomitant psychosocial burden (1,3). Guidance on type of TT to use exists (2,4), however, there is currently little specific guidance on how to select the size of TT for adults. Anecdotally practice varies widely between sites. This study aimed to investigate current TT-size selection practices in the UK.

Methods

Data were collected at the Royal College of Speech and Language Therapists Tracheostomy Clinical Expert Network meeting in London, UK, in May 2019 using Mentimeter online voting software. Smaller data sets were collected in June 2019 from ICU-based doctors and nurses. Descriptive statistics were used to analyse the survey findings.

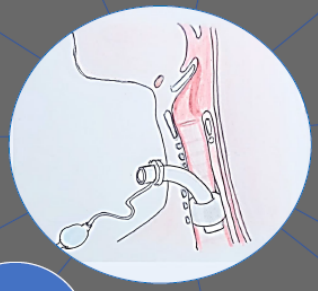
Results

Eighty-six clinicians completed the survey: 64 therapists (62 speech and language therapists, 2 physiotherapists); 14 doctors and 8 nurses.

Differences were found between factors reportedly *being used* in practice to decide TT size versus factors clinicians reported *should be used* (see Table 1).

Top 5 factors in tracheostomy tube size decisions reported by clinicians as...

	..being used	..should be used
1	Patient size	Patient size
2	Gender	Anatomy/trachea size
3	Availability/What's in the cupboard	Weaning
4	Consultant preference	Gender
5	Neck size	Secretions



- Tracheal diameter was rarely mentioned as a factor used in practice n=3
- 20 reported a minimum outer diameter of 10mm where they worked
- 15 reported a maximum TT inner diameter of less than 8mm at their place of work.
- 'Gender' was the most frequently considered factor by doctors.
- Use of TTs without an inner cannula was less frequent (18%).
- The frequency of marking optimal positions of adjustable flange TTs was 45%.
- 'What is in stock/closest to hand' was a common factor used in decision-making (therapists and nurses 66%; doctors 33%)
- Downsizing TTs was common and occurred twice as frequently as upsizing.
- Dimensions of TTs were compared on average 54% of the time when switching between brands.
- Most commonly used TT brands: Portex (68%); Tracoe Twist (63%) and Shiley (32%).
- All groups reported 'patient size' was and should be considered

Conclusion

There is variation in UK practices relating to TT size selection. Factors that clinicians feel should be used to guide decisions are not always used in practice. Factors that are used are often subjective, non-specific or non patient-related. The range of TT sizes used at some sites may be inadequate and place some patients at risk. Future research should seek to provide evidence regarding which factors are valid in TT size decisions, and has the potential to have an impact on tracheostomised patients' physical and psychological outcomes.

References
1. Wilkinson KA, Martin IC, Freeth H, Kelly K, Mason M. *On the right Trach.?* The National Confidential Enquiry into Patient Outcome and Death. 2014. Available from: https://www.ncepod.org.uk/2014tc.htm [Accessed 20th November 2018].
2. Intensive Care Society (ICS), *Tracheostomy Standards*. 2014. Available from: https://www.ics.ac.uk/ICS/guidelines-and-standards.aspx [Accessed 25th November 2018].
3. Happ MB. Interpretation of nonvocal behavior and the meaning of voicelessness in critical care. *Soc Sci Med*. 2000;50(9):1247–55.
4. McGrath B. *Comprehensive Tracheostomy Care - The NTSP Manual*. Chichester, West Sussex: Wiley Blackwell; 2014.

positively welcoming
actively respectful
clearly communicating
visibly reassuring

NHS Royal Free London NHS Foundation Trust

H. Observational study HRA and site approvals

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor Daniel S Martin

[redacted]

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

29 July 2021

Dear Professor Martin

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Concordance Of MEthods to select Tracheostomy tube Size for adults in intensive care (COMETS)**
IRAS project ID:	**272157**
Protocol number:	**136601**
REC reference:	**21/SC/0211**
Sponsor	**UCLH/UCL Joint Research Office**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **272157**. Please quote this on all correspondence.

Yours sincerely,

[redacted]
Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: [redacted]

IRAS 272157 Confirmation of Capacity and Capability at Royal Free London NHS Foundation Trust

You replied on Thu 11/11/2021 21:03

PL [redacted] +5 others

Tue 09/11/2021 17:59

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RE: IRAS 272157. Confirmation of Capacity and Capability at Royal Free London NHS Foundation Trust.

Full Study Title:	Concordance Of MEthods to select Tracheostomy tube Size for adults in intensive care (COMETS)
Site PI	Dr Helen Newman
Site Accrual Contact	Franki Gowing
Protocol version:	Version 2, Dated 20/08/2021
Latest HRA Approval date:	29/07/2021
Royal Free Ref Code	136601

This email confirms that **Royal Free London NHS Foundation Trust** has the capacity and capability to deliver the above referenced study. Please find attached the agreed OID as confirmation.
Royal Free London NHS Foundation Trust agrees to start this study on a date to be agreed when you as sponsor give the green light to begin. Please ensure the R&D office is provided with this date.
If you wish to discuss further, please do not hesitate to contact us
Please note, in line with the national HRA approvals process, you will no longer receive a NHS R&D Approval/Permission letter.
RFL R&D coordinator: please take the email as a prompt to open the study on the EDGE database.
Kind regards

Lucy

Lucy H H Parker
R&D Manager

[redacted]

I. Observational study participant information sheet

Study Title: Concordance Of MEthods to select Tracheostomy tube Size for adults in intensive care (COMETS)

Participant Information Sheet

Introduction

We would like to invite you to take part in our research study. This information sheet is designed to help you decide if you would like to take part. It is important that you understand why the research is being done and what it involves. Please feel free to contact the Research Team (contact details below), if you require any further information after reading this sheet.

1. What is the purpose of this study?

This study is part of a larger PhD project. The aim of the overall project is to provide evidence to help healthcare staff choose the best size tracheostomy breathing tube for patients in intensive care.

The aim of this part of the project is to compare methods of choosing the size tracheostomy tube. Four methods are based on physical characteristics of patients (sex, height, Body Mass Index and shoulder width). These will be compared with a recommended method that is based on how wide a person's windpipe (trachea) is. The results of this study will inform healthcare staff how well the different ways of choosing the size of tube relate to the fit of a tube in the trachea.

2. Why am I being asked to take part in this research?

You have been approached to take part in this study because you are an adult patient at one of the Royal Free Hospital NHS Foundation Trust hospitals. We would like to collect information on a diverse group of people, without unnecessarily bringing people into the hospital who would not normally be there.

3. Do I have to to take part?

No, this is voluntary. You do not have to take part and this will not affect your continuing care at the hospital. You are free to withdraw at any time, without giving a reason, by telling the researcher directly, or by contacting the Primary Investigator (Helen Newman). We will stop collecting research information from you if you do choose to withdraw or become unable to give informed consent. The data collected up until that point will be kept and analysed.

4. What will happen to me if I agree to take part?

If you agree to take part we will ask to collect some information about you. The information we need will be collected in a one-off appointment that will last between 30-60 minutes. You can choose an appointment slot that is most convenient to you. On the day of the research appointment you will be asked to provide consent to take part in the study. We will then collect the following information about you:

- hospital number
- sex
- age

- ethnicity (to ensure we invite a diverse group of people, and to make the research relevant to everyone)
- height
- weight
- shoulder width
- history of airway disease or surgery (including tracheostomy)
- details of medical conditions or surgeries
- width of your windpipe (trachea)

We will put some gel on the front of your neck and use ultrasound to measure your windpipe. This is painless. You can sit on a chair or lie on a couch. We will time ourselves taking the measurements so we can tell clinicians how long it takes. We expect these measurements to take about 10 minutes.

You can confirm that that you wish to take part in the study by calling or emailing the research team. Alternatively you can speak to a member of your care team who can pass on your contact details to the research team. Please let the research team know if you have any specific individual needs (e.g. communication or mobility difficulties) which mean that the appointment will need to be adapted in some way.

After the appointment we will put the information we have collected about you into secure hospital/university databases. Your name and any other identifiable personal information will be kept separately from the research information we will have collected. We will not need to contact you again following your appointment. If you would like us to contact you with the results of the research, please indicate this on the consent form.

5. What are the possible disadvantages and risks of taking part?

There is no identified risk of direct physical or psychological harm from taking part in this study. The researcher who will measure your trachea is a therapist. They are not trained to diagnose abnormalities, and the ultrasound procedure in this study is not a health assessment. In the unlikely event that abnormalities are suspected during the ultrasound measurement, this will be referred to a consultant who will follow up if required.

There is a chance that some of the ultrasound gel could get on your clothing. We will use a paper covering to reduce the chances of this. The gel is water-based and will come out with normal washing.

6. What are the possible benefits of taking part?

There are no anticipated benefits to people who take part in this study. However, knowledge generated by this research could help clinicians make better decisions about what size tracheostomy tube to give patients. This could help reduce the risk of damage to a patient's trachea, swallowing difficulties and the distress of losing their voice. It could also help a patient to be liberated from a mechanical ventilator.

7. What if there is a problem?

Every care will be taken in the course of this study. However, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff

you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the injury is the result of the Sponsor's (University College London) or hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Professor Daniel Martin, who is the Chief Investigator for the research and is based at the Royal Free Hospital. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Royal Free London Patient Advice and Liaison Service (PALS) on line (https://www.royalfree.nhs.uk/contact-us/patient-advice-and-liaison-service-pals/contact-pals-online-form/) or via your local hospital:

Barnet Hospital

Tel: 07929 790604/07929 790603 – Mondays (9:30 am – 4.00 pm)
Tel: 0208 216 4924 Tues – Fri (9:00 am – 4:00 pm)
Email: bcfpals@nhs.net
Mail: Patient Advice and Liaison Service (PALS), Barnet Hospital, Wellhouse Lane, Barnet EN5 3DJ
Visit: Monday to Friday, 10am-4pm, ground floor of Barnet Hospital, near the main entrance.

or

The Royal Free Hospital

The Patient Advice and Liaison Service for the Royal Free Hospital in the hospital's main reception. 10am to 4pm, Monday to Friday, except Wednesday, when the service is open from 10.30am to 4pm.

Tel: 020 7472 6446/6447 Mon – Fri 10:00am - 4:00pm (except Wed – 10:30am – 4:00pm)
Tel: 020 7472 6445 - 24 hour answer phone
SMS: 447860023323 (Deaf, hard of hearing and hearing impaired patients only)
Email: rf.pals@nhs.net

8. How will we use information about you?

We will only ask you for information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

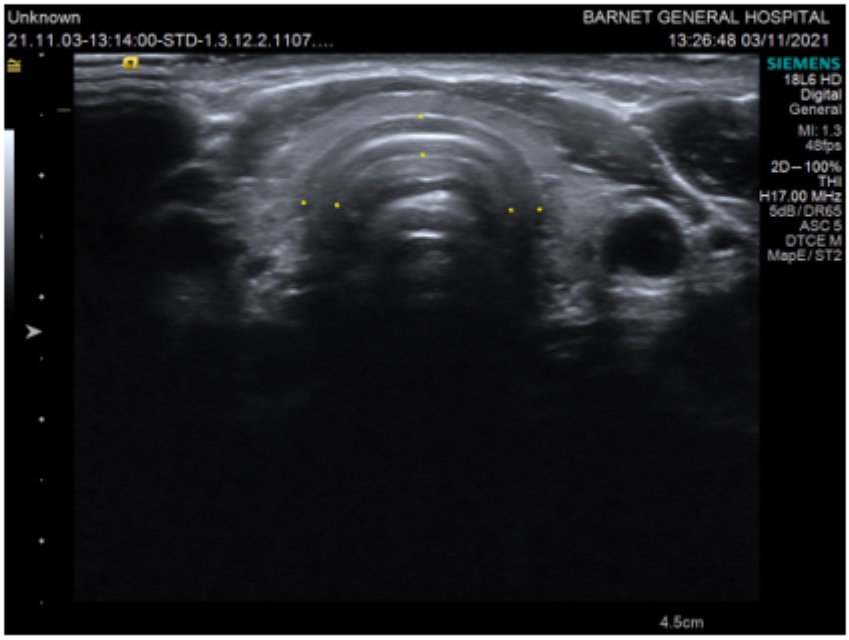
The information we collect will include your:

- hospital number
- name

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will only see anonymised data and will not be able to see your name or contact details. We will keep all information about you safe and secure.

J. Observational study measurement reference guide used at time of data collection

Reference Guide for Tracheal Imaging and Measurements



- Measure width at level of widest point of trachea
- Depth: 4.5 (adjust if nec.)
- Focus: at level of widest point
- Take measurements from LOWEST INTER-CARTILAGE SPACE WITH THYROID ISTHMUS PRESENT (aim for central white line to be thinnest, i.e. no cartilage present)
- dB – 5 (adjust as needed)
- THI on
- 16MHz

K. Observational study case report form

Data Collection Tool – Paper Version

1. Participant Study ID number: _____

2. Are you a patient or member of staff or both? Staff / Patient / Both (please circle)

3. Sex (tick as appropriate)

Male	
female	

4. What is your age (whole years)? _____

5. What is your ethnic group or background (circle as appropriate)?

White/White British	Mixed/multiple ethnic groups	Asian/Asian British	Black/African/ Caribbean/ Black British	Arab/ British Arab	Other
White English	White and Black Caribbean	Indian	Black African	Arab	
White Welsh	White and Black African	Pakistani	Black Caribbean		
White Scottish	White and Asian	Bangladeshi	Any other Black background		
White Northern Irish	Any other Mixed/ Multiple ethnic background	Chinese			
White British		Any other Asian background			
White Irish					
Gypsy or Irish Traveller					
Any other White background					

If 'Other' in any category please describe: _____

_____

L. Benchtop list of equipment

List of equipment:

3D printed airway models:

- straight tube trachea with tracheostomy stoma x 3 sizes
- biomimetic trachea with tracheostomy stoma x 3 sizes
- biomimetic trachea with no tracheostomy stoma x 3 sizes - ‘plain trachea’ for baseline data, same sizes as trial data tracheas)

Core trial tracheostomy tubes (cuffed)

- Portex BLU size 6, 7, 8, 9, 10
- Portex BLU size 8 with cuff removed

Comparator tracheostomy tubes (cuffed)

- Uniperc size 7
- Tracoe twist plus size 7
- Shiley size 6

Lung simulator

- Ingmar ASL 5000 wih laptop and ASL software interface

Circuit board and sensors

- Arduino Nano breadboard
- Differential pressure sensors x2 (lower to upper trachea, lower trachea to external environment)
- Flow sensors x2 (lower trachea + above upper trachea)

Tubing and connectors

- Ventilator tubing
- Connectors to connect vent tubing to ASL and trachea

Laptop and software

- Dell Latitude 5430 laptop
- Arduino Sketch data collection app
- Arduino visual data display app

M. Benchtop trials SOP

Trials SOP

Equipment set up

Insert TT in 3D printed trachea and fix in place (inflate cuff +/- tape and adhesive putty)

Ensure cuff is inflated or cuff deflated + one-way valve in situ as per trial conditions

Connect Q1 via ventilator tubing to ASL

Connect lower end of model trachea to flow meter Q1

Connect larynx to upper end of model trachea and flow meter Q2 to larynx via ventilator tubing

Connect differential pressure sensors to relevant pitot tubes on model trachea

Connect breadboard to laptop via USB port 1

ASL settings

Adult Normal setting

inspiratory rise time: 25

inspiratory release: 10

Tracheal resistance: 3L/min (minimum setting)

select Closed loop, constant Vt

Select lung compliance 50 (standard)

Data collection and visual display apps

Open Arduino app v3 and check Arduino Nano board selected

Open serial monitor and check data is being collected, then close

Open data visualisation app and set P0 while ASL off or pressure tubing disconnected

Reset data in data visualisation app frequently whilst waiting for ASL to achieve targets

While waiting for targets to be achieved write/update trial file label in Word window

Trial data collection

Set required values for RR and TV

Once within 1% of target TV, reset data in visual display app

Set one-minute timer

Note down inspiratory muscle pressure from ASL display (to compare with OM)

Trials SOP
Take photo of screens showing: ASL Realtime Analysis display, data visualisation app and Word trial label When timer goes, copy Word file label and use as trial file label, save in Data folder under today’s date Repeat steps for trial data collection with new values for independent variables

N. Processing of raw data in benchtop study

Processing of a trial file involved the following steps:

- rename columns to ‘t’, ‘Q1’, ‘Q2’, ‘DP1’, ‘DP2’
- use file name to generate new variables and populate values for trachea model, tracheostomy size/make, RR, TV and cuff/owv condition
- convert data to correct units to give work in Joules per 60 seconds (time in seconds, flow in metres cubed, pressure in Pascals)
- create new variables: Q3, flow through the TT; DP3, pressure difference across the larynx
- create QP variables for each component of system (flow x pressure differential through the TT, around the TT, through the laryx); also make a ‘whole system’ QP variable for comparison. Make these the same sign as flow so -ve sign indicates inhalation.
- select the central 30 seconds of data to standardise across trials and in case target not quite achieved at start of trial
- reset time to t=0 at start of selected section
- calculate area under the curve of QP plotted against time for each component of the system (airflow through the TT, around the TT, through the larynx), and for the system as a whole:
  - use interpolation to add points in line between data points and get points close to zero on y-axis
  - split data into inhalation/exhalation portions by splitting into positive/negative values of QP
  - calculate area under the curve using component approach and whole system approach

- mutliply area under the curve values for each component by two to obtain WOB for one minute

N.1. Loop script

Load packages

```
library(stringr)
library(readr)
library(dplyr)
library(tidyverse)
library(tidyr)
library(pracma)
```

Give address for data and create list of files and empty full results table

```
data_folder <- "./data/march_july_data/"

flist <- list.files(data_folder, pattern = ".dat")

full_results <- data.frame(ID = character(),
                           trachea_model=character(),
                           tt_type = character(),
                           RR = double(),
                           TV = double(),
                           cuff_owv_plain_trachea = character(),
                           AUC_tt_in = double(),
                           AUC_tt_ex= double(),
                           AUC_around_in = double(),
                           AUC_around_ex = double(),
                           AUC_la_in = double(),
                           AUC_la_ex = double(),
                           total_in = double(),
                           total_ex = double(),
                           AUC_whole_in = double(),
                           AUC_whole_ex = double(),
```

```
                              sum_inex = double(),
                              sum_whole = double(),
                              difference = double(),
                              stringsAsFactors = FALSE)
```

Open a for loop and write code to process data files, calculate outcome variable and add row to full results table

```
for(i in 1:length(flist)) {
  cat(sprintf("Loading file: %d, %s\n", i, flist[i]))

  if(exists("df")) {rm(df)}
  if(exists("results_tab")) {rm(results_tab)}
  if(exists("filename")) {rm(filename)}

  filename <- as.character(flist[i])

  df <- read.table(paste(data_folder, flist[i], sep= ""), skip = 1, col.names = c("t", "Q

  df <- df%>%
    mutate(Q1 = Q1/60000)%>%
    mutate(Q2 = Q2/60000)

  df <- df%>%
  mutate(Q3 = Q1 - Q2)%>%
  mutate(DP3 = DP2 - DP1)%>%
  mutate(QPtt = Q3*abs(DP2))%>%
  mutate(QPla = Q2*abs(DP3))%>%
  mutate(QParound = Q2*abs(DP1))%>%
  mutate(QPwhole = Q1*abs(DP2))%>%
  filter(t >= median(t)-15, t <= median(t) +15)%>% # select central 30 seconds
  mutate(t = t-t[1])

  #interpolate QP/t values for tt/around/la components
  #tt
  dfi_tt <- as.data.frame(approx(df$t, df$QPtt, n = 100000))
```

```
  dfi_tt <- dfi_tt%>%
  rename(t = x, QPtt = y)

  #around
  dfi_around <- as.data.frame(approx(df$t, df$QParound, n = 100000))

  dfi_around <- dfi_around%>%
  rename(t = x, QParound = y)

  #la
  dfi_la <- as.data.frame(approx(df$t, df$QPla, n = 100000))

  dfi_la <- dfi_la%>%
  rename(t = x, QPla = y)

  #whole system
  dfi_whole <- as.data.frame(approx(df$t, df$QPwhole, n = 100000))

  dfi_whole <- dfi_whole%>%
  rename(t = x, QPwhole = y)

  #calculate AUC
  tt_in <- dfi_tt%>% filter(QPtt <= 0)

tt_ex <- dfi_tt%>% filter(QPtt >= 0)

around_in <- dfi_around%>% filter(QParound<= 0)

around_ex <- dfi_around%>% filter(QParound>= 0)

la_in <- dfi_la%>% filter(QPla <=0)

la_ex <- dfi_la%>% filter(QPla >=0)

#calculate AUC for each component/section, by phase of breath cycle
```

```r
AUC_tt_in <- trapz(tt_in$t, tt_in$QPtt)

AUC_tt_ex <- trapz(tt_ex$t, tt_ex$QPtt)

AUC_around_in <- trapz(around_in$t, around_in$QParound)

AUC_around_ex <- trapz(around_ex$t, around_ex$QParound)

AUC_la_in <- trapz(la_in$t, la_in$QPla)

AUC_la_ex <- trapz(la_ex$t, la_ex$QPla)

total_in <- AUC_tt_in + AUC_around_in +AUC_la_in

total_in <- abs(total_in) #to get rid of negative sign

total_ex <- AUC_tt_ex + AUC_around_ex + AUC_la_ex

sum_inex <- total_in + total_ex

whole_in <- dfi_whole%>% filter(QPwhole <= 0)

whole_ex <- dfi_whole%>% filter(QPwhole >=0)

AUC_whole_in <- trapz(whole_in$t, whole_in$QPwhole)

AUC_whole_in <- abs(AUC_whole_in)

AUC_whole_ex <- trapz(whole_ex$t, whole_ex$QPwhole)

sum_whole <- AUC_whole_in + AUC_whole_ex

minute_inex <- 2*sum_inex # to get results for a whole minute

minute_whole <- 2*sum_whole # to get results for a whole minute
```

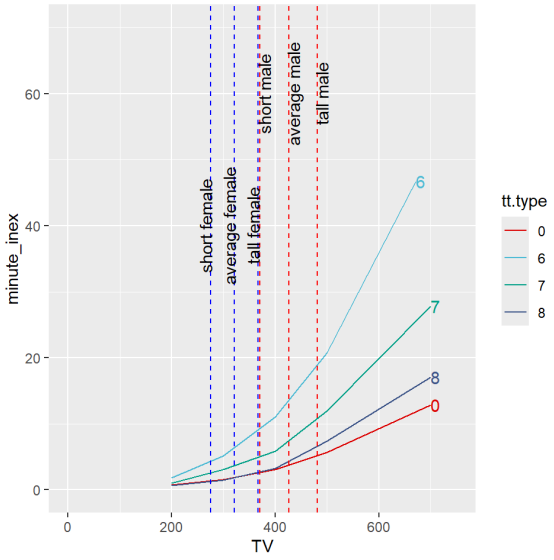
```
difference <- minute_inex - minute_whole #Difference in methods

results <- list(filename, AUC_tt_in, AUC_tt_ex, AUC_around_in, AUC_around_ex, AUC_la_in,

results_var <- c("Filename", "AUC_tt_in", "AUC_tt_ex", "AUC_around_in", "AUC_around_ex",

results_tab <- as.data.frame(results, col.names = results_var)

results_tab <- results_tab%>%
  mutate(ID = Filename)%>%
  separate_wider_delim(Filename, delim = "_", names = c("trachea model", "tt type", "RR",
  select("ID", "trachea model":"difference")

full_results <- rbind(full_results, results_tab)
}
```

Create csv file of results

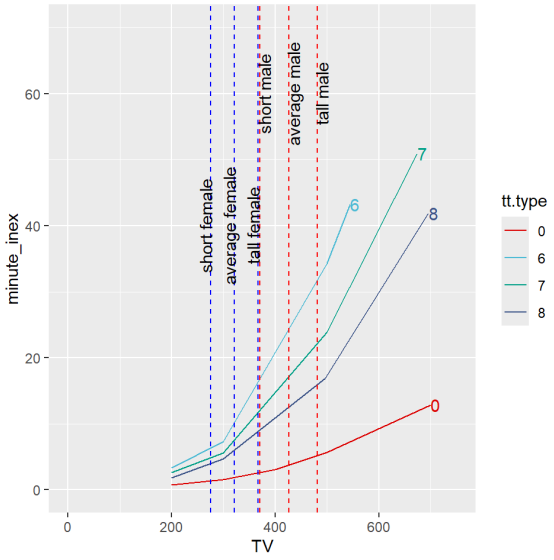
```
write.csv(full_results, "./data/Benchtop_results_march_july.csv")
```

O. Work of breathing with lung-safe tidal volumes

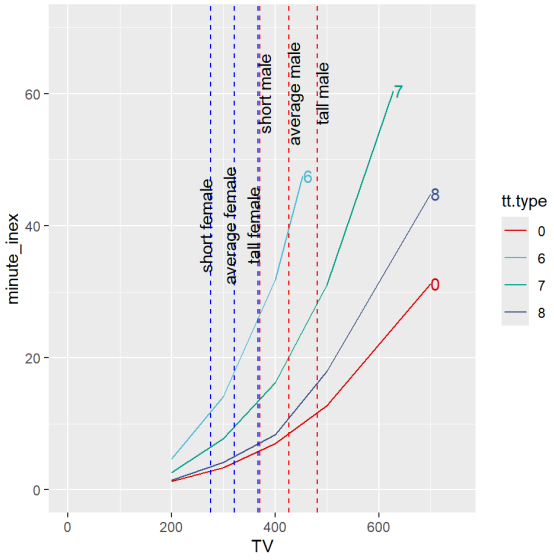
The following figures show lung-safe tidal volumes for short, average and tall males and females superimposed over plots of work of breathing against tidal volume stratified by by TT size.



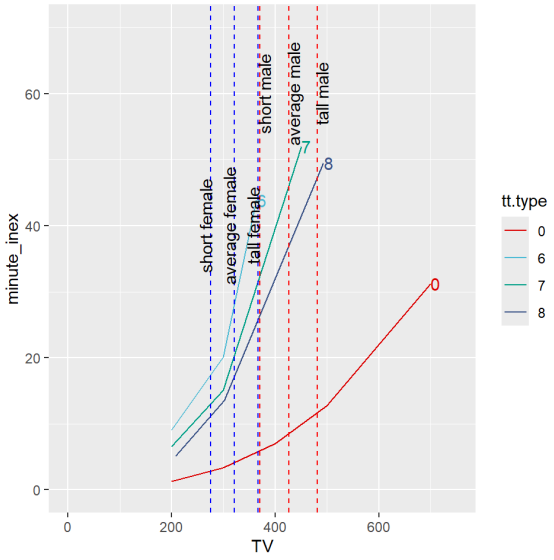
(a) Small trachea, RR 24, cuff inflated



(a) Small trachea, RR 24, cuff deflated, OWV

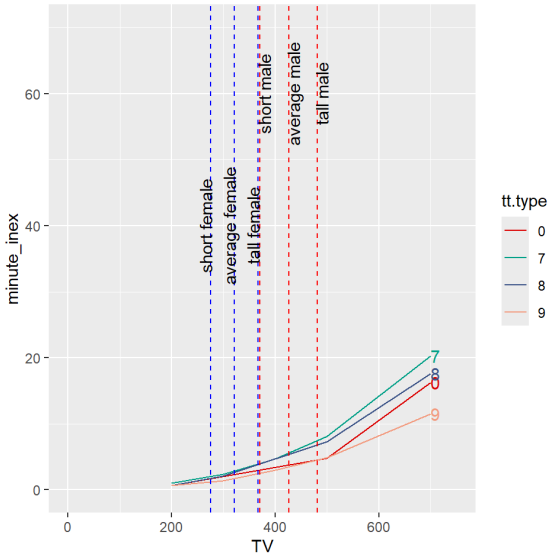


(a) Small trachea, RR 36, cuff inflated

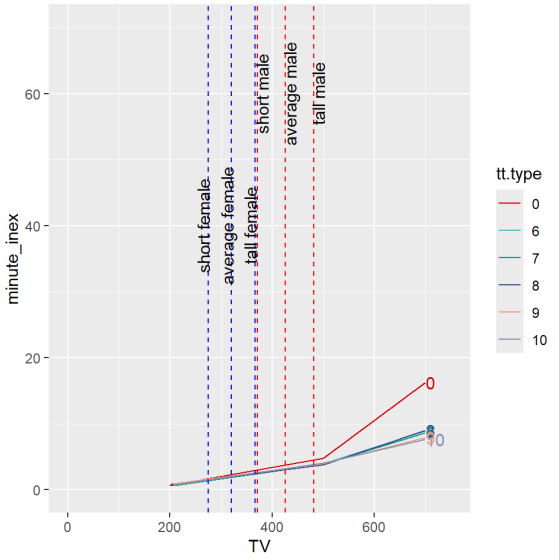


(a) Small trachea, RR 36, cuff deflated, OWV

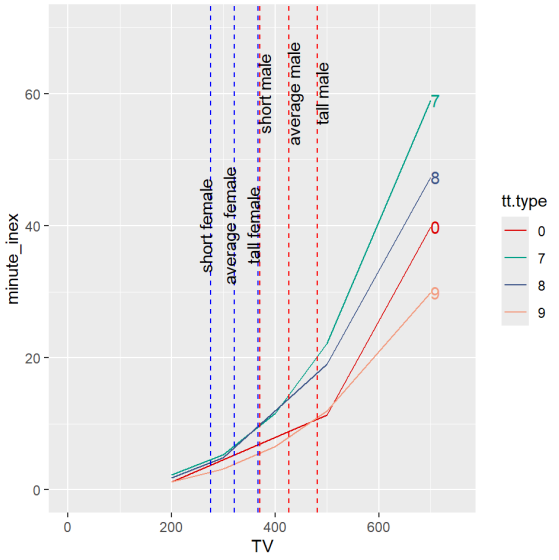
Figure O.4.: Small trachea



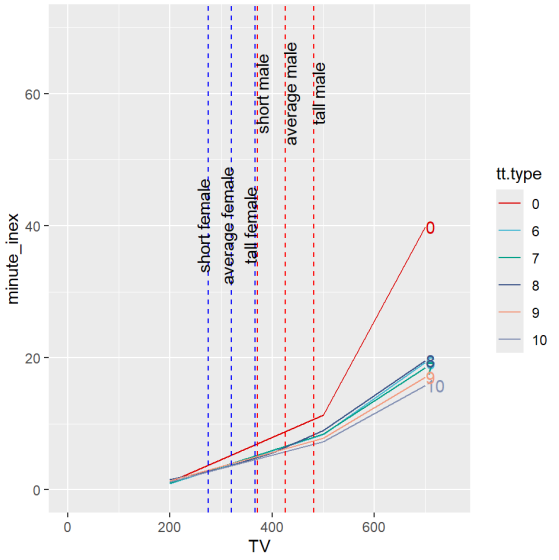
(a) Large trachea, RR 24, cuff inflated



(a) Large trachea, RR 24, cuff deflated, OWV

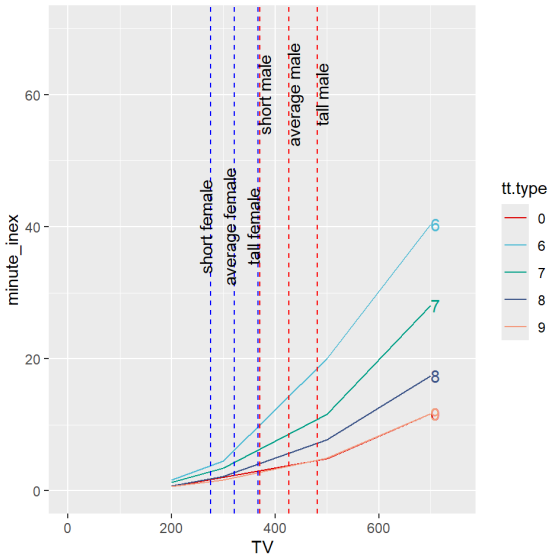


(a) Large trachea, RR 36, cuff inflated

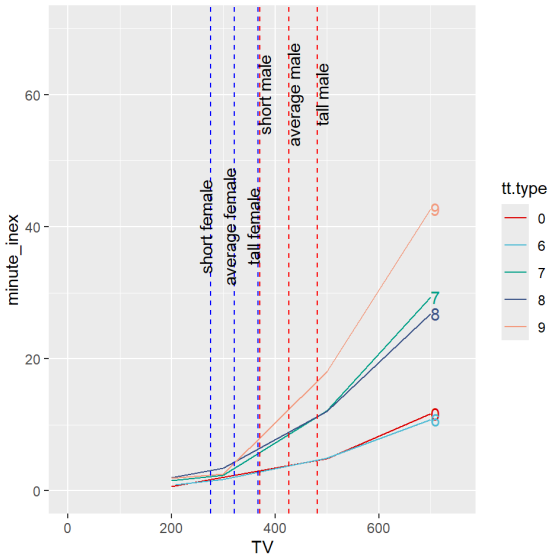


(a) Large trachea, RR 36, cuff deflated, OWV

Figure O.8.: Large trachea



(a) Medium trachea, RR 24, cuff inflated



(a) Medium trachea, RR 24, cuff deflated, OWV

P. Focus Group Moderator Guide

Moderator Guide

Choosing the right size tracheostomy tube for adults in ICU: barriers and facilitators to changing practice

- Welcome
- Introductions
- Housekeeping
- Presentation of research findings

Focus Group Questions

[THESE ARE EXEMPLAR QUESTIONS AND MAY BE AMENDED.]

Based on COM-B model of Behaviour Change Theory: Capability – Opportunity – Motivation

How is the size of tracheostomy tube selected for patients where you work?
Prompt/follow-up:

- What influences the decision?
- Do clinical issues affect decisions?
- Does staffing affect decisions?
- Does equipment supply affect decisions?
- When does the decision get made?
- Who makes the decision?

How do you think decisions should be made?

- What factors should be taken into account?
- What factors should take priority?
- What are your colleagues thoughts (same/other profession)?

How would you implement a change in the method of tracheostomy tube size selection where you work?
Prompt/follow-up:

- Would change be achievable where you work? Why?
- What do you think the attitudes of staff would be towards changing?
- What issues might there be in trying to change decision-making?
    - Equipment supply
    - Tracheal assessment
    - Training
- What would have to change?

How important do you think it is to select the right size tracheostomy tube?
Prompt/follow-up:

- How important is it to your colleagues?
- What are the potential impacts of decisions?
- Where does it sit in the bigger picture of the ICU context?

Summary

Summarise key points and invite last comments

Figure P.1.: Moderator Guide for Focus Groups

Q. Focus Group Participant Information Sheet

NHS
Royal Free London
NHS Foundation Trust

Study Title: **Choosing the right tracheostomy tube for adults in ICU: size matters**

Participant Information Sheet

Introduction

We would like to invite you to take part in our research study. This participant information sheet provides information about the study to help you decide if you would like to continue to participate. It is important that you understand why the research is being done and what it involves. Please feel free to contact the principal investigator (contact details below) if you require any further information after reading this sheet.

1. What is the purpose of this study?

This study is part of a larger PhD project. The aim of the overall project is to provide evidence to help healthcare staff choose the best size tracheostomy breathing tube for patients in intensive care.

The aim of this study is to gather the views of ICU clinicians on the research undertaken so far, and to identify barriers and facilitators to changing clinical practice in sizing tracheostomy tubes in line with our findings. It is hoped that the results of this study will help shape guidance for clinicians and inform strategies to implement changes in practice.

2. Why am I being asked to take part in this research??

You have been approached to participate in this study because you are a healthcare professional working in a UK ICU and have post-graduate experience working with ICU patients with a tracheostomy.

3. Do I have to to take part?

No, participation is voluntary. If you do not wish to take part that is OK. If you do decide to take part you are free to withdraw at any time, without giving a reason, by informing the interviewer directly, or by contacting the research team. If you do withdraw, the data collected up until this point will be kept and analysed.

4. What will happen to me if I agree to take part?

If you agree to participate in a focus group we will collect some information including your:

- Name
- Contact details
- Profession
- Banding/Grade
- Number of years of experience
- Geographical region (e.g. county/city/London borough)

The primary investigator will then contact you with further details including the date, time and joining instructions for afocus group. You may be asked about your availability for a face-to-face focus group. The focus groups may be uni- or multi-professional and consist of doctors, surgeons, nurses, therapists or advanced critical care practitioners. In addition, a member of the project Patient and Public Involvement and Engagement group may attend the focus group to enhance their understanding of the research and foster two-way relationships between researchers and PPI/E. PPI/E feedback will be incorporated as appropriate in the findings. We will record and transcribe discussions to support data analysis. Please let the primary investigator or research team know if you have any specific individual needs (e.g. communication difficulties) which mean that the focus group will need to be adapted in some way.

During the focus groups we will identify participants by first name only. Participants will be asked not to disclose the content of focus group discussions or details of attendess outside the focus group setting. Questions will focus on feedback on the previous work in this project and thoughts on barriers and facilitators to implementing change in practice. It is anticipated that the focus group will last no longer than 90 minutes.

A transcript will be created for each focus group. Participant comments will be de-identified, with each participant receiving a participant ID code based on their profession, e.g. Nurse 1. Your name, location, or other identifiable personal information will not appear anywhere on the transcript. We may give details of seniority to give context to the reader.

5. What are the possible disadvantages and risks of taking part?

There are no identified risks of direct physical or psychological harm from taking part in this study, but the impact on individual clinicians is considered. It is acknowledged that participating in this study could cause you to have concerns about your own or others' practice. Participants may hold opposing views which could present a source of conflict. Care will be taken in the development of the focus group questions to keep this an exploratory, information gathering study, and participants will be requested to maintain courteous communication throughout the focus groups. Where junior and senior professionals from the same geographical area enrol, they will be invited to different focus groups to promote free discussion. We cannot guarantee confidentiality in a focus group discussion setting, however, attendees will be asked not to disclose the identity of other attendees or content of discussions outside of the focus groups.

In the event of a participant disclosing something which indicates any malpractice, gives evidence of any harm to patients or staff, or discloses any incidents relevant to the criminal justice system, then the chief investigator would need to disclose this, and action relevant local reporting procedures by contacting the participant's direct line manager. Additionally, should you have any concerns or issues with anything that arises during the focus group, we advise you to seek support from your local line manager, professional body or Intensive Care Society wellbeing resources as appropriate.

6. What are the possible benefits of taking part?

There are no anticipated immediate benefits to taking part in this study, however this project will add to the evidence base for this patient group and has the potential to inform future practice and further

research into this topic. Participating in this study will allow you the opportunity to express your views and experiences on this subject and contribute to improving practice within ICU.

7. What if there is a problem?

Every care will be taken in the course of this study. However, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of the research team, please contact the Primary Investigator, Professor Daniel Martin via email at [redacted]

Chairs of the UCL Research Ethics Committee at ethics@ucl.ac.uk .

8. What will happen to information collected about me during the study?

We will only ask you for information that we need for the research study. Only the direct research team or regulatory bodies who may audit the work will have access to your name or contact details. People will use your research data to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will only see de-identified data. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the de-identified data so we can check the results. We will destroy any personal data such as contact information following transcription and write our reports in a way that no-one can work out that you took part in the study. We may share your de-identified information with other researchers to support future ethically approved research for patient benefit.

All interviews will be conducted by PhD candidate Helen Newman and Professor Natalie Pattison. Focus groups will be recorded using an encrypted digital voice recorder and online meeting software as appropriate. Recordings will be stored on a secure university network. Transcription files will identify individuals only by study code. The recordings and de-identified transcripts will be analysed by the research team.

There will be no identification of individual participants or their workplaces in any of the results or reports written about the study and any identifiable features will be removed from any direct quotes taken from the interviews.

It is intended that the results will be written up for publication in a peer reviewed professional journal, disseminated through special interest professional groups and presented at appropriate conferences and seminars.

A summary of the results of this research will be made available to all participants at the end of the study on request.

9. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep the information that you have already contributed; due to the nature of a group interview, it will not be possible to redact individual quotes.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the focus group data we hold about you. We will destroy any personal data such as contact information following transcription.

10. Local Data Protection Privacy Notice

Notice:
The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows:
- Name
- Contact details

The lawful basis that would be used to process your *personal data* will be 'performance of a task in the public interest'.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

11. Who is sponsoring, organising and funding the research?

University College London (UCL) is the sponsor for this study. The Chief/Primary Investigator for the study is Professor Daniel Martin. This study has been funded by a National Institute for Health Research (NIHR) Clinical Doctoral Research Fellowship (CDRF), awarded to Helen Newman.

12. Who has reviewed the study?

The study has been peer reviewed by the NIHR CDRF Selection Committee and the UCL Division of Surgery (Research Ethics ID: 24511/001). UCL's Research Ethics Committee has approved this study.

Contact details:

If you are happy to proceed, please use the QR code below on a smart phone or email Helen Newman at helen.newman.20@ucl.ac.uk with 'Trache Study' in the subject line. Please indicate your preferred contact email address.

Research Contact: Helen Newman
Job Title: Clinical Specialist Speech and Language Therapist – Critical Care
Contact Address: Woodlands Unit, Level 0, Barnet Hospital, Barnet EN5 3DJ
Telephone: 02082164720 (work)
Email: Helen.newman.20@ucl.ac.uk

Focus Group Participant Information Sheet

R. Thematic map of focus group study descriptive themes

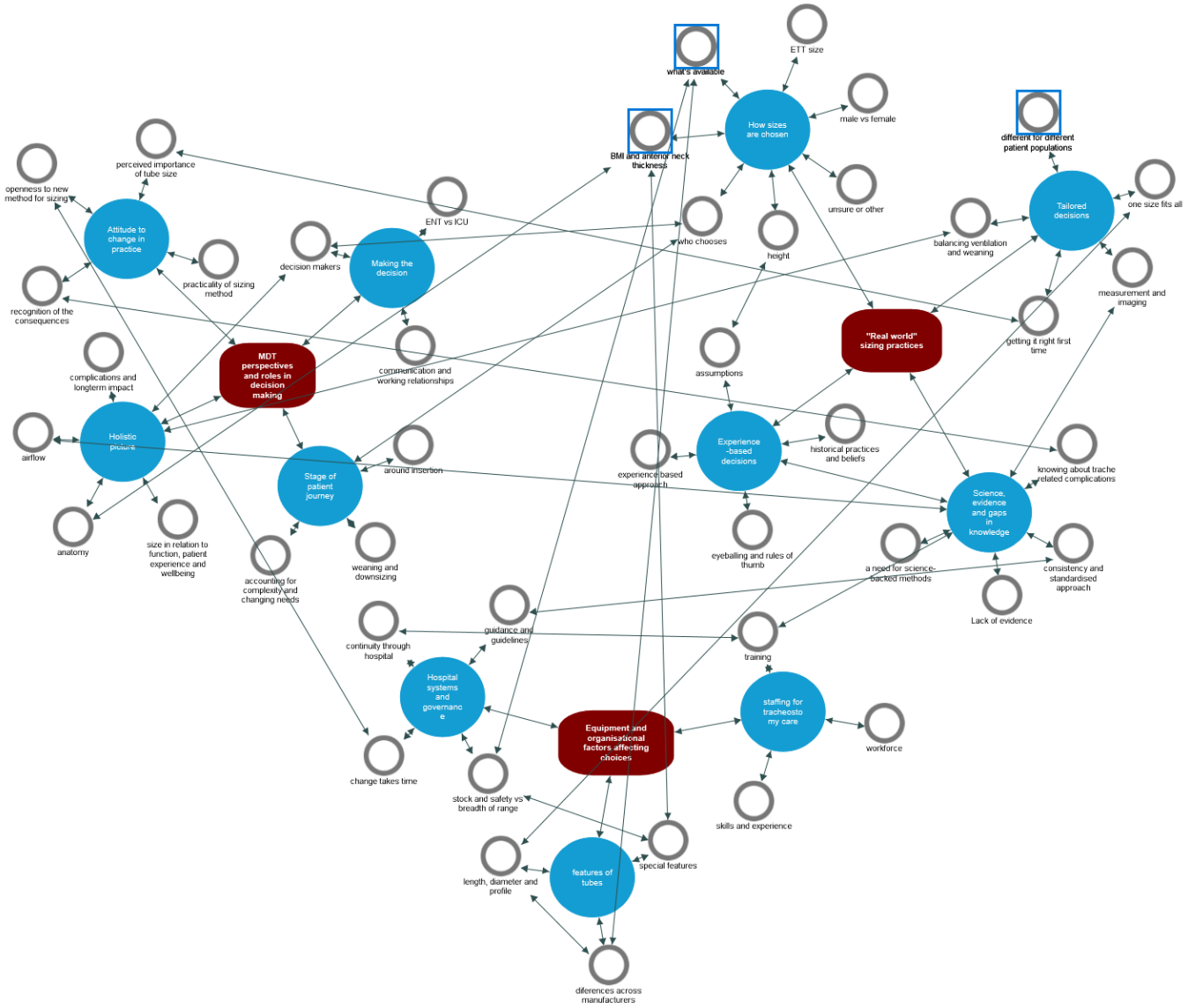


Figure R.1.: Thematic map of focus group descriptive themes including code level

S. Thematic map of integration findings

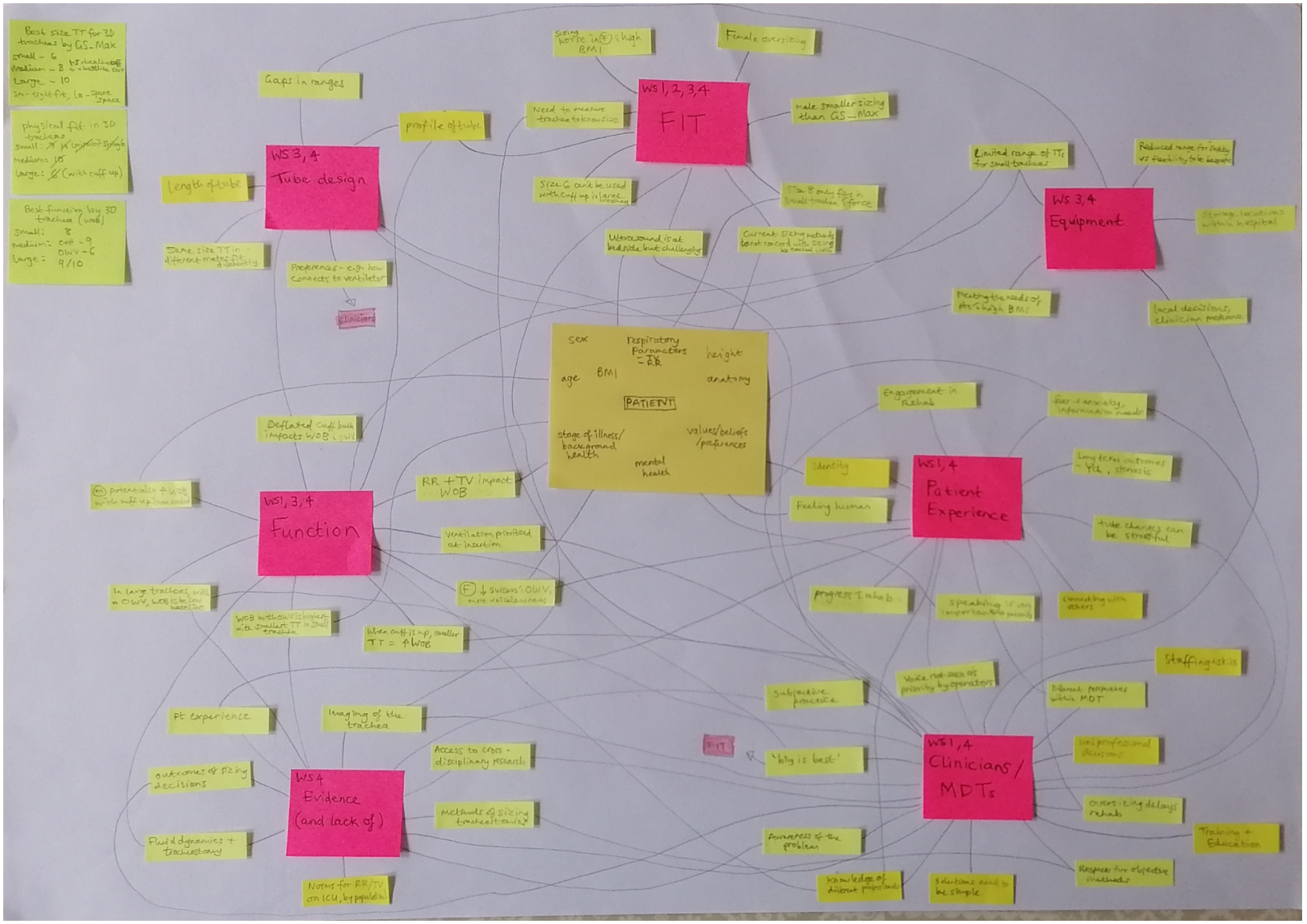


Figure S.1.: Thematic map of key concepts in decision making around tracheostomy tube size for adults in ICU

T. Summaries of workstream findings matrices

T.1. Metasynthesis and observational study + cadaver study

Findings of these two studies drew together information on what matters to patients with the outcomes of current TT sizing methods. The interaction of the metasynthesis and observational study findings indicated that females and particularly those with high BMI were more likely to receive a TT that was too large and therefore more likely to experience voicelessness. The metasynthesis highlighted the depth of associated impacts on all aspects of care and wellbeing. For males, who were more likely to receive a TT that was smaller than the maximum recommended size, there were potentially negative consequences for WOB with an inflated cuff and on delivery of mechanical ventilation.

T.2. Metasynthesis and benchtop study

The matrix of WS1 and WS3 findings indicated that patients with smaller tracheas were more likely to experience voicelessness and the associated impacts on all aspects of care and wellbeing due to the high WOB when attempting to use a OWV. Since females have on average smaller tracheas, this again suggested that females were more likely to experience voicelessness than males, though this might be offset to some extent by females having lower tidal volumes which would reduce WOB. Equally those with low respiratory rate would be less affected since flow was also shown to impact WOB.

T.3. Metasynthesis and focus group study

The matrix of WS1 and WS4 findings confirmed that methods leading to over-sizing of TTs in females (in WS2), were common practice. The focus groups expanded on this by

highlighting the divergence in the perspectives and priorities of patients and MDT member professions, with patients and therapists giving higher priority to having a voice than ICU doctors, and head and neck or specialist ENT surgeons more likely to choose smaller TTs to avoid tracheal trauma. Since TT size decisions were almost exclusively made by ICU doctors, the inference was that decisions might frequently not meet patient priorities. The focus groups also highlighted lack of awareness among ICU doctors of patient experience and priorities, but also that knowledge of patient experience was likely to influence doctors' practice, if this information was disseminated and easily accessible. Data on equipment, manufacturing issues and stock availability from the focus group study and knowledge of patient priorities from the metasynthesis led to the inference that these external factors could impact the ability to deliver care targeted to achieve the best patient centred outcomes.

T.4. Observational study + cadaver study and benchtop study

The matrix of WS2 and WS3 suggested that females and especially those with high BMI, would likely have lower WOB when the cuff was inflated if clinicians used current methods of TT sizing, since these tended to oversize for females. However, it indicated that females, especially those with a high BMI, were likely to experience higher WOB with the cuff deflated and a OWV due to the oversizing of TTs in females under current practices. It also suggested a risk for those with a small trachea of clinicians attempting to insert TTs that were too large to fit in the trachea. In contrast, for males it suggested they might be more likely to experience higher WOB than necessary when the cuff was inflated and lower WOB than if using gold standard sizing methods when using a OWV, since current sizing methods tended to recommend smaller than the M-BP-Max size for males.

Findings were further interrogated to explore how the M-BP-Max method of sizing used in the observational study mapped onto findings in the benchtop experiment. @tab-tt-3dmodel-match shows compatibility of TTs and trachea models according to M-BP-Max, including recommended size for each trachea and details of TT dimensions. The last two rows show how well the recommended TTs performed in terms of WOB in the benchtop study, both with the cuff inflated and with the cuff deflate and a OWV in place. As can be seen, only the size 6 TT would be inserted in the small trachea according to M-BP-Max and this TT generated the highest WOB in both cuff trials and OWV trials in the small trachea. The size 8 was the largest TT that would be inserted in the medium trachea using M-BP-Max and it generated the second lowest WOB in cuff and OWV trials in the

Table T.1.: Table to show fit of tracheostomy tubes in model tracheas following M-BP-Max and WOB performance with an inflated cuff or deflated cuff and one-way valve

TT size	OD	Cuff diameter	Min trachea size	Small (13 mm)	Medium (17 mm)	Large (22 mm)
6	9.2	20	12.4	yes	yes	yes*
7	10.5	24	14	no	yes	yes
8	11.9	30	15.9	no	yes	yes
9	13.3	30	17.7	no	no	yes
10	14	30	18.7	no	no	yes
			Best fit	6	8	10
		Performance	Cuff	worst	2nd best	joint best
			OWV	worst	2nd best	joint best

*cuff too small to occlude trachea

medium trachea. All TTs fitted the large trachea (though the size 6 could not be used with an inflated cuff as it was too small), and the size 10 performed well with the cuff up and with a OWV. Looking more closely at the relationship between TT dimensions and tracheal inner diameter, the small trachea was close to the minimum width necessary for a size 6 TT (+0.6 mm), whereas there was a much wider margin between the large trachea and the minimum tracheal diameter for a size 10 TT (+3.3 mm), i.e. the small trachea could only accommodate a slightly larger TT than a size 6, which would improve WOB, whereas the large trachea could take a substantially larger TT than a size 10 but was already generating below baseline WOB. This suggests that the M-BP-Max method of sizing may not be suitable across all trachea and TT sizes; in the large trachea there was no need for a TT with a diameter 3/4 of the large trachea's diameter, yet a TT close to 3/4 the diameter of the small trachea appeared to suit neither cuff nor OWV scenarios.

However, as highlighted in Section 7.2 and in Chapter 5, RR and TV are also important factors in WOB and lower RR and/or TV could mitigate the high WOB seen in the size 6 TT in the small trachea. The following vignettes present cases based on participants in the observational study to explore this idea further.

T.5. Observational study + cadaver study and focus group study

The findings for WS4 confirmed the use of sex, height, and BMI were the basis of many sizing decisions in practice, supporting the use of the comparator methods used in WS2. Shoulder width was not mentioned though phrases such as 'patient size' and 'smaller patients' were used in relation to sizing methods in two focus groups. Oversizing was highlighted in both workstreams, though there was discordance in the frequency of occurrence found in each. WS2 found that oversizing occurred in 27-40% of female cases, depending on sizing method and in males between 16-19% of cases. In WS4 there were differences in perceived frequency of oversizing across professions, with ICU doctors

feeling that problems were rare. Therapists and ENT surgeons described oversizing as a common problem but still reported downsizing was not needed most of the time. This may be explained by the discussions in Section T.4 around suitability of M-BP-Max across trachea sizes and the impact of RR and TV on WOB. Perhaps oversizing is not detected often in males as they are less likely to receive an oversized TT using current sizing methods and because it is impossible to oversize in those with a large trachea: there are no TTs with bigger diameters than 3/4 the diameter of the large trachea, patients with a tracheal width of 18.7 mm or above can accommodate the largest (size 10) TT. In females, lower average tidal volumes may keep WOB levels low enough in many to tolerate using a OWV.

There was greater dissonance between workstreams on the incidence of 'undersizing', or selecting TTs smaller than recommended using M-BP-Max. In WS4, all participants were conscious of the theoretical risks of undersizing in terms of impact on WOB with an inflated cuff, secretion clearance and ability to create a cuff seal for ventilation and airway protection. However, frequency of undersizing was described in terms of 'a couple of cases' and 'a patient' who required exchange of TT to a larger size. This contrasts with WS2's finding that 19-31% of females and 45-57% of males were recommended tubes that were smaller than recommended by M-BP-Max when using current sizing methods. This suggests flaws in M-BP-Max, which may be explained again by the impact of RR and TV on WOB. RR and TV did not feature in sizing methods used in WS2. Sizing methods in WS2 were primarily oriented towards achieving good 'fit' of TT in the trachea. Likewise, initial discussions of TT sizing in FGs were oriented to achieving good fit, with reference to supporting ventilation but no attempt to map patient specific respiratory parameters to TT size. As discussions evolved, participants discussed respiratory parameters more, for example differences across groups of patients with neurological disorders or head and neck cancer versus those with respiratory failure, and linked these to a potential need for different approaches to sizing decisions. In two FGs clinicians also linked sizing decisions to timing of tracheostomy, suggesting that if an intubated patient required very high levels of ventilatory support (and consequently a larger airway tube), they may not be ready for TT insertion. However no participants discussed mapping TVs to TT until after watching a video summary of previous workstreams (WSs 1, 2 and 3). Following the summary of the benchtop study, an ICU doctor suggested that running trials of the maximum TV through the small trachea might have been an unfair test, comparing it to a horse breathing through a human trachea:

> 'a horse has got a massive trachea but it's also got a massive pair of lungs

and if you try to breath with a horses lungs via a human trachea, you're going to end up in problems'

The implication is that smaller size TTs might be suitable for those with smaller TVs if they also have smaller lung volumes. Extending this to RR and the point above about different patient groups, those with lower RRs for example in spinal cord injury or head & neck cancer may experience lower airflows and consequently lower WOB and be likely to tolerate smaller TTs better than those with high RR.

The concept of tracheal trauma in relation to sizing decisions was discussed in all FGs, with participants mainly linking oversizing but also undersizing (due to positioning of the tip of the TT against the posterior tracheal wall), to tracheal stenosis and poorer longer-term outcomes. The observational study was not designed to address tracheal trauma, but the high rates of oversizing in females might suggest higher risk of stenosis in this group. A poor awareness of the incidence of stenosis and confidence in current sizing methods among ICU doctors identified in WS4 might sustain the use of sizing methods used in WS2. Equally, WS2 showed that height could not be used to obtain tracheal diameter, though most participants (all professions), in WS4 assumed that it could, again sustaining the use of this method in practice.

WS2 found BMI could not predict tracheal width and led to the high rates of oversizing in females and highest rates of smaller than recommended TTs in males. In WS4, participants outlined a more complex picture of the relationship between BMI and TT sizing in practice. For patients with high BMIs clinicians wanted to reduce the chance of accidental dislodgement of TTs by ensuring a long enough TT to traverse anterior neck tissues and sit well in the trachea. This was achieved through the use of adjustable flange or longer TTs where available, but when not available clinicians reported upsizing was sometimes the only option to get the desired length. This detail was not reflected in WS2's data, where sizing decisions were only based around a standard range of TTs, but might explain the poor outcomes of sizing by BMI in WS2. Additionally, participants only spoke of factoring in BMI to sizing decisions when BMI was high, not when BMI was low, whereas in WS2 the BMI sizing method was applied to all participants, which may explain the mismatch of very high rates of selecting smaller tubes in reported in WS2 and the absence of suggestion in WS4 that males were frequently given TTs that were too small in practice.

In WS4, all professions felt measurement of the airway would be helpful in TT sizing and improve objective decision making. They also felt any proposed TT sizing method needed to be easy to learn, quick and practical. Ultrasound machines are readily available on

ICU and even used during TT insertion, however the work presented in Chapter 3 shows ultrasound of the airway is challenging, dependent on individual anatomy, and prone to mis-interpretation.

T.6. Benchtop study and focus group study

In focus groups, ICU doctors felt bigger tubes were indicated at insertion since these would allow easier ventilation, and the benchtop study confirmed that WOB increased as TT size decreased, regardless of trachea size. However, the benchtop study also gave information on physical fit and showed that only the size 6 and 7 TT could be inserted in the small trachea without force. In the absence of tracheal measurement to guide TT sizing and tendency of current methods to oversize for females, this suggests that current practices would disadvantage females through increased risk of tracheal trauma from insertion of larger TTs. As also described in the previous section, the specific respiratory requirements of the individual might also mean that larger tubes were not necessary, but there was no evidence in FGs that an individuals RR and TV are currently considered at time of insertion.

Findings were less convergent when comparing benchtop findings from OWV trials with FG findings. FG participants assumed that when using a OWV WOB would be easier with a smaller TT. However, as seen in Chapter 5, this depended on size of trachea. In the small trachea, bigger TTs were best in terms of WOB, though as above, might not fit well in the trachea. In the medium trachea, the smallest TT did produce the lowest WOB and the largest caused the highest WOB but sizes in between were reversed in order. In the large trachea, any TT produced lower than baseline WOB. Overall therefore, as seen in Table T.1 showed that a ‘big is best’ approach did work for the the large trachea but for the medium trachea this meant the worst performance when using a OWV. In a small trachea, the biggest TT might have generated the lowest WOB but risked damaging the trachea. Again, this suggests females are disadvantaged under current approaches to TT sizing.

Combining findings of WS3 and WS4 provided insights on performance across TT brands. Some participants reported improved outcomes for patients following transition to the Tracoe Twist Plus (TPP) TT, a model that offers thinner walls and longer length than standard TTs. In WS2, trials of a size 7 TTP generated slightly higher WOB than the size 8 Portex in cuff trials but substantially lower WOB in OWV trials. Clinicians particularly liked the longer tube since it reduced the need for adjustable flange TTs, which were generally not

popular. This appears contradictory to benchtop findings, which indicate better performance of the Uniperc adjustable flange TTs than the size 8 Portex TT in both cuff and OWV trials. However, this divergence in findings might be explained by the fact that no benchtop data were available for the Uniperc TT in the small trachea as it could not be inserted in it. This was mainly due to the straight distal end of the Uniperc TT compared to the curved profile of the size 8 Portex, since both TTs had similar outer diameters. The size 7 is the smallest in the Uniperc range, which suggests that if Unipercs were inserted in patients with a small trachea in clinical practice they might cause trauma to the posterior tracheal wall and sit poorly in the trachea. The most at risk group would be females with a high BMI, since females have on average smaller tracheas and the presence of significant anterior neck tissue might mean clinicians opt for an adjustable flange TT, dependent on local stock choices and availability. Findings from WS4 and WS3 converged on the concept of inter-manufacturer differences impacting patient outcomes. WS4 data expanded on this to include the influence of clinician preference for specific brands or features and the need to balance breadth of choice with restricting range for ease of training and to ensure staff familiarity with equipment.

U. Vignettes

Case discussions illustrating the application of benchtop data to participant cases from the observational study were based on the following cases. Plots show WOB in TT sizes recommended by M-BP-Max and other methods.

Case one: average-tall height female, small trachea. Recommended TTs by sizing method: size 6 for M-BP-Max; 6, 7, or 8 by other sizing methods.

At normal RR, there was relatively little difference in WOB across these sizes. Rises in WOB progressively increased with higher RR and/or TV, with greater increases in the smaller TTs. A OWV further increased WOB with greater effect in size 7 and 8 TTs, though the highest WOB as still seen in the size 6 and lowest in the size 8. The highest WOB while restricting TV to 6 mL/kg IBW was just under 30 J/min with an inflated cuff and just under under 45 J/min with a OWV, both in the size 6 TT.

Case two: short-average height female; small trachea. Same range of TT sizes were recommended as Case 1, though recommendation by height was lower and by shoulder width or BMI were higher.

Since this participant was shorter, lung-safe TVs were smaller and WOB consequently lower. The highest WOB when restricting TV to 6 mL/kg IBW was just under 20 J/min with the cuff inflated and just under 30 J/min with a OWV, both in the size 6 TT.

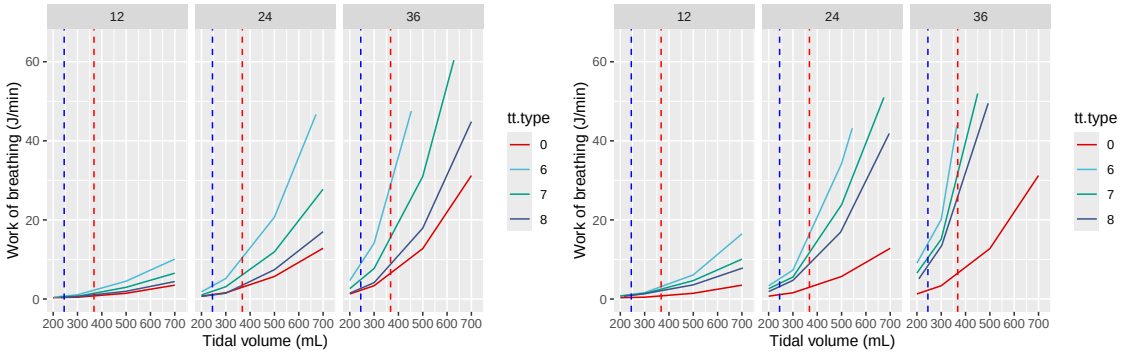
Case 3: tall male, medium size trachea. M-BP-Max recommendation - size 8. Other methods - size 8 or 9.

At a RR of 12, WOB remained below 5 J/min, with the cuff up or with a OWV. At higher RRs, WOB was highest with a size 8 when the cuff was inflated but highest with a size 9 with a OWV. The highest WOB when restricting TV to 6 mL/kg IBW was just under 20 J/min with the cuff inflated (size 8) and just under 50 J/min with a OWV (size 9).

Case 4: average height male; large trachea. M-BP-Max - size 10. All other methods - size 8 (size 9 data plotted as size 10 not trialled with the cuff inflated; size 10 expected to produce lower WOB than this).

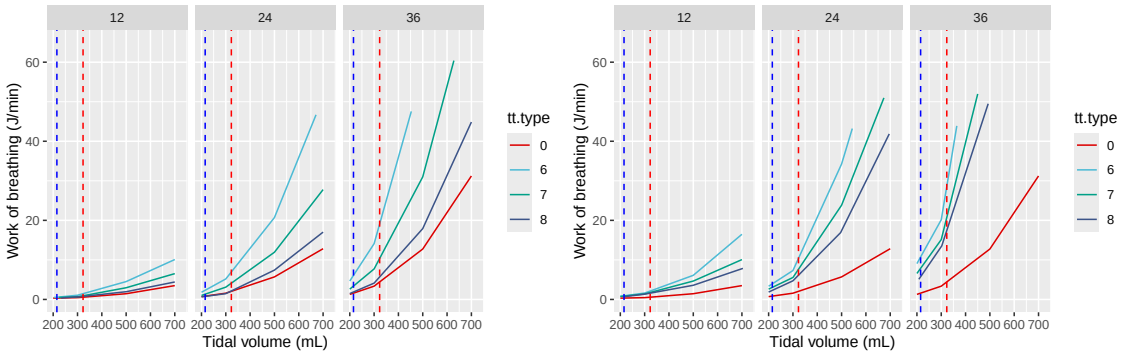
As this participant was shorter, the recommended TVs for lung-safe ventilation were lower, but a larger tracheal diameter allowed a larger TT. The highest WOB within lung-safe TVs was just over 15 J/min with the cuff inflated (size 8) and just over 5 J/min with a OWV (size 10), which was below baseline.

At normal respiratory rate, WOB remained below 5 J/min for all combination of variables in all cases.



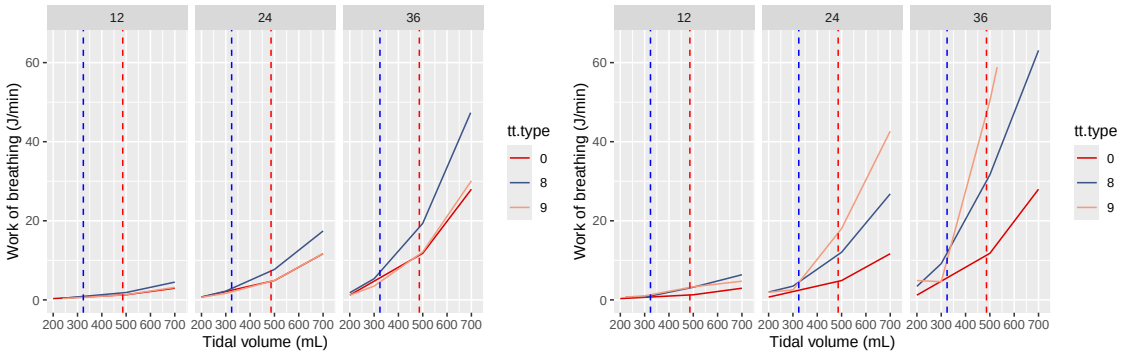
(a) Case 1, cuff up, M-BP-Max = 6

(b) Case 1, cuff down + OWV, M-BP-Max = 6



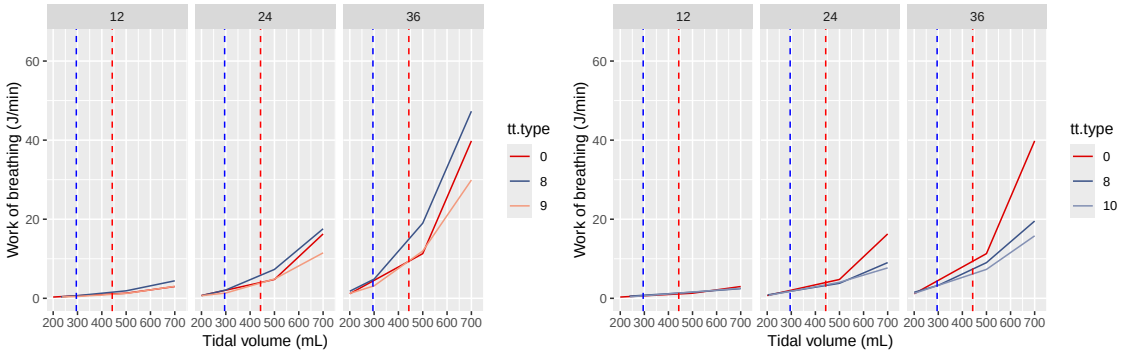
(c) Case 2, cuff up, M-BP-Max = 6

(d) Case 2, cuff down + OWV, M-BP-Max = 6



(e) Case 3, cuff up, M-BP-Max = size 8

(f) Case 3, cuff down + OWV, M-BP-Max = size 8



(g) Case 4, cuff up, M-BP-Max = 10

(h) Case 4, cuff down + OWV, M-BP-Max = 10

Figure U.1.: Outcomes of sizing recommendations for cases from observational study. Red/blue dotted lines = limits of tidal volumes in lung protective ventilation based on 6 mL/kg or 4 mL/kg of IBW. Case 1 = average height female, case 2 = short-average female, case 3 = tall male, case 4 = average height male