The ACoUSTiC Study

Exploring the potential benefits of Above CUff VocaliSation in TraCheostomy: communication, swallowing, decannulation, and cost savings

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Intellectual property rights and publication statements

The candidate confirms that the work submitted is her own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

Details of candidate contributions to manuscript publications relating to the thesis:

i. **Mills, C.S., Michou, E., King, N., Bellamy, M.C., Siddle, H.J., Brennan, C.A. and Bojke, C. 2022. Evidence for Above Cuff Vocalization in Patients With a Tracheostomy: A Systematic Review. *The Laryngoscope*. 132(3), pp.600–611.**

The candidate (Mills, C.S.) was responsible for planning and designing the study, completing the analysis, and developing and finalising the manuscript. Co-authors provided supervisory feedback and oversight. King, N., provided feedback on the search strategy. Michou, E., undertook secondary screening of abstracts and full texts. The research presented in this manuscript is included in Chapter 3 of the thesis.

ii. **Mills, C.S., Michou, E., Bellamy, M.C., Siddle, H.J., Brennan, C.A. and Bojke, C. 2022. Determining the Prevalence, Implementation Approaches, and Opinions of Above Cuff Vocalization: A Survey of Health Care Professionals. *Archives of Physical Medicine and Rehabilitation*. 103(3), pp.394–401.**

The candidate was responsible for planning and designing the study, completing the analysis, and developing and finalising the manuscript. Co-authors provided supervisory feedback and oversight. The research presented in this manuscript is included in Chapter 4 of the thesis.

iii. **Mills, C.S., Cuthbertson, B.H. and Michou, E. 2023. What's new in reducing the impact of tracheostomy on communication and swallowing in the ICU. *Intensive Care Medicine*. pp.1-4.**

As part of the thesis, the candidate developed collaborations outside the University of Leeds and was invited to write an editorial for Intensive Care Medicine. The candidate drew on work from across the thesis to write this manuscript as the primary author. Co-authors provided feedback and oversight. The research discussed in this manuscript is included in Chapters 3, 4, 5, and 7 of the thesis.

Details of candidate contributions to published conference proceedings relating to the thesis:

i. **<u>Mills, C.</u>, Michou, E., Bellamy, M., Siddle, H., Brennan, C. and Bojke, C. 2020. An international survey about Above Cuff Vocalisation: what are the risks and benefits? *Intensive Care Medicine Experimental*. 8(Suppl 2), pp.76, 001507**

This conference proceeding relates to the study outlined in publication (ii) above. The research presented in this poster is included in Chapter 4 of the thesis.

ii. **<u>Mills, C.S.</u>, Michou, E., Bellamy, M., Siddle, H., Brennan, C. and Bojke, C. 2022. An International Survey to Determine the Prevalence, Implementation, and Healthcare Professionals' Opinions of Above Cuff Vocalization. *Dysphagia*. 38(Suppl 1), p.S41.**

This conference proceeding relates to the study outlined in publication (ii) above. The research presented in this poster is included in Chapter 4 of the thesis.

iii. **<u>Mills, C.</u>, Michou, E., Bellamy, M., Siddle, H., Brennan, C. and Bojke, C. 2023. Worth a try or a last resort: Healthcare professionals' experiences of above cuff vocalisation *Canadian Journal of Anesthesia/Journal canadien d'anesthésie*. 70(Suppl 1), pp.189-191.**

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Abstract

Background: Approximately 15,000 patients receive a tracheostomy annually in the UK. A tracheostomy has a profound impact on communication, swallowing, and other co-morbidities. Above cuff vocalisation (ACV) involves the application of an external airflow via the subglottic port of the tracheostomy tube. This intervention facilitates restoration of airflow through the laryngo-pharynx, with the potential for vocalisation and improved swallowing.

Aim: To explore the potential for ACV to improve outcomes for patients with tracheostomy, investigate the prevalence of complications and safety issues, and explore the cost-effectiveness of ACV.

Methods: Six objectives were addressed in the thesis. The current evidence for using ACV in patients with a tracheostomy was examined via a systematic review. Current ACV and tracheostomy weaning practice was investigated using an online survey. Healthcare professionals' (HCPs) experiences and opinions of ACV were explored using an online survey and individual interviews. An early-stage decision-analytic health economic model was developed to explore the cost-effectiveness of ACV and identify the value of future research.

Results: There is limited and low-level evidence available for ACV. There are various potential benefits for patients receiving ACV, but there is a lack of agreement about the extent of these benefits and which patients benefit the most. Severe adverse events and minor complications can occur, and HCPs have developed a cautious approach towards ACV use. There is wide variability in ACV application and a lack of agreement about the optimal approach. HCPs have diverse opinions of ACV, and this is likely due to the uncertainty and variability. ACV is potentially cost-effective according to the data available, and critical drivers for cost-effectiveness have been identified.

Conclusions: Further research is needed to reduce the level of uncertainty in the data and to provide more guidance for clinicians regarding ACV adoption decisions and optimal clinical application.

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Abbreviations

AAC	augmentative and alternative communication
ACCP	advanced critical care practitioner
ACV	above cuff vocalisation
AGP	aerosol generating procedure
ALS	amyotrophic lateral sclerosis
AMED	allied and complementary medicine database
APS	airway protection scale
ARDS	acute respiratory distress syndrome
BLUSA	Blue Line Ultra SuctionAid
CAP	community acquired pneumonia
CEAC	cost-effectiveness acceptability curve
CFIR	Consolidated Framework for Implementation Research
CHEERS	consolidated health economic evaluation reporting standards
CHERRIES	checklist for reporting results of internet e-surveys
CHF	chronic heart failure
cmH_2O	centimetre of water
CNS	central nervous system
COPD	chronic obstructive pulmonary disease
COREQ	consolidated criteria for reporting qualitative studies
CPD	continuing professional development
CT	computed tomography
CV	cervical vertebrae
CVA	cerebrovascular accident
CXR	chest x-ray
DAM	decision-analytic model
dB SPL	decibel sound pressure level
DSU	decision support unit
ECMO	extracorporeal membrane oxygenation

ENHB	expected net health benefit
EQ-5D	European quality of life 5-dimensions
EQ-5D-5L	European quality of life 5-dimensions 5-levels
ESAF	external subglottic air flow
ETT	endotracheal tube
EVPI	expected value of perfect information
EVPPI	expected value of perfect parameter information
EVSI	expected value of sample information
F	female
FEES	fibreoptic endoscopic evaluation of swallowing
FG	French gauge
FOIS	functional oral intake scale
GBS	Guillain Barré Syndrome
GI	gastrointestinal
GORD	gastro-oesophageal reflux disease
GRADE	grading of recommendations assessment, development and evaluation
GRBAS	voice scale of Grade, Roughness, Breathiness, Asthenia, and Strain
GVHD	graft versus host disease
HCP	healthcare professional
HIV	human immunodeficiency virus
HoTN	hypotension
HRQoL	health-related quality of life
HTN	hypertension
ICER	incremental cost-effectiveness ratio
ICTRP-WHO	international clinical trials registry platform World Health Organisation
ICU FCS	intensive care unit functional communication scale
ICU	intensive care unit

INAHTA	international network of agencies for health technology assessment
INHB	incremental net health benefit
INMB	incremental net monetary benefit
IQR	interquartile range
ITU	intensive treatment unit
JBI	Joanna Briggs Institute
L/min	litres per minute
LoS	length of stay
M	male
MDT	multi-disciplinary team
mini-BAL	mini-bronchoalveolar lavage
mL	millilitre
N/A	not applicable
N	number
NBM	nil-by-mouth
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NIH	National Institute of Health
NIHR	National Institute for Health Research
NINR	National Institute of Nursing Research
ODN	operational delivery network
OHCA	out of hospital cardiac arrest
ONS	Office of National Statistics
ORIF	open reduction with internal fixation
OT	occupational therapist
OWV	one-way valve
PAS	penetration aspiration scale
PCPI	patient, carer, and public involvement
PD	Parkinson's Disease

PEEP	positive end-expiratory pressure
PICOS	population intervention comparators outcomes study
PMV	Passy Muir Valve
PPE	personal protective equipment
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis
PROSPERO	Prospective Register of Systematic Reviews
PS	pressure support
PT	physiotherapist
QALY	quality-adjusted life-years
QoL	quality of life
QOL-MV	quality of life in mechanically ventilated patients
RCT	randomised controlled trial
RT	respiratory therapist
SCI	spinal cord injury
SD	standard deviation
SEM	standard error of the mean
SGS	subglottic suction
SIRS	systemic inflammatory response syndrome
SIT	speech intelligibility test
SLE	systemic lupus erythematosus
SLT	speech and language therapist
SOFA	sequential organ failure assessment
SSRS	secretion severity rating scale
SURE	specialist unit for review evidence
T2RF	type II respiratory failure
UC	usual care
UK	United Kingdom
USA	United States of America
USD	United States Dollars

VAP	ventilator associated pneumonia
VAS	visual analogue scale
VASES	visual analogue self-esteem scale
VIM	variable interval method
VOI	value of information
voiceTOM	voice therapy outcome measure
V-RQOL	voice-related quality of life
VTT	voice tracheostomy tube
WTP	willingness-to-pay

Chapter 1 Introduction

This chapter provides an introduction to this research topic and a justification for the work presented in the thesis. Section 1.1 outlines the rationale for the thesis and a justification for the work completed. Section 1.2 presents the aims, objectives and hypotheses. Section 1.3 explains the structure of the thesis. Section 1.4 outlines the composition and role of the research advisory group and the patient, carer, and public involvement groups, and Section 1.5 summarises the introduction.

1.1 Thesis rationale and justification

Above cuff vocalisation (ACV) is an intervention for patients with a tracheostomy. A tracheostomy is a breathing tube that is inserted through the front of the neck into the trachea to enable the delivery of respiratory support. In England and Wales approximately 15,000 patients receive a tracheostomy annually (McGrath, Wallace, et al., 2020). Tracheostomies are typically inserted in the intensive care unit (ICU), primarily for prolonged respiratory failure (Durbin, 2010). Tracheostomy tubes have a cuff, or balloon, surrounding the distal end of the tube. Some tracheostomy tubes also have a subglottic port with an exit above the cuff, primarily used to remove any secretions that may accumulate above the cuff. When this cuff is inflated, it makes a seal with the trachea (windpipe), and all airflow by-passes the larynx (voice box), with all air entering and exiting the trachea to the lungs via the tracheostomy tube. For most patients, where a good cuff seal is achieved, no air can pass through the vocal folds (or vocal cords), and patients cannot vocalise. A prolonged absence of airflow through the larynx and upper airway can also lead to desensitisation and dysphagia (difficulty swallowing) (Sasaki et al., 1977; Siebens et al., 1993; Ding and Logemann, 2005; Wallace and McGrath, 2021). Patients unable to communicate, eat, and drink typically become frustrated, anxious, and low in mood (Patak et al., 2006; Carroll, 2007; Kjeldsen et al., 2018). This often has a substantial effect on their quality of life (QoL) and psychological well-being (Rose et al., 2014; Freeman-Sanderson et al., 2018) and can have a consequent effect on relatives and carers (Jones et al., 2004; Wintermann et al., 2016).

ACV, an intervention available since 1967, offers a potential solution for some of these issues (Whitlock, 1967). It involves applying an external airflow, via the subglottic port of the tube, directly into the trachea above the level of the inflated cuff. This airflow then passes up through the vocal folds, offering the potential for vocalisation and re-sensitisation of the upper airway (Figure 1). All patients with a tracheostomy have periods when they cannot have the tracheostomy cuff deflated – allowing air to pass through the vocal folds – and for some patients, this period of cuff inflation can be prolonged. Limited communication options exist which enable patients to communicate

verbally when there is a total absence of trans-laryngeal airflow (Leder, 1990a). Non-verbal communication options, such as Augmentative and Alternative Communication (AAC), are often perceived by patients as limiting, unnatural, and cognitively challenging (Fried-Oken et al., 1991). Patients also prefer verbal communication over AAC (Lohmeier and Hoit, 2003; Sutt and Fraser, 2017). ACV is the only widely-available alternative option to cuff deflation that restores airflow through the larynx (Zaga et al., 2019; Rose et al., 2021). However, there has been limited research on this topic to date.

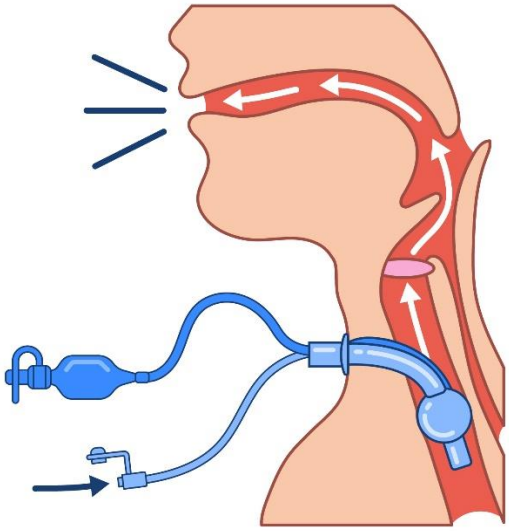

Figure 1 Tracheostomy tube with subglottic suction port. The blue arrow indicates where the airflow is applied to the port. The white arrows indicate the direction of airflow through the vocal folds and exiting via the oral cavity.

The literature indicates that ACV offers potential benefits for communication, swallowing, cough, and QoL (Kothari et al., 2017; McGrath et al., 2019; Pandian et al., 2020; Petosic et al., 2021). Theoretically, ACV may have additional benefits, including accelerated decannulation (tracheostomy removal), reduced ventilator-associated pneumonia (VAP), and reduced ICU and hospital length of stay (LoS). Any intervention that reduces ICU or hospital LoS has the potential to generate considerable cost savings for the healthcare system.

Despite ACV being in use for more than 50 years, there has yet to be a consistently used approach, and there are no national or international guidelines for its use. There has also yet to be a systematic evaluation of the ACV literature, and the quality and importance of the available evidence requires examination. Currently, there is no information available regarding how widely ACV is being used; which ACV approaches are being implemented in clinical practice; how healthcare professionals (HCPs) are

making decisions about which approach to take; HCPs' perceptions about the effectiveness of ACV; or about the type and frequency of issues that HCPs face when using ACV. The research literature has also not evaluated the impact of ACV on VAP, time to decannulation, or the laryngeal mucosa. There has also been no evaluation of the cost-effectiveness of ACV.

The COVID-19 pandemic was declared part-way through this research. ACV was determined to be an aerosol generating procedure (AGP) by many critical care experts. Therefore, initial recommendations were for HCPs to avoid using ACV (McGrath, Ashby, et al., 2020; Zaga, Pandian, et al., 2020). This considerably impacted the research and is discussed in detail in Chapter 7.

1.2 Thesis aims, hypothesis, and objectives

The primary aims of this research are to explore the potential for Above Cuff Vocalisation (ACV) to improve outcomes for patients with tracheostomy, to investigate the prevalence of complications and safety issues, and to explore the cost-effectiveness of the intervention.

The over-arching hypothesis of the thesis is:

Regular use of ACV can result in improved swallow function, improved ability to communicate, reduced length of time to decannulation, reduced LoS, improved Health-Related Quality of Life (HRQoL), and cost savings, indicating the need for a full definitive randomised controlled trial (RCT).

This PhD thesis explores the following objectives:

- Objective 1: To examine the current evidence for the use of ACV in patients with tracheostomy via a systematic review.
- Objective 2: To investigate current ACV and tracheostomy weaning practices in the United Kingdom (UK) and internationally using an online survey.
- Objective 3: To understand HCPs experiences with ACV via an online survey.
- Objective 4: To explore the opinions of HCPs regarding the use of ACV using one-to-one online interviews.
- Objective 5: To describe the impact of COVID-19 on ACV use via HCP interviews.
- Objective 6: To explore current expected cost-effectiveness using an early-stage decision-analytic health economic model and the application of Value of Information (VOI) framework principles to identify information gaps to inform current adoption decisions and identify the value of future research.

1.3 Thesis structure

The thesis seeks to critically appraise the evidence to identify gaps in the ACV literature and guide the conduct of this and future research. It also aims to understand current practices and explore HCPs' opinions and experiences of ACV. Finally, an early-stage health economic model and application of VOI principles will bring together all the evidence to examine the cost-effectiveness of ACV and identify areas for future research.

This section outlines the structure of the thesis and which objectives are focused on in each chapter. The thesis consists of seven chapters:

Chapter One (current chapter): provides an introduction to ACV, provides justification for the thesis, and outlines the thesis structure.

Chapter Two: outlines the background information vital to understanding ACV and the approach taken for this research. This will include a discussion of the evidence available for ACV, intubation and tracheostomy management, the impact of tracheostomy, and decision analytic modelling for cost-effectiveness analysis.

Chapter Three: describes the findings from the first published systematic review of the ACV literature. It outlines the levels of evidence and risk of bias in the included studies. The methods of ACV application, the outcome measures used, the efficacy, effectiveness, and safety of ACV, and the acceptability of ACV to patients and HCPs are evaluated. It also discusses ACV's potential mechanism of action and recommendations for ACV application. This chapter addresses objective 1.

Chapter Four: presents the published findings of an international survey of HCPs. It is the first study to investigate the prevalence of ACV use and evaluate clinical practice. It explores how ACV is being implemented into clinical practice, how it is being delivered at the bedside, the opinions of staff regarding the benefits and risks for patients, and the barriers to use. It also reports on two factors that may influence ACV use: tracheostomy management approaches and the availability of speech and language therapy services. This chapter explores objectives 2 and 3.

Chapter Five: describes qualitative semi-structured interviews of HCPs, exploring their opinions and experiences of ACV. It also reports on the impact of COVID-19 on ACV use. Data were explored with reflexive thematic analysis ensuring that participants' experiences and opinions of ACV were central to the analysis. This chapter focuses on objectives 4 and 5.

Chapter Six: presents an early-stage decision-analytic model and the findings of the first cost-effectiveness analysis of ACV. It also describes the application of VOI principles to the decision-analytic model to identify specific aspects of research that

should be the focus of future studies to enable critical research gaps to be filled. This chapter is vital to improve understanding of ACV and provide supporting evidence for decision-makers regarding the adoption of this intervention. It will also ensure that research funding is appropriately directed to where it will be most effective and provides the groundwork for future cost-effectiveness analysis, which will facilitate conclusive decisions regarding ACV's clinical utility and cost-effectiveness. This chapter addresses objective 6.

Chapter Seven: summarises and discusses the findings of the thesis. The strengths and limitations of the work are reported, the clinical implications considered, new theoretical insights are described, and the potential directions of future ACV research are outlined. It also describes the impact of COVID-19 on this research and how alterations were made to this research programme as a result.

1.4 Patient, carer, and public involvement group and research advisory group

The patient, carer, and public involvement (PCPI) group was composed of two patients, one family member, and one carer. The advisory group for this research was composed of two intensivists, one critical care nurse, one speech and language therapist, a methodologist, a speech and language therapy manager, a health economist, a statistician, one patient representative, and one family representative. Both groups provided advice and guidance with the design, planning, conduct, interpretation, and dissemination of this research.

1.5 Summary

Large numbers of patients in the ICU require a tracheostomy each year. The insertion of a tracheostomy typically results in patients having difficulties communicating and swallowing. This can have a marked impact on patients' short- and long-term QoL. ACV restores trans-laryngeal airflow and offers the potential to facilitate vocalisation and improve laryngo-pharyngeal sensation and swallowing function. However, there is currently limited evidence available for ACV, and the primary aim of this research is to explore the potential for ACV to improve outcomes for patients with a tracheostomy. The thesis makes a considerable and original contribution to the ACV field by critically appraising the literature, investigating current ACV practice, exploring HCPs' experiences and opinions of ACV, describing the impact of COVID-19 on ACV use, evaluating the cost-effectiveness of ACV, and identifying the value of future research.

Chapter 2 Literature Review

This chapter introduces the key topics of the thesis. To appreciate the complexities of ACV, this section will discuss the literature surrounding ACV, as well as endotracheal intubation, tracheostomy insertion, and tracheostomy weaning. Section 2.1 outlines the background of the subject matter, explaining the basic information needed to understand endotracheal intubation and tracheostomy. Section 2.2 describes the variation in tracheostomy management and what implications this has for ACV. Section 2.3 explains the impact of a tracheostomy and discusses the potential implications for ACV. Section 2.4 discusses the ACV literature. Section 2.5 briefly describes cost-effectiveness and Decision-Analytic Modelling and why it is important for the thesis. Section 2.6 considers the implications of the preceding information for ACV. Section 2.7 summarises the chapter.

2.1 Endotracheal intubation and tracheostomy

Patients requiring invasive respiratory support from a ventilator are typically first orally intubated with an endotracheal tube (ETT) (Figure 2). In the UK, patients that are orally intubated are generally sedated for their comfort. Patients that require prolonged invasive respiratory support of approximately 14 days or more tend to require the insertion of a tracheostomy (Durbin, 2010). However, there is a significant variation in the timing, with many HCPs advocating for insertion within seven days of intubation (Krishnan et al., 2005). These issues are explored further in Section 2.2.1.

In England and Wales, approximately 15,000 patients annually have a tracheostomy inserted (McGrath, Wallace, et al., 2020). A tracheostomy is a tube inserted through the front of the neck into the trachea to direct respiratory support to the lungs bypassing the upper airway (Figure 3). Reasons for tracheostomy insertion vary and include prolonged respiratory failure, reduced airway protection, decreased consciousness levels, and airway obstruction (Durbin, 2010). The primary indications for tracheostomy are:

- to facilitate weaning from mechanical ventilation
- to facilitate the removal of pulmonary secretions, and
- to protect the airway from aspiration

(NCEPOD, 2014).

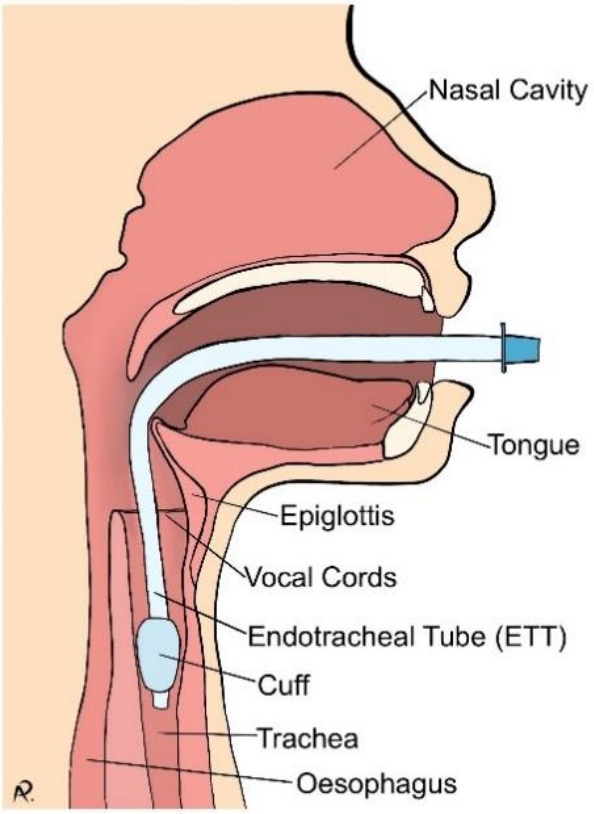

Figure 2 Endotracheal tube (ETT) passes through the oral cavity between the vocal folds and into the trachea.

Aspiration is when food, drink, oral secretions, or stomach contents pass into the airway below the level of the vocal folds (Rosenbek et al., 1996).

Respiratory disease is most commonly the principal diagnosis for patients requiring a tracheostomy (NCEPOD, 2014). However, the underlying clinical condition of patients receiving tracheostomy is highly variable. It can include post-surgical (e.g., general surgery, cardiac surgery, cardiothoracic surgery, thoracic surgery, liver transplantation, neurosurgery, head and neck surgery, gastroenterology), trauma, sepsis, urology, cardiovascular, hepatology, nephrology, oncology, acute respiratory distress syndrome, neurology (e.g., stroke, spinal injuries, neurodegenerative conditions), and burns. An audit of UK tracheostomy care in 2014 revealed that the median age of a patient receiving a tracheostomy in the adult population is 61 (range: 16-93) (NCEPOD, 2014). The insertion of a tracheostomy tube usually allows sedation to be withdrawn, which supports patients to be awake for participation in their care and recovery (Nieszkowska et al., 2005).

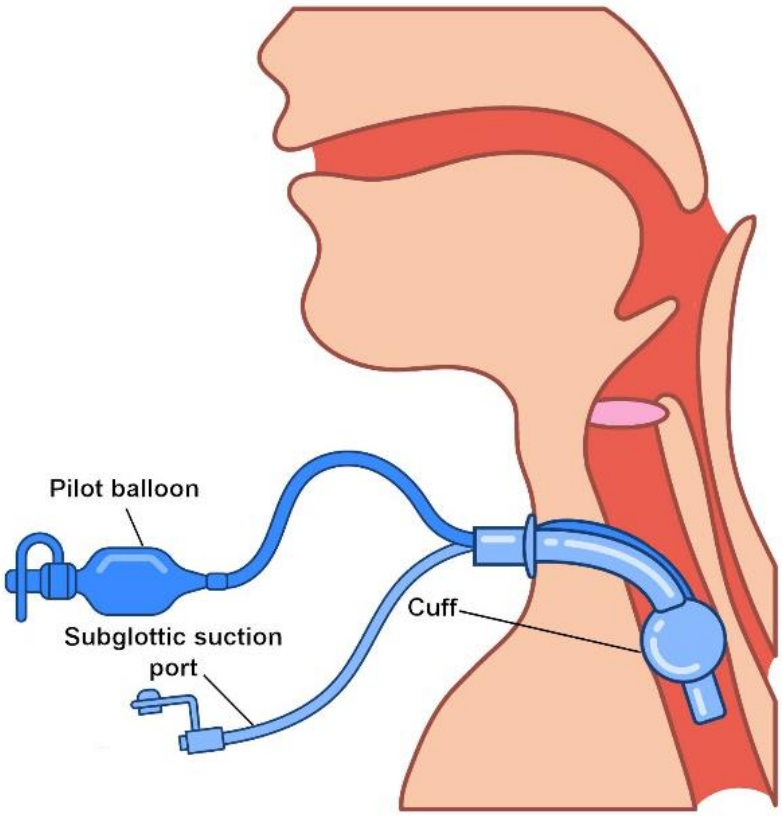

Figure 3 Tracheostomy inserted through the front of the neck directly into the trachea

2.2 Variation in tracheostomy management

2.2.1 Tracheostomy Insertion

2.2.1.1 Timing of insertion

There are varied opinions on the appropriate timing for tracheostomy insertion. Some advocate for tracheostomy insertion by 21 days, others by 14 days and others still earlier at around 3-4 days after intubation (Durbin, 2010). The largest multi-centre randomised controlled trial (RCT) – with 909 patients – evaluating mortality between early tracheostomy (within four days) versus late tracheostomy (after 10 days) found that there was no difference in all-cause 30-day or 2-year mortality or LoS between the two groups (Young et al., 2013). However, a more recent systematic review and meta-analysis, incorporating evidence from eight RCTs, including a total of 1977 patients, evaluated the evidence for the effectiveness and safety of early (2-10 days) versus late (>10 days) tracheostomy insertion (Andriolo et al., 2015). The authors concluded that there were lower mortality rates (moderate quality evidence) and a higher probability of ICU discharge by day 28 (high-quality evidence) in the early group (Andriolo et al., 2015). Notably, these differences in mortality were found by comparing the longest follow-up time points. None of the studies showed significant differences at each follow-

up (Andriolo et al., 2015). They reported no difference in pneumonia rates, and the impact on the dependence on mechanical ventilation was inconclusive but favoured early insertion (Andriolo et al., 2015).

Much of the literature comparing outcomes between early and late tracheostomy suggests no clear or conclusive benefits to early tracheostomy insertion. However, this research tends to focus primarily on outcomes of mortality, duration of mechanical ventilation, and LoS. Critical care research is beginning to move towards increasing inclusivity and prioritisation of patient-focused outcomes of survivorship and QoL (Needham et al., 2011; Iwashyna and Netzer, 2012; Turnbull et al., 2016; Kean et al., 2021). This shift in focus from survival to survivorship and rehabilitation may help shed a different light on the timing of tracheostomy insertion. One recent study reported various benefits for patients receiving earlier tracheostomy, including earlier opportunities for communication, earlier participation in care, earlier resumption of oral intake, earlier mobility, and reduced use of sedatives and analgesics (Sutt et al., 2020). They reported that 51% of patients could talk, resume oral intake, and perform exercises out of bed whilst their tracheostomy was in situ (Sutt et al., 2020).

2.2.1.2 Method of insertion

There are two broad methods of tracheostomy insertion: surgical and percutaneous. Surgical insertion was first described in 1909 (Jackson, 1909), whilst the percutaneous technique was developed much later in 1957 (Shelden et al., 1957) and further refined by Ciaglia in 1985 (Ciaglia et al., 1985).

Surgical insertion of a tracheostomy usually occurs in an operating theatre. However, it can be safely performed in the ICU (Klotz et al., 2018). In the UK, the procedure is most commonly performed by an ear, nose and throat surgeon (NCEPOD, 2014). Following surgical tracheostomy insertion, the stoma is unstable for 4-5 days, and tracheostomy reinsertion can be problematic during this period.

Percutaneous tracheostomy insertion usually occurs at the bedside in the ICU and is performed by an intensivist (Veenith et al., 2008). The procedure is performed under deep sedation or general anaesthesia and involves passing a guide wire between the second and third tracheal rings (Durbin, 2010). A dilator is then passed over the wire to gradually increase the stoma's size in readiness for the tracheostomy tube. The tracheostomy tube is inserted into the stoma using an insertion dilator.

Surgical tracheostomy is favoured with specific patient groups, for example, the morbidly obese, head and neck cancer patients, patients with complex or altered airways, or patients with bleeding or clotting disorders (Krishnan et al., 2005; Al-Ansari and Hijazi, 2005; NCEPOD, 2014; Klotz et al., 2018). It is also more commonly inserted electively (38%) compared with percutaneous insertion (11%) (NCEPOD, 2014).

Percutaneous insertion is used more frequently in the UK (Veenith et al., 2008; NCEPOD, 2014).

2.2.2 Weaning

Decannulation, or tracheostomy removal, is a complex process. It involves ventilator weaning so that patients are breathing for themselves without the assistance of the ventilator and tracheostomy weaning so that patients are breathing through their upper airway rather than through the tracheostomy tube. Ventilator weaning involves incrementally reducing the level of respiratory support the ventilator provides (Brochard et al., 1994; Blackwood et al., 2006). Ventilator weaning and tracheostomy weaning can occur simultaneously and have a complex interaction (Sutt et al., 2016; Sutt et al., 2017).

2.2.2.1 Ventilator weaning

A conventional ventilator weaning approach involves gradually reducing the level of respiratory support the ventilator provides (Blackwood et al., 2006). This is often combined with overnight 'rest' periods, where patients receive a higher level of support. In contrast, sprint weaning – or progressive ventilator-free breathing – involves short periods of total, or near total, withdrawal of ventilator support (Denton and McKinlay, 2009). For example, ventilator support may be withdrawn for a few minutes a few times daily (Brochard et al., 1994). These periods without ventilator support gradually increase until the patient no longer relies on the ventilator. As with conventional weaning, patients are usually rested overnight (Denton and McKinlay, 2009). Sprint weaning has been shown to be of particular benefit in patients with spinal injuries (Peterson et al., 1994). However, in a mixed group of patients, conventional weaning – employing a gradual reduction in pressure support – has been shown to be significantly more effective than sprint weaning in achieving successful decannulation, reducing the duration of mechanical ventilation, and reducing ICU LoS (Brochard et al., 1994).

2.2.2.2 Tracheostomy weaning

Tracheostomy weaning in ventilated patients involves deflating the air-filled cuff and using a one-way valve (OWV), which allows air to enter via the tracheostomy tube but prevents air from exiting the tube, redirecting all the expired air into the upper airway (Figure 4) (Kaut et al., 1996). The most commonly used OWV in ventilated patients is called a Passy Muir Valve (PMV). These periods of cuff deflation and use of PMV are gradually increased until it is determined that the patient is swallowing their oral secretions safely and breathing through their upper airway. Success in tracheostomy weaning is usually heavily dependent on effective swallowing function and airway protection.

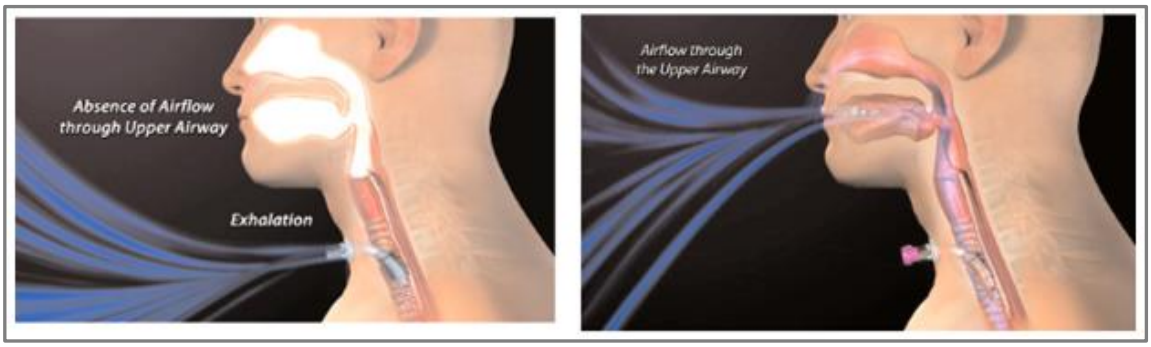

Figure 4 Tracheostomy tube in situ showing the flow of air during exhalation. *Left:* Exhalation via the tube when the cuff is inflated. *Right:* Exhalation via the upper airway when the cuff is deflated, and the Passy Muir Valve is on the end of the tracheostomy tube.

Images courtesy of Passy Muir®, Inc. Irvine, CA

There is much variation in how this is done, for example, whether and when an OWV is used (Kutsukutsa et al., 2019; Zaga et al., 2019; Martin et al., 2021). Additionally, some weaning approaches involve a step called 'capping off' where the tube is completely blocked off, and the patient has to inhale and exhale around the tube (McGowan et al., 2014; Pandian, Miller, et al., 2014; Kutsukutsa et al., 2019). There has been limited research evaluating tracheostomy weaning protocols, and, as with other elements of weaning, this leads to considerable variation in practice.

2.2.2.3 Simultaneous ventilator and tracheostomy weaning

One approach to weaning is to wait until weaning from the ventilator has been achieved before attempting cuff deflation trials (Spencer and Clifford, 2009). However, evidence suggests that tracheostomy and ventilator weaning can occur simultaneously without compromising respiratory function (Sutt et al., 2017). One study has demonstrated that using cuff deflation and PMV while mechanically ventilated may improve respiratory recruitment, with the potential to benefit recovery and accelerate the weaning process (Sutt et al., 2016). A recent RCT explored the use of accelerated cuff deflation and PMV (comparing ≤24 hours with ≥48 hours) and reported no adverse events or complications in either group (Martin et al., 2021). A simultaneous weaning approach is now more commonly used in the UK and internationally (Sutt et al., 2017; McGrath, Wallace, et al., 2020; Martin et al., 2021). The benefits of this simultaneous approach include reducing time to cuff deflation, facilitating earlier communication, and resumption of oral intake (Sutt et al., 2020; McGrath, Wallace, et al., 2020; Martin et al., 2021). A systematic review and meta-analysis of the evidence for the use of OWV also found a significant reduction in the frequency of aspiration with OWV use (O'Connor et al., 2019).

2.3 Impact of a tracheostomy

A tracheostomy can have various negative and positive consequences for patients. This can include effects on laryngeal sensation, swallowing, laryngeal function, airway protection, communication, safety, ventilator-associated pneumonia (VAP), QoL, LoS, hospital discharge, mortality, and costs (Durbin, 2010). Sections 2.3.1 to 2.3.9 will consider each of these aspects in turn.

2.3.1 Sensation and swallowing

The insertion of a tracheostomy tube offers the potential for a resumption of oral intake due to the unobstructed oral cavity (Nieszkowska et al., 2005; Sutt et al., 2020). Pryor and colleagues reported a median of 10.5 days to resume oral intake after tracheostomy insertion, with individual variations, some of which were substantial in specific clinical populations (Pryor, Ward, et al., 2016). Another study found that early tracheostomy was associated with a mean earlier return to oral intake of 7 days (Sutt et al., 2020).

Although tracheostomy improves the opportunity for the resumption of oral intake, prolonged cuff inflation – and the consequent lack of airflow – can exacerbate the desensitisation of the upper airway that is commonly initiated during prolonged intubation (Sasaki et al., 1977; Siebens et al., 1993). Dysphagia, or swallowing difficulties, in patients with a tracheostomy may present with reduced laryngo-pharyngeal sensation; reduced subglottic and pharyngeal pressures; reduced swallowing frequency; disuse atrophy; reduced hyoid excursion; reduced respiratory-swallow coordination; and aspiration or penetration of saliva, food or liquid (Ceriana et al., 2015). Effective swallowing, with appropriate glottic closure and airway protection, requires adequate laryngo-pharyngeal sensation and subglottic and pharyngeal pressures (Eibling and Gross, 1996; Suiter et al., 2003). Sensory input in the oropharynx is critical for triggering a functional swallow (Sulica et al., 2002), and patients with a tracheostomy frequently exhibit reduced swallowing frequency, likely due to reduced sensation (Kothari et al., 2017; McGrath et al., 2019). Subglottic pressures are also thought to play an essential role in respiratory-swallow coordination by activating stretch receptors which delay inhalation after swallowing (Eibling and Gross, 1996).

The body’s protective response to aspiration is to trigger a reflexive cough to clear the material from the airway. However, if this response is ineffective or absent, it can lead to severe consequences (Ramsey et al., 2005). Silent aspiration is when material passes below the level of the vocal folds without any reflexive cough response, and there are no outward signs of difficulty (Ramsey et al., 2005; Leder et al., 2011). When the tracheostomy cuff is inflated, with no trans-laryngeal airflow, there is a higher risk of

silent aspiration because patients lack the sensation or airflow required for reflexive coughing.

A scoping review exploring dysphagia in tracheostomised patients reported a dysphagia incidence of between 11% to 93% (Skoretz et al., 2020). However, the studies included in the review incorporated various assessment methods known to have lower sensitivity for detecting dysphagia and aspiration, for example, clinical bedside evaluation and modified Evans blue dye test (Skoretz et al., 2020). This is particularly important, as silent aspiration in this population is common, with the same study reporting silent aspiration rates of between 28% and 83% (Skoretz et al., 2020). This means the dysphagia incidence is probably towards the higher end of this range. Indeed, Skoretz and colleagues reported that 66% of the included studies found dysphagia rates of more than 40% (Skoretz et al., 2020).

The development of dysphagia in this population typically results in difficulties managing oral secretions and oral intake (Ding and Logemann, 2005; Wallace and McGrath, 2021). Dysphagia and aspiration can result in adverse patient outcomes, including malnutrition, dehydration, aspiration pneumonia, and may lead to death (Marik, 2001; Mandell and Niederman, 2019). Furthermore, dysphagia in tracheostomised patients significantly impacts QoL (Rose et al., 2014). Ninety-three percent of patients who had spent time in a prolonged weaning centre reported that their most troublesome experience was feeling thirsty (Rose et al., 2014). Resuming oral intake is viewed as a milestone in ICU recovery and can help improve psychological well-being (Newman et al., 2022).

In addition to the impact of the tracheostomy and prolonged intubation on swallow function, some drugs used in the ICU can contribute to xerostomia (dry mouth) (S. Blot et al., 2008). These drugs include anticholinergics, antihypertensives, antipsychotics, anticonvulsants, anorectics, antihistamines, antineoplastics, antidepressants, sympathicomimetics, and diuretics. This can make the experience of being nil-by-mouth (NBM) for patients even more unpleasant. Furthermore, some of these same drugs and others used in the ICU – anticholinergics, antipsychotics, neuromuscular blocking agents, benzodiazepines, narcotics, and muscle relaxants - can induce or exacerbate dysphagia (Stoschus and Allescher, 1993; Balzer, 2000).

2.3.2 Laryngeal function and airway protection

The presence of an ETT passing through the glottis (area between the vocal folds) and larynx is known to cause laryngeal damage (Rumbak et al., 2004), which can persist long after extubation (Brodsky et al., 2018). These complications include oedema, erythema, desensitisation, granulation, ulceration, atrophy, vocal fold immobility, dysphonia (voice disorder), trauma to the arytenoid cartilage, stenosis, and tracheomalacia (Wallace and McGrath, 2021). A systematic review has shown that

83% of patients experience laryngeal injury after oral intubation, with moderate-severe injuries occurring in 13-31% of patients (Brodsky et al., 2018). The most frequent symptoms reported were dysphonia (76%), pain (76%), and hoarseness (63%) (Brodsky et al., 2018). Vocal fold immobility was the most commonly reported severe laryngeal complication, occurring in 21% of patients (Brodsky et al., 2018). These injuries can lead to reduced airway patency which can considerably impact tracheostomy weaning.

There is an increase in the prevalence and the severity of laryngeal complications with increasing duration of oral intubation (Brodsky et al., 2018). Therefore, inserting a tracheostomy tube, particularly at an early stage, may help to reduce the effects of prolonged intubation on the larynx. Blot and colleagues substantiate this theory, reporting fewer laryngeal symptoms at two months in patients who received early tracheostomy (F. Blot et al., 2008). However, inserting a tracheostomy tube amplifies or adds a host of potential complications in addition to those that may already have developed during the intubation period. These additional complications include infection or granulation of the stoma site, vocal fold tremor, incoordination of the vocal folds, and reduced cough strength (Wallace and McGrath, 2021).

Whilst a tracheostomy does not directly impinge on the larynx, when the cuff is inflated, it can exert pressure on the anterior branch of the recurrent laryngeal nerve (Matta et al., 2017; Wallace and McGrath, 2021). This nerve innervates the laryngeal adductor muscles, which allow the vocal folds to be brought together for vocalisation. If the cuff elicits excessive compression, it can damage the nerve and cause vocal fold paresis (Matta et al., 2017). Whether vocal fold paresis occurs due to direct laryngeal injury or nerve damage, this can lead to reduced airway patency dependent on the position of the paralysed vocal fold. Additionally, when the cuff is inflated, there is an absence of airflow through the vocal folds and upper airway. This prolonged absence of airflow combined with other factors, such as oedema and polyneuropathy, can lead to desensitisation of the laryngo-pharynx, as described in Section 2.3.1 (Sasaki et al., 1977; Macht et al., 2013; Wallace and McGrath, 2021).

One of the functions of the larynx and the vocal folds is to protect the airway and lungs from foreign bodies (Fontana and Lavorini, 2006; Widdicombe, 2006). If material enters the larynx, a cough reflex should be triggered to expectorate it (Haji et al., 2013). The hypo-sensitivity typically seen in tracheostomised patients and post-extubated patients can lead to a lack of awareness of secretions, food, or drink in the larynx and a reduced or absent cough reflex (Kallesen et al., 2015; Kallesen et al., 2016; Wallace and McGrath, 2021). The lack of airflow through the larynx means that even if laryngeal sensation is intact, the patient would be unable to produce a cough, which requires a build-up of pressure and a forceful movement of air from below the vocal folds (Fontana and Widdicombe, 2007; Magni et al., 2011).

Vocal folds produce sound when air travelling between the vocal folds causes the mucosa to vibrate (Kotby and Haugen, 1970). Once cuff deflation can be achieved – and air can flow through the larynx – there is potential for a patient to vocalise again. However, if cuff deflation is used without an OWV, there will be limited airflow through the larynx, as some will escape via the tracheostomy tube, likely affecting the strength and quality of voice production (Morris et al., 2015). Additionally, the patient will be unable to cough efficiently due to the air escape preventing the build-up of subglottic pressure required for forceful coughing. With cuff deflation and placement of an OWV, the subglottic pressure is usually restored, optimising the production of voice and cough (Dettelbach et al., 1995; Elpern et al., 2000). However, any laryngeal injury sustained, ICU-acquired weakness, respiratory compromise, and neuromuscular disease may all continue to impact the effectiveness of vocalisation and cough (Morris et al., 2015; Zuercher et al., 2019; Wallace and McGrath, 2021; Taylor, 2021).

2.3.3 Communication

The insertion of a tracheostomy tube offers patients the potential to communicate verbally, which is impossible with an ETT that obstructs the oral cavity and vocal folds. However, one study found that early tracheostomy was associated with a non-significant trend towards a delay in return to speech, compared to prolonged intubation (F. Blot et al., 2008). This delay is most likely due to the tracheostomy tube having an air-filled cuff surrounding the tube to maintain ventilator pressures below the cuff and prevent oral secretions from entering the lungs. One of the negative impacts of this cuff is that it impedes airflow upwards through the larynx, preventing vocalisation (Grossbach et al., 2011).

Experiencing difficulty communicating are some of the most well-recalled and distressing memories for ICU patients, with 57% of patients stating they recalled having difficulty communicating and 100% of these rating it as moderately to extremely bothersome (Rose et al., 2014). The inability to produce voice and communicate with staff and relatives can lead to high levels of frustration, fear, anger, and worry (Menzel, 1998; Patak et al., 2006; Carroll, 2007). Menzel found an association between the number of days with ETT or tracheostomy and more intense worry and fear (Menzel, 1998). In one study, participants' descriptions of their experiences without a voice were themed as 'a storm of dark emotions' and included feelings of helplessness, frustration, stress, isolation, and vulnerability (Freeman-Sanderson et al., 2018). Patients have also described voicelessness as a form of physical restriction that results in feelings of powerlessness (Carroll, 2007). An individual's sense of humanity and identity is bound up in their voice, and patients' voices have been described as a 'key currency in humanising care' (Newman et al., 2022). Supporting patients to vocalise helps them 'to be seen and heard as a whole person' (Newman et al., 2022). Newman and colleagues

suggest that voice restoration should be a focus to ensure quality care in the ICU (Newman et al., 2022).

As well as leading to feelings of fear and uncertainty for patients, voicelessness profoundly impacts staff and family members (Happ, 2000). Alasad and Ahmad reported that some nurses found interactions with patients who had difficulty communicating to be frustrating and not enjoyable, with some staff even going so far as to say that they preferred working with sedated, unconscious patients because it was easier (Alasad and Ahmad, 2005).

Tracheostomy weaning can take a few days to many months (NCEPOD, 2014; Kowalski et al., 2017). Some patients may have an inflated cuff and be unable to vocalise for prolonged periods. This may result from specific weaning practices, such as not deflating the cuff until the patient no longer requires ventilator support. Alternatively, it may be that the patient is not ready for cuff deflation, for example, if they are still sedated, in a disorder of consciousness, or are at risk of aspiration pneumonia from copious amounts of oral secretions (Pryor, Ward, et al., 2016). Where early cuff deflation and the use of PMV are employed, the time to speech can be substantially reduced (Freeman-Sanderson et al., 2016; Martin et al., 2021). When early cuff deflation and PMV use are combined with early tracheostomy placement, patients have been found to vocalise a mean of 7.4 days earlier (Sutt et al., 2020).

Once vocalisation is restored, there can be increased participation in care, improved autonomy, augmented socialisation, and, more generally, an accelerated recovery (Freeman-Sanderson et al., 2018). Some patients report feeling relief, freedom, and happiness once they can speak again (Carroll, 2007). Nonetheless, even when a patient's voice is regained, the impact of these negative experiences can last many months after discharge home (Freeman-Sanderson et al., 2018).

Communication options for patients with a tracheostomy broadly fit into two categories: 1) Augmentative and Alternative Communication (AAC) and 2) adaptations or modifications to the tracheostomy tube. Both are briefly outlined below.

2.3.3.1 Augmentative and Alternative Communication

There are low-tech and high-tech AAC options to support communication for individuals with limited or absent ability to verbalise. Low-tech options include pen and paper, whiteboard and marker, picture charts, alphabet charts, communication boards, and eye-transfer (e-tran) frames – where individuals communicate by spelling or identifying pictures by looking at them (Grossbach et al., 2011). High-tech options may comprise electrolarynx (a device that can be held against the neck or cheek and produces an alternative vibration source to the larynx that is transmitted into the oral cavity to facilitate the production of speech); communication applications on mobile phones,

portable tablet devices or laptops; and computerised eye-gaze devices (Grossbach et al., 2011; Maringelli et al., 2013). The ability to use some of these AAC devices can be hampered by reduced upper limb mobility, either due to physical restraints or ICU-acquired weakness (Happ, 2001; Happ, Fontela, et al., 2004). There are also a variety of barriers to using some of the high-tech options, including inadequate positioning of the equipment, limited availability of staff, lack of staff knowledge due to high staff turnover, deterioration or fluctuation in medical status, the increased cognitive load required, and overly complicated layouts for patients (Happ, Roesch, et al., 2004).

These AAC options provide a much-needed route for communication for those unable to vocalise. However, research suggests that patients prefer verbal options wherever possible, as it is the most natural form of communication and makes them feel more human (Happ, 2001; Freeman-Sanderson et al., 2018; Newman et al., 2022). One patient in a qualitative interview stated, “It wasn’t until the speaking valve that I was able to make decisions.” (Freeman-Sanderson et al., 2018). Additionally, the successful use of AAC requires staff to persevere, give the individual plenty of time, and be extremely patient (Happ, 2001). This can be difficult to achieve in a busy ICU. The combination of staffing pressures and limited time can result in staff avoiding using AAC with patients and opting for other quicker approaches (Happ, Roesch, et al., 2004).

2.3.3.2 Adaptations or modifications of the tracheostomy tube

Various adaptations and modifications can be made to a tracheostomy tube to facilitate vocalisation. ACV sits in this group of possible communication options for patients with a tracheostomy tube.

There are a variety of specially designed tracheostomy tubes that can be adapted to facilitate vocalisation. The Blom tracheostomy tube has fenestrations and works in conjunction with a silicone, bubble-valved speech cannula to allow vocalisation with an inflated cuff (Kunduk et al., 2010; Leder et al., 2013). However, this tube is not suitable for patients with thick or copious oral secretions (Kunduk et al., 2010), and these patients are typically those who might have more difficulty with a standard cuff deflation and OWV approach. The voice tracheostomy tube (VTT) facilitates vocalisation using automated cuff deflation and inflation. When the patient inhales, the cuff expands to seal off the trachea, and when the patient exhales, the cuff deflates to allow air to exit via the vocal folds (Nomori, 2004). Nomori evaluated the VTT in 16 patients and demonstrated that 15 could successfully vocalise with the new tube without any adverse effects on respiration or signs of increased aspiration (Nomori, 2004). However, whilst showing great promise, this tracheostomy tube is not widely available. One case study presented the modifications made to an extended-length tracheostomy tube (de la Cruz et al., 2013). The authors used a scalpel to cut fenestrations in a

silicone tracheostomy tube to divert airflow past a region of stenotic trachea and facilitate vocalisation (de la Cruz et al., 2013). These kinds of direct modifications to individual tracheostomy tubes, however, are rare.

As discussed in Section 2.2.2.2, one of the most important options to enable communication is to deflate the tracheostomy cuff allowing air to pass around the tube through the vocal folds, enabling vocalisation. There are various options for this strategy. Ventilator-adjusted leak speech uses partial cuff deflation and minor ventilator setting adjustments to provide a small flow of air for speech (Morris et al., 2015; Zaga et al., 2019). Complete cuff deflation can be used in isolation or simultaneously with an OWV. As discussed in the previous section, the approach will typically impact the strength and quality of the voice elicited.

Cuff deflation with an OWV in-line with the ventilator is generally considered the optimal approach for communication and swallowing (Wallace et al., 2022). However, a Cochrane review evaluating interventions to enable communication in patients with an artificial airway has found very low confidence in the effectiveness of any communication option because of the heterogeneity of outcome measures, imprecision, inconsistencies in results, and high risk of bias (Rose et al., 2021). This review included the single RCT evaluating ACV. They concluded that there is currently insufficient evidence to direct the selection of communication options for patients with an artificial airway or the timing of introduction (Rose et al., 2021).

Of the various options available for communication, restoration of airflow through the larynx is believed to be best. This is because it facilitates verbalisation, which is generally the patients' preferred option for communication (Newman et al., 2022). Although cuff deflation with an OWV is usually perceived as the optimal route to restore airflow, this option is not always available for patients because of a lack of tolerance or readiness or the particular weaning approach adopted (Wallace et al., 2022).

2.3.4 Safety

There is a wide range of complications that can occur as a result of a tracheostomy. These complications can be broadly divided into those that occur peri-operatively (during the procedure) and post-operatively, with post-operative complications split into early and late (Kearney et al., 2000; Krishnan et al., 2005). Peri-operative complications include premature decannulation, bleeding, creation of a false passage, incorrectly sized tracheostomy tube, and pneumothorax (Kearney et al., 2000). Early complications include bleeding, airway obstruction, premature decannulation, and surgical emphysema (Kearney et al., 2000; Krishnan et al., 2005). Late complications include dysphagia, dysphonia, laryngo-tracheal stenosis, tracheomalacia, and airway obstruction.

Intra-procedural and early complication rates are reported to be 5-6% (Kearney et al., 2000; Young et al., 2013). Kearney and colleagues found that 5% (of 548 patients) had late complications an average of 461 days post-decannulation (Kearney et al., 2000). General ICU clinicians surveyed in 2005 reported that the most common complication of tracheostomy insertion was bleeding (70%), followed by surgical emphysema (35%), false passage (24%), and pneumothorax (4%) (Krishnan et al., 2005). A UK-wide review of tracheostomy care for 2.5 months in 2013 reported on tracheostomy complications in the ICU and the ward (NCEPOD, 2014). They found that 24% of patients experienced a complication in the ICU. These complications included respiratory infections, bleeding, accidental decannulation or tube displacement, obstruction, pneumothorax, local infection, dysphagia, surgical emphysema, aspiration, pneumo-mediastinum, trache-oesophageal fistula formation, mediastinitis infection, and damage to the tracheal ring or tracheal necrosis. However, some of these defined complications could be due to causes other than the tracheostomy or have different contributing factors. They reported that 57% of complications occurred during the first seven days after tracheostomy insertion (NCEPOD, 2014).

In some ICUs, once patients no longer require ventilation, they can step down to a ward to continue the tracheostomy weaning process (Durbin, 2010). On the other hand, in other ICUs, the entire ventilator and tracheostomy weaning process occurs in the ICU. The latter approach is usually taken for safety reasons, as outside of the ICU, staff may be less experienced in tracheostomy care, which, in contribution with lower staff-to-patient ratios, can lead to a greater risk of adverse events (NCEPOD, 2014). The NCEPOD report found that 31% of ward patients experienced tracheostomy complications, with similar complications to those occurring in the ICU, but with differing frequencies. For example, accidental decannulation occurred more frequently on the ward compared with on the ICU, 6.3% and 4.1%, respectively (NCEPOD, 2014). Long-term adverse outcomes due to complications were rare, occurring in 4.1% of patients (NCEPOD, 2014).

2.3.5 Ventilator-associated pneumonia

Ventilator-associated pneumonia, or VAP, is an infection of the lungs that occurs in people receiving invasive mechanical ventilation for at least 48 hours (Papazian et al., 2020). It is believed to be primarily due to the aspiration of secretions around the cuff of the tracheostomy or ETT (Chastre and Fagon, 2002). As such, some individuals have even suggested that the term VAP is a misnomer and that the term ETT-Associated Pneumonia is more appropriate (Pneumatikos et al., 2009). However, this term would not be inclusive of this type of pneumonia in tracheostomised patients.

Many speech and language therapists (SLTs) would argue that VAP is simply a form of aspiration pneumonia, defined as oral secretions, food, drink, or stomach contents

passing below the level of the vocal folds (Rosenbek et al., 1996). Oral hygiene status is believed to play a substantial role in the risk of VAP (Papazian et al., 2020). Oral hygiene in intubated patients has been shown to deteriorate with time in the ICU, even with basic oral care (Haghighi et al., 2017). With a standardised and thorough oral care protocol, the condition of the oral cavity can improve (Haghighi et al., 2017; Dale et al., 2021). However, these studies could not demonstrate that improving oral hygiene significantly reduced the incidence of VAP, ICU mortality, or time to extubation (Haghighi et al., 2017; Dale et al., 2021). This suggests that the development of a VAP may be more associated with the quantity of aspiration rather than the quality of the secretions.

One systematic review has shown that the incidence of VAP in critically ill patients is 10 to 23% (Safdar et al., 2005). Another study found that the risk of developing a VAP increases over the first few days of mechanical ventilation until day five and subsequently decreases (Cook, 1998). A systematic review and meta-analysis found that pooled incidence of VAP was significantly lower in early tracheostomy (39%) when compared with late or no tracheostomy (48%) (Siempos et al., 2015). A survey of UK ICU lead clinicians found that one quarter believed that tracheostomy insertion reduced the incidence of pneumonia (Krishnan et al., 2005).

The consequences of VAP can be severe for patients and the healthcare system, specifically regarding ICU LoS, mortality, and costs. These will be addressed further in Sections 2.3.7; 2.3.8; and 2.3.9, respectively.

2.3.6 Quality of life

Critically ill patients have lower QoL than matched healthy individuals (Oeyen et al., 2010). Admission to the ICU, in and of itself, can impact patient QoL (O'Donnell et al., 2010). Therefore, it is possible that tracheostomised patients – who typically have a protracted ICU stay – may have even lower QoL than non-tracheostomised patients in the ICU. There have been relatively few studies into QoL in the ICU. One of the issues with capturing this data is that recall of experiences on the ICU is often incomplete and, in some instances, totally absent (Rose et al., 2014). Engoren and colleagues found that tracheostomised patients had significantly reduced social functioning compared with decannulated patients (Engoren et al., 2004). One study found that patients with a tracheostomy had reduced satisfaction with life compared with patients without a tracheostomy (Gilony et al., 2005). Post-traumatic stress disorder and anxiety are also common sequelae of ICU admission. One study found that 9% of patients scored positively on a scale for post-traumatic stress disorder, and 39% scored positively on an anxiety scale (Rose et al., 2014).

Even after tube removal, QoL may continue to be impacted. A qualitative study reported that three of the eight patients interviewed experienced panic attacks following

decannulation (Sherlock et al., 2009). The impact of ICU admission on patients can be long-lasting, with reduced physical QoL and low quality-adjusted life-years (QALYs) gained for five years after discharge (Cuthbertson et al., 2010). Patients report a wide range of negative psychological effects post-ICU which requires a 'significant biopsychosocial adjustment process' after discharge home (Walker et al., 2015). Mental health QoL was lower than the norms for up to 6 months post-ICU admission (Cuthbertson et al., 2010). Despite these lower QoL scores, 88% of patients stated they were satisfied with their QoL five years post-ICU admission (Cuthbertson et al., 2010). This may suggest that most individuals adjust to their long-term reduced QoL and physical limitations (Cuthbertson et al., 2010).

The term post-intensive care syndrome (PICS) was conceived to describe new or worsening symptoms experienced by patients after discharge from acute care (Needham et al., 2012). This syndrome can include physical, cognitive, and mental health symptoms, with anxiety, acute stress disorder, post-traumatic stress disorder, and depression (Needham et al., 2012). Furthermore, recognition that family members can also experience PICS, with 'complicated grief' being experienced in addition to the same potential mental health symptoms as patients (Needham et al., 2012). Acknowledging the psychological impact of the ICU on family members and patients is an important step towards a shift in focus from patient survival in the ICU to optimising QoL during and after critical illness. Some research has shown that sedatives and analgesics significantly contribute to the development of PICS (Davydow et al., 2008; Hughes et al., 2012).

The impact of a tracheostomy on QoL is probably a result of the combined effects of various other adverse sequelae of tracheostomy, such as swallowing, communication, body image, and mobility. One study reported that when vocalisation was restored, there were improvements in the visual analogue self-esteem scale (VASES) in the domains of feeling misunderstood, cheerful, mixed-up, angry, and trapped (Freeman-Sanderson et al., 2018). However, there was no statistically significant improvement with the European Quality of Life 5-Dimensions (EQ-5D) score with voice restoration, suggesting that this scale may not be sensitive to detect improvements associated with voice or communication (Freeman-Sanderson et al., 2018). To this end, a specific QoL scale has been developed for ICU patients, called the Quality of Life in Mechanically Ventilated Patients (QOL-MV), which includes domains for swallowing, speech, saliva control, comfort, mood, anxiety, and autonomy (Pandian et al., 2015). Another study reported that speech was one of the most critical factors contributing to QoL in critically ill patients (Pandian, Bose, et al., 2014). This suggests that inability to vocalise with a tracheostomy may play a role in the reduced QoL observed in these patients. Similarly, as discussed in Section 2.3.1, thirst and being unable to drink are some of the most

distressing memories for most ICU patients (Rose et al., 2014), contributing to the reduced QoL observed in these patients.

2.3.7 Length of stay

Mean ICU and hospital LoS are generally more prolonged for tracheostomised patients than non-tracheostomised patients (Freeman et al., 2013). This is likely because patients requiring tracheostomy tend to be more unwell, and the prolonged LoS is probably associated with their general acuity level rather than the tracheostomy itself (Young et al., 2013). Nevertheless, the speed and success of the tracheostomy and ventilator weaning process will presumably impact ICU and hospital LoS (Cetto et al., 2011; Speed and Harding, 2013; Blackwood et al., 2014). This will particularly impact ICU LoS in those centres that do not allow or limit the step-down of patients with a tracheostomy to the ward.

Successful decannulation is a crucial component of the tracheostomy wean. A UK-wide audit of tracheostomy care reported that 49% were decannulated in the ICU, and 34% were discharged from the ICU with a tracheostomy (NCEPOD, 2014). For those discharged to the ward, outcomes are slightly better, with 60% being decannulated and 15% being discharged from the hospital with a tracheostomy (NCEPOD, 2014). When decannulation is not achieved, there is usually a complex discharge process involving ascertaining whether a patient can be discharged back to their previous place of residence – and the level of support needed – or whether transfer to a care facility is required (Bowers and Scase, 2007; Scales, 2015).

Another critical factor that may impact LoS for patients with a tracheostomy is the development of VAP, which is known to prolong LoS in the ICU and hospital. Safdar and colleagues reported that VAP leads to an associated increase in ICU LoS of five to seven days (Safdar et al., 2005). There has not been any evidence to show that improved communication in patients with a tracheostomy might help to reduce time to decannulation and LoS (Freeman-Sanderson et al., 2016). However, improved communication might help to reduce frustration and agitation, with the potential for a reduction in the levels of sedatives and anti-psychotics used. This could help to reduce VAP, time to decannulation, and LoS.

2.3.8 Mortality

The mortality rate for ICU patients is high, with 33% of patients reported to have died by five years post-admission in one study (Cuthbertson et al., 2010). This figure is probably an underestimate, as 35% of patients were lost to follow-up, and researchers could not rule out mortality as the cause (Cuthbertson et al., 2010). One study that specifically looked at mortality in tracheostomised patients reported 10% ICU mortality and 36% mortality during hospitalisation (Arabi et al., 2009). A UK-wide audit of

tracheostomy care found that 18% of tracheostomised patients died during their ICU stay and 7% during their ward stay (NCEPOD, 2014). Similarly, a retrospective chart review in the United States of America (USA) reported an ICU mortality of 19% for tracheostomised patients (Engoren et al., 2004). An international multi-centre RCT identified tracheostomised patients as a high-risk group with an all-cause mortality at discharge of 41% (Young et al., 2013). This mortality risk continues to rise post discharge, with a 47% mortality one-year post-discharge and 53% at two years (Young et al., 2013). The USA study also reported mortality increasing to 24% at 100 days; 36% at one year; and 42% at two years (Engoren et al., 2004).

Despite the high and ongoing risk of mortality for tracheostomised critically ill patients, the risk of mortality is not thought to be a direct result of the presence of the tracheostomy itself. Inpatient mortality rates for tracheostomised patients are lower than for non-tracheostomised patients with acute respiratory failure (Freeman et al., 2013). This may be because patients who receive an early tracheostomy are at a lower risk of developing VAP than those who receive a late tracheostomy (Rumbak et al., 2004; Zheng et al., 2012). A systematic review estimated that the attributable mortality from a VAP was between 3% and 17% (Melsen et al., 2013). In contrast, another study reported VAP mortality to be as high as 42% (Forel et al., 2012). Therefore, it might be expected that the mortality rate would be lower in patients receiving early tracheostomy. Additionally, any intervention that helps to reduce the incidence of VAP would probably reduce the risk of death.

Although the presence of a tracheostomy itself is not thought to increase the risk of mortality directly, the patient's location in the hospital is associated with an increased mortality risk. Two studies have shown that mortality rates are higher in those patients that are discharged to the ward with a tracheostomy (26% and 26%) compared to patients who were entirely weaned in the ICU (7% and 11%) (Fernandez et al., 2008; Martinez et al., 2009). Martinez and colleagues reported that cardiorespiratory arrest was the cause of death in 90% of patients with a tracheostomy on the ward, and just 33% in those who were decannulated (Martinez et al., 2009). They also found an association between mortality and tenacious sputum at ICU discharge (Martinez et al., 2009). This suggests that difficulties swallowing oral secretions, impaired airway protection, and impaired airway clearance may contribute to mortality in patients with a tracheostomy in a ward-based setting.

2.3.9 Costs of tracheostomy

Although in the UK the cost of treatment is not payable by the patient, this is not the case in many countries. The mean total hospital cost for a patient with a tracheostomy has been reported in the USA to be $285,509, more than three times that of a non-tracheostomised patient (Freeman et al., 2013). A meta-analysis comparing

percutaneous versus surgical tracheostomy found that the costs for percutaneous insertion were a mean of $456 less (United States Dollars (USD)) (Higgins and Punthakee, 2007).

Some of the increased costs associated with tracheostomy result from the related complications. Patients who have a tracheostomy and are ventilated in the ICU are at risk of VAP due to aspiration of oral secretions (Ledgerwood et al., 2013). Those patients who develop a VAP are likely to be ventilator-dependent for longer, have an increased ICU and hospital LoS and require more antibiotics than patients who do not develop VAP (Hayashi et al., 2013). Employing a micro-costing approach – incorporating the costs of increased ICU LoS, diagnostic costs, and antibiotic treatment costs – they calculated that a single episode of VAP could lead to increased costs of between $10,019 and $13,647 (USD) (Safdar et al., 2005). Given that the prices used in these calculations were from 2005, the estimated increased costs for an episode of VAP today are probably much higher. A more recent study estimated the cost of a single episode of VAP at $39,828 (USD) (Kollef et al., 2012). Cost analysis of a large cohort of intubated patients has indicated that the average LoS for patients with laryngo-tracheal injury is 1.1 days more than those without injury, with an associated additional cost of $1888 (USD) (Bhatti et al., 2010). Furthermore, 6% of patients were readmitted for treatment of their laryngo-tracheal injury for an average of 4.7 days at an average cost of $11,025 (Bhatti et al., 2010).

The most significant costs associated with tracheostomy are the ICU bed costs per day, which are substantial. Overall ICU bed cost estimates per day for the UK are variable. The National Schedule of National Health Service (NHS) costs for 2020/21 reports costs ranging from £1778 to £4,249 per day for an ICU bed with one organ support and between £2625 to £7,354 for an ICU bed with two or more organs supported (NHS England, 2020). Any intervention that can reduce the number of episodes of VAP, the duration of mechanical ventilation, or the number of days in the ICU can substantially impact individual patient costs.

2.4 Above Cuff Vocalisation

This section provides a brief overview of all the ACV literature and highlights some of the major gaps in the research. Chapter 3 provides a more detailed, systematic review of the key ACV research.

2.4.1 Development

Some tracheostomy tubes have a subglottic port. This narrow tube passes from outside the person and has an opening above the air-filled cuff. This subglottic port was initially created for speech and was first reported in 1967 (Whitlock, 1967). An external airflow applied via this subglottic port into the trachea and through the larynx enables

vocalisation (Figure 5). This novel approach provided patients who were previously unable to vocalise due to the inflated cuff the opportunity to speak and be heard. It was not until 1977 that these subglottic tubes were modified to enable the removal of aspirated oral secretions (Shahvari et al., 1977). The removal of oral secretions from above the cuff has been shown to reduce the micro-aspiration of secretions around the cuff into the lungs and reduce the rates of VAP (Ledgerwood et al., 2013).

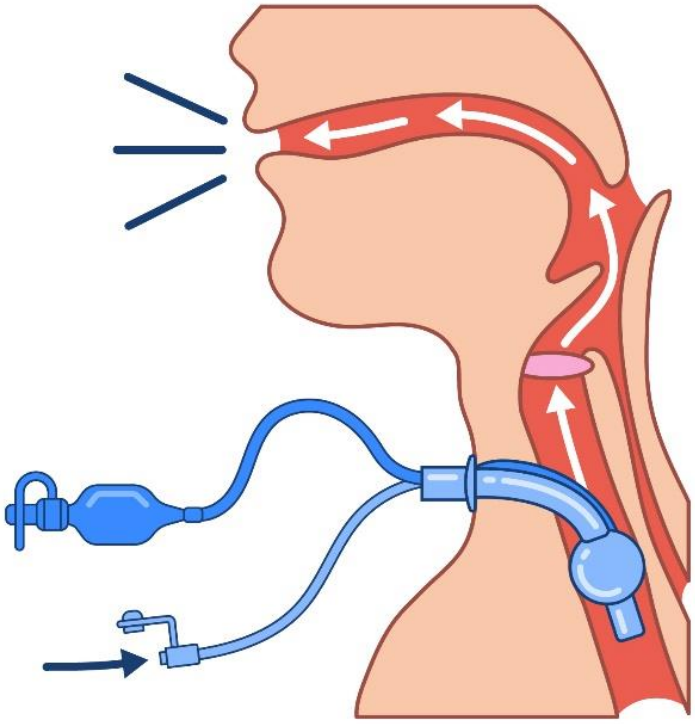

Figure 5 Tracheostomy tube with subglottic suction port. The blue arrow indicates where the airflow is applied to the port. The white arrows indicate the direction of airflow through the vocal folds and exiting via the oral cavity.

2.4.2 Terminology

Since 1967 when the term “speaking-aid” was used to describe this new technique (Whitlock, 1967), various nomenclature has been used to describe this intervention. These have included Above Cuff Vocalisation (ACV) (McGrath et al., 2016; Calamai et al., 2018; McGrath et al., 2019); External Subglottic Air Flow (ESAF) (Kothari et al., 2017); Talking Tracheostomy (Leder, 1991; Pandian et al., 2020); Speaking Tracheostomy (Shahvari et al., 1977; Mitate et al., 2015); and Vocalaid (Akhtar and Bell, 1993). This variation in terminology can lead to some confusion when discussing this intervention. In particular, all but one of the terms used – ESAF – refers to speech or vocalisation, which could imply that this is an intervention that purely benefits

communication. In the thesis, the term ACV will be used to describe all forms of external airflow application through the subglottic port of a tracheostomy tube.

2.4.3 Variations in tracheostomy tubes

The older research – conducted pre-1996 – used tracheostomy tubes specifically designed for ACV. These specialised tubes were called the Communi-Trache I® (Leder and Astrachan, 1989; Leder and Traquina, 1989); the Portex Vocalaid (Feneck and Scott, 1983; Akhtar and Bell, 1993); the Pitt-speaking cuffed tracheostomy (Gordan, 1984); and the Portex "Talk" tracheostomy tube (Kluin et al., 1984; Leder, 1990b; Leder, 1991). The Communi-Trache I® tracheostomy tube delivered an external airflow through eight fenestrations (Leder and Astrachan, 1989). The Portex "Talk" and the Portex Vocalaid tracheostomy tubes delivered an external airflow through a single opening (Leder, 1990b). These tracheostomy tubes are no longer in production. More recent research uses the Blue Line Ultra SuctionAid (BLUSA) Portex tube (Pandian, Smith, et al., 2014), sometimes called the Portex BLUSA, and the Argyle Aspiraid (Naito et al., 1996). Both tubes were primarily designed for removing secretions rather than for communication and have a single opening above the cuff.

Only one study has investigated ACV's efficacy with different brands of tracheostomy tubes. Leder compared voice intensity and time to adequate voice production with the Communi-Trache I® and Portex "Talk" tracheostomy (Leder, 1990b). They reported that there were no significant differences between the voice intensity produced, but that there was a significantly shorter time to adequate voice production with the Portex "Talk" tube (2.1 days versus 5.6 days) (Leder, 1990b). This has implications for patient-reported outcomes, such as satisfaction, as well as cost and time ramifications for staff needing to provide additional patient training to facilitate successful ACV use with the Communi-Trache I®. One study found a serious design flaw in the Communi-Trache I®, with the external position of the subglottic port irritating the stomal site and frequently causing the development of stomal complications, such as granulation tissue, pressure necrosis, infection, and extension of the stoma. These studies suggest that the tracheostomy tube design may impact ACV's efficacy, patient-reported outcomes, costs, and resources. Anecdotally, other brands of tracheostomy tubes are currently being used to deliver ACV, including TRACOE® tracheostomy tubes and Shiley™ tracheostomy tubes. There is no specific research investigating the efficacy or safety of these tubes or comparing these tubes with the Portex BLUSA (the Argyle Aspiraid appears to have been discontinued). It is currently unclear whether current ACV research findings can be generalised to all brands of tracheostomy tubes.

2.4.4 Technique

The critical elements of ACV delivery are airflow type (e.g., oxygen or medical air, both of which can be humidified or non-humidified); airflow delivery (e.g., continuous or intermittent, controlled using a thumb port); airflow rate in litres per minute (L/min); and frequency and duration of airflow delivery. There is wide variation in the precise technique of ACV delivery used in the research literature, and many authors did not outline the detail of the approach taken (Table 1).

Most studies use flow rates varying from 1–6 L/min, which is a reasonable range given the variability in patient tolerance of the applied airflow. In contrast, there was a period from 1984 to 1991 where studies were using higher flows of 10-15 L/min. The different brands and designs of tracheostomy tubes may influence the airflow rates required to achieve vocalisation and how patients tolerate the airflow. Of those studies that reported duration or frequency, this mainly was reported imprecisely or partially.

This variety in ACV delivery, combined with the lack of detail provided by some authors, is problematic for evidence interpretation. Comparison of studies is challenging, and no clear evidence supports any particular approach. This has the potential to make the implementation of this intervention complex and confusing for HCPs. Additionally, the lack of methodological detail in most studies makes replication challenging.

2.4.5 Target population

ACV is used with patients with a wide variety of primary diagnoses. This includes burns, respiratory, spinal cord injury, haematology, neurological (including neurosurgery and neurodegenerative conditions), surgery (e.g., general, thoracic, cardiac, cardiothoracic), progressive immune disorders, oncology, renal, haematology, genetic diseases, and out-of-hospital cardiac arrest. The only consistent contraindication mentioned in the literature is upper airway obstruction, which excludes many head and neck patients (Pandian, Smith, et al., 2014; McGrath et al., 2016). Although some of the research suggests that ACV should only be used with alert patients attempting to communicate (Pandian, Smith, et al., 2014; McGrath et al., 2016), one study successfully evaluated ACV in patients with a disorder of consciousness (Kothari et al., 2017).

Table 1 Key elements of airflow delivery

Study	Airflow type	Airflow delivery	Airflow rate used or recommended	Airflow duration and frequency
Whitlock, 1967	Not specified	Continuous	Upper limit of 5 L/min	Whenever the patient wants to communicate
Hansen, Niemala and Olsen, 1975	Oxygen	Not specified	1.5–2 L/min	Not specified
Safar and Grenvik, 1975	Not specified	Intermittent	4–10 L/min	Not specified
Feneck and Scott, 1983	Oxygen	Continuous	2–4 L/min	Not specified
Gordan, 1984	Warmed humidified airflow (oxygen/medical air not specified)	Continuous	Not specified	Stated it should be used 4-5 times per day or 'whenever indicated'
Kluin, Maynard and Bogdasarian, 1984	Not specified	Not specified	5–10 L/min	Not specified
Levine, Koester and Kett, 1987	Humidified and non-humidified oxygen	Intermittent	Approximately 5 L/min	Not specified
Sparker *et al.*, 1987	Not specified	Intermittent	Not specified	Not specified
Leder and Astrachan, 1989	Not specified	Intermittent	2–15 L/min	Not specified
Leder and Traquina, 1989	Not specified	Intermittent	2–15 L/min	5 seconds of airflow at each of three rates of flow; also state daily rehabilitation with an SLT

Leder, 1990	Medical air	Not specified	2–15 L/min	5 seconds of airflow at each of three rates of flow; also state daily rehabilitation with an SLT
Leder, 1991	Not specified	Intermittent	2–15 L/min	Not specified
Akhtar and Bell, 1993	Oxygen	Continuous	6 L/min	30 seconds on the first attempt, but not specified for further attempts
Naito *et al.*, 1996	Humidified oxygen	Continuous	1 L/min	Not specified
Husain, Gatward and Harris, 2011	Not specified	Not specified	2–5 L/min	Not specified
Pandian, Smith, *et al.*, 2014	Medical air	Intermittent	2–5 L/min	Not specified
Mitate *et al.*, 2015	Humidified oxygen	Not specified	5 L/min with BLUSA, details not provided for Vocalaid	'patient-dependent' duration; a few minutes tolerated with Blue Line Profile Cuff tracheostomy tube and up to 10 minutes with the Vocalaid
McGrath *et al.*, 2016	Oxygen	Intermittent	3–6 L/min	'5-minute spells' reported for two of five patients
Kothari *et al.*, 2017	Medical air	Intermittent	3 L/min	5 minute episodes (with a total of 100 seconds of airflow application) repeated three times during a 150-minute period

Calamai *et al.*, 2018	Medical air	Not specified	2–3 L/min	‘a few minutes’
McGrath *et al.*, 2019	Not specified	Not specified	1–5 L/min	Prescribed up to 15 minutes every two hours. Median duration of three days. Median of nine ACV episodes. Median of 15-minute episodes (range: 1-20 minutes)
Pandian *et al.*, 2020	Not specified	Not specified	Mean: 4.7 ± 1.3	Not specified

2.4.6 Purpose and Outcomes

ACV appears to have been developed primarily to facilitate speech production for patients who would otherwise be unable to vocalise. Early research, with the Communi-Trache l® and the Portex “Talk” Trache, focussed primarily on communication outcomes and safety (Leder and Astrachan, 1989; Leder and Traquina, 1989; Leder, 1990b; Leder, 1991). In contrast, the newer research using the Portex BLUSA has also included outcomes for swallowing, airway protection and cough, QoL, and LoS (Naito et al., 1996; Pandian, Smith, et al., 2014; McGrath et al., 2016; Kothari et al., 2017; McGrath et al., 2019; Pandian et al., 2020). This research has shown benefits in communication, swallowing, cough, and QoL. The inclusion of HRQoL outcomes is essential to allow the identification of drivers that may impact cost-effectiveness.

2.4.6.1 Communication

Most of the benefits reported in the literature are for communication. These reported benefits are predominantly subjective descriptions, such as “intelligible whisper” (Gordan, 1984); “communicating effectively” (McGrath et al., 2016); “audible whisper” (McGrath et al., 2019); “meaningful communication with staff and family” (Pandian, Smith, et al., 2014); “easier communication” (Whitlock, 1967); “able to converse” (Shinnick and Freedman, 1981); “able to talk with a whisper” (Safar and Grenvik, 1975); “hoarse whisper for few minutes” (Mitate et al., 2015); “vocalise with a whisper-type voice” (Husain et al., 2011); “vocalisation was possible” (Hansen et al., 1975); “whispered intelligible speech” (Levine et al., 1987); and “used effectively for communication” (Safar and Grenvik, 1975). Subjective reports of speech intelligibility – where, for example, statements that 74% of patients were able to produce intelligible speech – typically provided no methodological detail of the assessment process or the professional background of the assessor (Kluin et al., 1984).

Benefits on various subjective scales were reported: improvements in the repetition score of the Voice-Related Quality of Life measure (V-RQOL) (Pandian et al., 2020); greater voice intensity than ambient noise measured using a sound level metre (Leder and Traquina, 1989; Leder, 1990b); improvements to the voice Therapy Outcome Measure (voiceTOM) (McGrath et al., 2016; McGrath et al., 2019); improvements to the ICU Functional Communication Scale (ICU FCS) (McGrath et al., 2016; McGrath et al., 2019); and improvements in the Assessment of Intelligibility of Dysarthric Speech (Sparker et al., 1987).

Not all patients received the positive benefits described above, and various issues were identified. Gordan found that none of the patients with neuromuscular disease could use ACV successfully (Gordan, 1984). Two studies which collected data on the voiceTOM and the ICU FCS found a lack of improvement in 20-40% and 40% of

patients, respectively (McGrath et al., 2016; McGrath et al., 2019). One study reported that 20% of patients could not vocalise with ACV and that most patients struggled to produce intelligible speech at airflows of 5 L/min, requiring higher airflows to achieve vocalisation (Leder and Traquina, 1989). They also found that achieving intelligible speech took a mean of 5.6 days, with one patient even requiring 70 days to use ACV successfully (Leder and Traquina, 1989). Likewise, in another study which used a different brand of tracheostomy, Leder found that it took patients a mean of five days to produce intelligible speech, with some patients becoming extremely frustrated during this period (Leder, 1990b). There were also reports of the development of hoarse or strained voice quality in some patients (Pandian, Smith, et al., 2014; McGrath et al., 2019). It is unclear whether ACV has the potential to cause maladaptive laryngeal function, which could have longer-lasting adverse effects. For example, an attempt to control the airflow using the larynx could lead to heightened muscle tension, leading to the development of muscle-tension dysphonia or dysphagia.

The current evidence suggests that there are potential benefits for communication for some patients using ACV. However, much of this evidence is subjective and gathered using unclear methodology. Additionally, the ACV literature was either observational or did not apply treatment allocation concealment. Research suggests that HCPs may exaggerate positive findings when using subjective outcome measures where there is a lack of blinding of treatment groups (Wood et al., 2008). It is unclear which types of patients benefit most from a communication perspective, and the extent of the benefit is uncertain. Given the lack of clarity on frequency and duration of delivery, it is difficult to judge the overall functional benefit for patients. For example, if a patient can achieve top scores on the ICU FCS or the voiceTOM whilst using ACV for 10 minutes a few times daily, it is ambiguous what difference that will make to overall functional communication benefit for the whole day.

2.4.6.2 Swallowing

Subjective observations of swallowing improvements have been noted in some of the literature; for example, Naito described “abolishing aspiration” (Naito et al., 1996). McGrath and colleagues stated that one patient’s swallow function “improved quicker than anticipated” and that ACV resulted in “stimulating a swallow” in another patient (McGrath et al., 2016). Additionally, McGrath and colleagues reported improvements in the Secretion Severity Rating Scale for 50% of patients with a median gain of 0.5 but found no significant difference in the Penetration Aspiration Scale (PAS) (McGrath et al., 2019). In terms of objective measures of swallowing, Kothari and colleagues found a significant increase in the mean swallowing frequency – from 0.60 ± 0.30 per minute to 2.10 ± 0.70 – and a reduction in the quantities of oral secretions collecting above the cuff – from 3.10 ± 0.31 millilitre (mL) to 0.50 ± 0.30 mL (Kothari et al., 2017). Similarly,

McGrath and colleagues found an increase in the number of spontaneous swallows occurring per minute in 80% of patients, with a median increase of two swallows per minute from a median of zero (McGrath et al., 2019).

The evidence indicates that ACV appears to have some positive impact on swallowing function, improving swallowing frequency in some patients. An increase in swallowing frequency of 1.5 to 2 per minute may be clinically meaningful because healthy individuals swallow approximately once per minute, and these patients were mostly not eliciting any swallows spontaneously (Ertekin, 2010). However, swallow frequency does not equal swallow efficacy. ACV may improve swallowing frequency but not impact the efficacy of oral secretions clearance or airway protection. The lack of observed improvement in the PAS suggests that swallowing efficacy may not improve. Nonetheless, the increase in swallowing frequency could have longer-term benefits to swallowing efficacy by acting to rehabilitate the swallowing musculature, but these longer-term effects have not been evaluated to date. The clinical utility of a 0.5 increase in the secretion severity rating scale (SSRS) is unclear. Research has been conducted to look at the association of the score with the risk of aspiration during oral intake; this indicated there are clinically meaningful differences in aspiration in whole point changes at specific points of the score, but it did not report on 0.5 changes on the scale (Ginsberg et al., 1996). A meta-analysis has shown that removing secretions from above the cuff can help to reduce pneumonia risk by approximately 50% (Dezfulian et al., 2005). However, the included studies removed secretions continuously or very frequently. It is unclear if the reductions in subglottic volumes achieved during the 150-minute treatment period would be sufficient to impact pneumonia risk (Kothari et al., 2017).

2.4.6.3 Cough

Reflexive and voluntary coughing are essential mechanisms for airway protection and clearance (Magni et al., 2011). McGrath and colleagues reported some subjective statements about the positive benefits for reflexive coughing with ACV, including “improved glottic closure reflexes” and “stimulating a cough”, but there were no measurements or objective outcomes reported (McGrath et al., 2016). One study reported a significant increase in the number of spontaneous coughs per minute with ACV (McGrath et al., 2019). However, this was an increase of 0.5 coughs per minute reported in 50% of patients. As discussed with swallowing, cough presence does not equate to cough effectiveness. Therefore, an increase in cough frequency does not necessarily signify improved airway protection. Indeed, they found no significant difference in the Airway Protection Scale (APS) or the PAS, suggesting no functional improvement to cough effectiveness. Thus, there is a lack of evidence to suggest any clinically meaningful benefit to patients for cough or airway protection. Despite this, as

with swallowing, cough frequency and effectiveness may improve over time with repeated exposure to ACV, and this has not been examined to date.

2.4.6.4 Quality of life

Most of the positive benefits reported for patient QoL are in the form of subjective descriptions. Examples include “improved quality of life” (Pandian, Smith, et al., 2014); “generally grateful for the reacquisition of intelligible speech” (Kluin et al., 1984); “improving both their overall care and well-being” (Husain et al., 2011); “independent voice control enhances communication and other aspects of treatment” (Levine et al., 1987); “relieves the patient from the frustration and fear of not being able to make his requirements known” (Whitlock, 1967); and “happiness and safety of these patients increase” (Safar and Grenvik, 1975). One study used subjective measures of QoL, employing the V-RQOL and the QoL-MV (Pandian et al., 2020). They found significant improvements in the V-RQOL but only found improvements in the QoL-MV when 10 of the 25 patients in the control group were excluded (these patients had progressed to cuff deflation and use of a PMV) (Pandian et al., 2020). A patient-reported satisfaction scale found that 41% of patients stated that they were somewhat or very satisfied with ACV, and 73% reported that they could use ACV independently to some extent (Pandian et al., 2020). The evidence to date signals potential benefits for QoL for patients receiving ACV. However, this evidence is subjective, limited, and biased due to the exclusion of patients in the RCT and the lack of control groups in all other studies.

2.4.7 Adverse events and complications

Diverse adverse events and complications are reported in the research (described in Table 2). One of the complications – drying of the laryngeal mucosa – is discussed as a potential issue in many studies. The limits suggested on duration or frequency of use are generally implemented to prevent this perceived complication. However, there are no reported examples of mucosal drying being observed. This may be due to the potential difficulties in assessment, as it is unclear whether nasendoscopic examination of the larynx could identify drying of the mucosa. One non-invasive way to identify laryngeal mucosal drying would be to measure the perturbation of sounds and evaluate jitter and shimmer (Zou et al., 2019). However, this technique has not been used in any of the ACV research. These adverse events and complications are often not reported stringently or comprehensively. It is uncertain whether some of the more minor complications are not reported because they were absent, not observed, or considered unimportant.

Table 2 Potential adverse events and complications

	Adverse events and complications	Reference
Serious adverse events	Subcutaneous emphysema	Safar and Grenvik, 1975; Akhtar and Bell, 1993; Calamai *et al.*, 2018
	Tracheal dilation from misapplication of the airflow to the pilot balloon, causing the tracheostomy cuff to burst	Feneck & Scott, 1983
Complications	Air trapping	Pandian, Smith, *et al.*, 2014; McGrath *et al.*, 2016
	Air leak around the stomal site	Whitlock, 1967; Hansen, Niemala and Olsen, 1975; Safar and Grenvik, 1975; Sparker *et al.*, 1987; Pandian, Smith, *et al.*, 2014; McGrath *et al.*, 2019
	Tissue damage at the stomal site	Leder and Astrachan, 1989
	Aerophagia (swallowing of air) which can cause discomfort and abdominal distension	McGrath *et al.*, 2016
	Excessive oral secretions	Shinnick and Freedman, 1981; Kluin, Maynard and Bogdasarian, 1984; Sparker *et al.*, 1987; McGrath *et al.*, 2019
	Discomfort	Whitlock, 1967; Hansen, Niemala and Olsen, 1975; Safar and Grenvik, 1975; Gordan, 1984; Leder and Traquina, 1989
	Gagging	McGrath *et al.*, 2019
	Nausea	McGrath *et al.*, 2019
	Hoarse or strained voice quality	Pandian, Smith, *et al.*, 2014; McGrath *et al.*, 2019
	Drying of the laryngeal mucosa	Whitlock, 1967; Kluin, Maynard and Bogdasarian, 1984; Naito *et al.*, 1996; Husain, Gatward and Harris, 2011; Pandian, Smith, *et al.*, 2014; McGrath *et al.*, 2016, 2019

2.4.8 Troubleshooting

Various perceived and actual issues with ACV are discussed frequently in the literature, including details of how to troubleshoot them. These issues and suggested solutions are outlined in Table 3. The number and variety of issues reported imply that ACV is a temperamental or unreliable intervention. However, there is limited evidence to support how common these issues are or their impact on the clinical application of ACV.

Table 3 Potential issues and troubleshooting suggestions

Potential issue	Troubleshooting suggestion	Reference
Blockage of subglottic port with secretions	Applying 1-2 mL of 10% acetylcysteine via the subglottic port once or twice per day to reduce the viscosity of secretions	Shinnick & Freedman, 1981; Kluin *et al.*, 1984
Tracheal dilation from misapplication of the airflow to the pilot balloon	Modifying the tube to make connection to the pilot balloon impossible	Feneck & Scott, 1983
	Labelling the pilot balloon and subglottic port	Pandian *et al.*, 2014
Drying or irritation of the laryngeal mucosa	Using a thumb port to allow intermittent flow	Feneck & Scott, 1983
	Avoiding prolonged use of non-humidified air	Naito *et al.*, 1996
	Using humidified air/oxygen	Pandian *et al.*, 2014; Levin *et al.*, 1987; Kluin *et al.*, 1984
	Using warmed, humidified air/oxygen	Whitlock, 1967
	Turning off the airflow when the patient does not want to speak	Whitlock, 1967
	Limiting duration and rate of airflow	Husain *et al.*, 2011
	Ensuring the thumb port is unoccluded when not being used by the patient	Pandian *et al.*, 2014

Granulation tissue at the stomal site	Re-designing tubes so that airflow lines do not cause damage to neck/stomal tissue	Leder & Astrachan, 1989
General complications	Experienced multi-disciplinary team and trained SLT supervising patient	McGrath *et al.*, 2016
Strained vocal quality	Using minimal airflow	Pandian *et al.*, 2014
	Endoscopy to assess vocal folds	Pandian *et al.*, 2014
Airway trapping/Subcutaneous emphysema	Avoiding using with patients with airway obstruction	Pandian *et al.*, 2014
	Waiting for 48 hours post-insertion	McGrath *et al.*, 2016; Akhtar & Bell, 1993; Safar & Grenvik, 1975
	Waiting for 72 hours post-insertion	Whitlock, 1967
	Using a pressure-relief valve in the airflow line	Whitlock, 1967
	Inserting a tube with a subglottic port as the second tube to avoid using ACV with a fresh stoma	Pandian *et al.*, 2014
Abdominal distension	Turning off the air when the patient does not wish to speak	Pandian *et al.*, 2014
Patient and staff frustration	Daily rehabilitation with SLT	Leder, 1990; Leder & Traquina, 1989
	Screening to select patients who will benefit to reduce the risk of disappointment	Sparker *et al.*, 1987
Poor connection of airflow to subglottic port	Taping of tubing to reduce airflow leak	Leder, 1990
	Reducing the size of the valve tip	Leder, 1990

Lack of synchronisation of vocal fold adduction with airflow	Daily rehabilitation with SLT	Leder & Traquina, 1989
	Training to speak only on ventilation expiration	Leder & Traquina, 1989
Lack of vocalisation	Cough/throat clear exercises	Leder & Traquina, 1989
	Checking the positioning of the tube	Leder & Traquina, 1989; Kluin *et al.*, 1984
	Checking the subglottic port is not blocked	Leder & Traquina, 1989
	Endoscopy/Fibreoptic Endoscopic Evaluation of Swallowing to exclude laryngeal pathology	Leder & Traquina, 1989; Leder, 1991
	Avoiding use it with patients with neuromuscular disease	Gordan, 1984
	Prevent kinking of airflow tubing	Leder & Traquina, 1989
	Replacing the tube	Kluin *et al.*, 1984
Air leak at stoma site	Manually adjusting the ventilator tubing to optimise the tracheostomy position	Leder & Traquina, 1989
	Applying gentle pressure to the tracheostomy to counteract the pull of the ventilator tubing	Sparker *et al.*, 1987
	Waiting 48 hours post-insertion to allow healing of the stoma site	Safar & Grenvik, 1975
	Waiting 72 hours post-insertion to allow healing of the stoma site	Whitlock, 1967
Difficulties with independent use	Providing extra airflow tubing to improve the location of the thumb port for the patient	Leder & Traquina, 1989

	Using devices or microswitches to allow the patient to control airflow	Whitlock, 1967; Levin *et al.*, 1987
Air leak around the cuff (e.g., damaged cuff, poorly fitting tube)	Replacing the tube	Sparker *et al.*, 1987
Lack of use	Ongoing support from SLT to encourage and monitor ACV use	Sparker *et al.*, 1987
	Staff and family motivating, supporting, and encouraging the patient	Leder, 1991
Incorrect use	Daily rehabilitation with SLT	Leder, 1991
Discomfort	Using humidified air/oxygen	Levin *et al.*, 1987
	Using individualised, appropriate airflow	Leder, 1991
	Using warmed and humidified air/oxygen	Safar & Grenvik, 1975
Increased risk of VAP	Aspirating subglottic secretions before commencing the airflow	Husain *et al.*, 2011

2.4.9 Evidence quality

Most of the ACV studies discussed in this chapter were commentaries, letters to the editor, case reports, case series, observational, and quasi-experimental, with only one RCT (Pandian et al., 2020). All studies were generally small-scale – the largest having 50 participants – with most having 20 or fewer. The positive outcomes reported in the research must be read in light of the methodological limitations observed. Although there are indicators of various positive benefits of ACV for patients, the extent of these benefits remains unclear. The evidence quality for ACV is discussed in more detail in systematic review (Chapter 3).

2.4.10 Evidence gaps

There are a variety of specific gaps in the ACV research. There has yet to be any recent research comparing the different brands of tracheostomy tubes that are currently in use, and there may be advantages and disadvantages with certain brands of tubes. There is wide variation in the application of ACV – in terms of airflow type, airflow delivery, airflow rate, frequency and duration – and the details of these aspects of the intervention are often omitted from the methods. As such, there is a lack of evidence to support any of the aforementioned approaches to ACV application.

Currently, there is no information available regarding how widely ACV is being used, what ACV approach is being implemented in clinical practice, how HCPs are making decisions about which approach to take, whether regular use of ACV can help to achieve improved patient outcomes, or about the type and frequency of issues that HCPs face when using ACV. A wide variety of outcome measures are used in the ACV research, and a preponderance of subjective measures are used. There is currently no core outcome set for communication or dysphagia research in the critical care setting, although work has commenced on both (Zaga, Cigognini, et al., 2020; Duncan et al., 2023). It is difficult to ascertain the clinical meaningfulness of some reported benefits, particularly for cough, swallowing, and communication. The research literature has also not evaluated the impact of ACV on VAP, time to decannulation, or the laryngeal mucosa. The only RCT evaluated the effect on ICU and hospital LoS, finding that ICU and hospital LoS were significantly greater in the ACV group, compared to the control group, with a difference of 20 days and 25 days, respectively (Pandian et al., 2020). However, given the different weaning approaches implemented between the two groups, and the exclusion of some patients from the analysis, it is challenging to attribute differences between the groups. It may be more likely that the increase in LoS is due to the different weaning protocols or other factors rather than any negative effects from ACV. These differences are discussed further in Chapter 3.

Despite the lack of a systematic approach to the development of ACV, with crucial development missing and significant evidence gaps, the intervention has been disseminated and appears to be used worldwide.

2.5 Cost-effectiveness

Good quality economic evaluation, as outlined in the international Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) – and as adopted by the National Institute of Clinical Excellence (NICE) as the ‘reference case’ model – requires good quality causal inference data on the impacts of different treatment options on the Health-Related QoL (HRQoL) of patients and the costs to the NHS and patients (Husereau et al., 2022). HRQoL has to be measured consistently to facilitate comparison across all disease types. It is widely agreed that the HRQoL measure of choice is the QALY, and in the UK, the preferred outcome measure of HRQoL to determine QALYs is the EQ-5D questionnaire (NICE, 2022).

The costs associated with tracheostomy care in the ICU are substantial. Sections 2.2 and 2.3 highlighted the various ways that tracheostomy care can impact healthcare costs. Similarly, ACV implementation and delivery could substantially impact healthcare costs. However, to date, there is no evidence about the potential costs associated with ACV implementation. As outlined above in section 2.4.6.4, there is minimal and biased evidence available for the effects of ACV on QoL. The evidence presented has

suggested potential cost-effectiveness drivers, including communication, swallowing, cough, LoS, and QoL. Nevertheless, the evidence does not provide quantitative causal estimates that could be used to conduct standard health economic evaluations. For example, the single RCT of ACV was the only study that used a QoL outcome measure. The duration of impact on QoL was unclear, and almost half of the patients from the control group were excluded from the analysis. It is unlikely that the two QoL measures used in this study, the V-RQOL and the QoL-MV, could be converted to QALYs. Indeed, there are no reports in the literature of utility values being calculated from these QoL measures. Obtaining adequate HRQoL information for ACV requires RCTs that use generic, approved HRQoL measures at several time points. This will allow utilities for patients receiving ACV to be compared to those receiving usual care.

There is also no published evidence evaluating the costs or cost-effectiveness of the intervention. Nonetheless, if ACV negatively impacts ICU and ward LoS, as reported in the RCT, this is likely to have a substantial negative impact on the cost-effectiveness of the intervention.

2.5.1 Decision analytic modelling

An essential step in decision-making regarding an intervention is understanding the relative costs, potential cost savings, and effectiveness. One way to evaluate the cost-effectiveness of an intervention is to use decision-analytic modelling.

A Decision-Analytic Model (DAM) is a framework to support decision-making with limited data and uncertainty of outcomes (Brennan and Akehurst, 2000), which appears to be the case for ACV. When used in healthcare – for health economic evaluation – it maps a clinical pathway to estimate outcomes and cost-effectiveness for a hypothetical patient cohort (Briggs and Sculpher, 1998). Decision-analytic modelling enables decision-makers to make informed and rational choices about which clinical approaches should be implemented (Elwyn et al., 2001).

Another tool which can be used with decision-analytic modelling is the Value of Information (VOI) analysis. VOI analysis allows a judgement to be made about the cost of obtaining additional information from further research that would facilitate the reduction of uncertainty in the model (Brennan and Akehurst, 2000). This provides a structured, methodological approach to determining where future research should focus (Wilson, 2015).

Decision-analytic modelling and VOI will be described in more detail in Chapter 6. This description will include information on what they are, how they can be used, how they have been used in critical care research, and how they have been used in the thesis.

2.6 Implications for ACV

As discussed in Sections 2.2 and 2.3, tracheostomy and tracheostomy management approaches can impact patients in various ways. Although other impacts exist, these sections highlighted those impacts with direct implications for ACV. This section describes some of the implications for ACV.

2.6.1 Tracheostomy insertion implications for ACV

The controversy surrounding the timing of tracheostomy insertion is particularly relevant to ACV, as it leads to a wide variation in practice internationally, nationally, and even within services. Most services do not protocolise the timing of tracheostomy insertion, which means that when evaluating the impact of ACV, the heterogeneity of timing of tracheostomy insertion may also impact patient outcomes, such as pneumonia rates, duration of ventilation, ICU LoS, and mortality. Additionally, there is conflicting evidence surrounding the impact of the duration of intubation on the likelihood of laryngeal injury, dysphonia and dysphagia developing (Barker et al., 2009; Skoretz et al., 2010; Brodsky et al., 2018; McIntyre et al., 2022), but increasing duration will likely increase the severity of laryngeal injury, dysphonia, and dysphagia, where present (Brodsky et al., 2014).

Most of the research related to ACV does not specify whether the intervention was delivered in patients with surgically or percutaneously inserted tracheostomy. However, one of the case reports of subcutaneous emphysema occurred in a patient with a surgically inserted tracheostomy (Akhtar and Bell, 1993) and another in a patient with a percutaneously inserted tracheostomy (Calamai et al., 2018). The instability of the stoma following surgical insertion creates more of a risk for subcutaneous emphysema, and delaying the introduction of ACV may help to reduce this risk. ACV could be used earlier in patients with a percutaneously inserted tracheostomy with a potentially lower risk of adverse events than those with a surgically inserted tracheostomy.

2.6.2 Weaning implications for ACV

ACV can potentially impact tracheostomy weaning by improving swallowing function, oral secretion management, and cough function. However, weaning from the ventilator and the tracheostomy is needed before decannulation is possible. Approaches to tracheostomy and ventilator weaning vary widely between hospitals within the NHS and internationally (Mitchell et al., 2013; de Lima Zanata et al., 2014; Smith et al., 2014; Cohen et al., 2016; Welton et al., 2016). Indeed, approaches to weaning can vary within the hospital from ward to ward and from staff member to staff member, with HCPs often having strong opinions about the best approaches (Pierson, 2005; Liu and Gropper, 2008). This variation in practice is likely due, in part, to the lack of evidence supporting any particular approach. There is also likely to be some heterogeneity due

to different approaches taken with different patient populations (Blackwood et al., 2014). Researchers attempting to evaluate weaning practices face various barriers, particularly the inability to blind HCPs and researchers, and the bias and lack of equipoise (Sugerman et al., 1997; Pierson, 2005; Blackwood et al., 2014). Pierson states, “When opinions are strongly held, as is the case with tracheostomy and weaning, truly objective research with clinically meaningful endpoints may not be possible” (Pierson, 2005).

This heterogeneity in weaning practice results in a high risk of bias in any critical care research study investigating outcomes that variable weaning approaches may impact. Without a highly protocolised ventilator and tracheostomy weaning approach for all patients in a study, it is difficult to judge the impact of an intervention like ACV on critical outcomes such as pneumonia, LoS, mortality, and costs. Indeed, even with a protocolised weaning approach, the strong views of HCPs can lead to a lack of adherence to those protocols (Sugerman et al., 1997; Pierson, 2005; Liu and Gropper, 2008).

2.6.3 Impact of tracheostomy implications for ACV

Table 4 summarises these key impacts, their relationships, and their implications for ACV.

2.7 Summary

This review of the literature provides essential background information for ACV. Managing critically ill patients is complex, particularly management decisions around weaning from mechanical ventilation. The ICU population is heterogeneous, and there is considerable variation in clinical practice, particularly regarding ventilator and tracheostomy weaning. Patients requiring a tracheostomy can expect to experience many wide-ranging adverse effects. The short- and long-term consequences of these effects can be profound for patients, family members, and staff. ACV restores airflow through the laryngo-pharynx and shows the potential to address some of these adverse effects. However, there is limited evidence available for ACV, and there is considerable variation in the application of ACV, the primary purpose of the intervention, and the outcomes used. Adverse events and complications can occur with ACV, and approaches to improve safety are uncertain. There are many gaps in the ACV evidence, and some of these gaps will be addressed in subsequent chapters. Chapter 3 reports on the first systematic review of ACV, evaluating the evidence for the acceptability of ACV, adverse events and complications, and its effectiveness for communication, swallowing, airway protection, QoL, and LoS.

Table 4 Summary of the key impacts of tracheostomy and the implications for ACV

References	Key impact of tracheostomy	Implications for ACV
Sasaki *et al.*, 1977; Siebens *et al.*, 1993; Stoschus and Allescher, 1993; Eibling and Gross, 1996; Ding and Logemann, 2005; Ceriana *et al.*, 2015; Kothari *et al.*, 2017; McGrath *et al.*, 2019; Skoretz *et al.*, 2020; Wallace and McGrath, 2021	Laryngo-pharyngeal **sensation** and **swallowing** are impacted by tracheostomy. Reduced swallowing frequency with associated muscular atrophy and altered subglottic pressures are critical components of dysphagia. Some drugs used in the ICU can also induce or exacerbate swallowing dysfunction.	If ACV improves laryngo-pharyngeal sensation by restoring trans-laryngeal airflow, this may help improve swallowing frequency, preventing further atrophy and rehabilitating atrophied muscles. If ACV improves subglottic pressures – which will likely depend on the airflow rates and whether airflow is applied continuously or intermittently – it may help to improve swallowing function.
Kallesen, Psirides and Huckabee, 2015; Brodsky *et al.*, 2018; Zuercher *et al.*, 2019; Wallace and McGrath, 2021	Laryngeal **sensation** is also vital for effective **cough;** patients must be sensate to material to trigger reflexive coughing.	If ACV improves laryngeal sensation, it may help to improve cough sensitivity and airway protection. The extent of the improvements to sensation is likely to vary dependent on airflow delivery (e.g., airflow rates).
Dettelbach *et al.*, 1995; Elpern *et al.*, 2000; Fontana and Widdicombe, 2007; Magni *et al.*, 2011; Morris *et al.*, 2015	Patients with an inflated cuff have no trans-laryngeal airflow. This means they cannot elicit a **cough** to clear material from the trachea or larynx and provide **airway protection**.	ACV provides a trans-laryngeal airflow, and this may be sufficient to facilitate coughing and airway protection. If ACV improves subglottic pressures, cough strength may be enhanced. The extent of improvements to subglottic pressures will likely vary depending on airflow delivery (e.g., airflow rates and whether the flow is intermittent or continuous). It is unlikely that ACV will provide the same

		improvements to sensation, pressures, and cough as cuff deflation and OWV provide. This is because cuff deflation and OWV provide a more normalised airflow from the lungs, with complete airflow diversion through the larynx and upper airway.
F. Blot *et al.*, 2008; Brodsky *et al.*, 2018; Wallace and McGrath, 2021	**Laryngeal injury** is common in patients with a tracheostomy, which can affect **cough** and the effectiveness of **airway protection**. It can also impair vocal function and reduce airway patency, affecting **safety** and tracheostomy weaning.	The assessment process undertaken for ACV may also help to detect laryngeal injury; if there is evidence of restricted airflow, it may indicate a potential airway obstruction, e.g., vocal fold paralysis. ACV may also be ineffective in patients with laryngeal injury. The high prevalence of laryngeal injury in these patients presents a potential safety concern for ACV, particularly in patients with reduced airway patency. The air may have nowhere to escape, resulting in air trapping, tissue damage, or subcutaneous emphysema. Patients with suspected upper airway obstruction should undergo nasendoscopic laryngeal assessment before using ACV (Pandian, Smith, et al., 2014).
Menzel, 1998; Happ, 2000; Patak *et al.*, 2006; Carroll, 2007; Grossbach, Stranberg and Chlan, 2011; Rose *et*	Patients with an inflated cuff cannot vocalise, as this requires a trans-laryngeal airflow. This usually results in impaired **communication**, leading to frustration,	Where cuff deflation is not possible, ACV offers another option to restore trans-laryngeal airflow and can help to facilitate vocalisation. This creates the potential for other benefits, e.g., QoL and safety. If communication improves

al., 2014; Freeman-Sanderson *et al.*, 2018; Newman *et al.*, 2022	agitation, and distress and substantially impacting **QoL**. There are different options for communication, but patients prefer interventions that facilitate vocalisation.	and frustration and agitation are reduced, this may help to reduce the use of antipsychotics and sedatives, which may consequently improve swallowing function and participation in rehabilitation.
Kearney *et al.*, 2000; Krishnan, Elliot and Mallick, 2005; Young *et al.*, 2013; NCEPOD, 2014	There are a variety of complications that can occur in patients with tracheostomy, and processes to reduce risk and maximise **safety** are critical. Some of the safety incidents reported are related to patient agitation and frustration, e.g., accidental decannulation.	If ACV improves communication, this can help to reduce agitation and frustration and may help to reduce the risk of adverse events. However, ACV is also associated with adverse events, such as subcutaneous emphysema and tracheal dilation. The balance of risks in ACV is unclear.
Rumbak *et al.*, 2004; Safdar *et al.*, 2005; Forel *et al.*, 2012; Kollef, Hamilton and Ernst, 2012; Zheng *et al.*, 2012; Hayashi *et al.*, 2013; Ledgerwood *et al.*, 2013; Melsen *et al.*, 2013; Papazian, Klompas and Luyt, 2020	**VAP** is associated with increased **LoS** and increased risk of **mortality**. The **costs** of VAP are high. Patients with **swallowing** difficulties are more likely to develop VAP due to aspirated oral secretions.	If ACV improves swallowing function and airway protection, it may result in improved management of oral secretions and a reduced quantity of secretions passing below the level of the vocal folds. This could reduce the incidence of VAP, which would likely reduce LoS, costs, and may reduce mortality.
Engoren, Arslanian-Engoren and Fenn-Buderer, 2004; Gilony *et al.*, 2005; Sherlock, Wilson and Exley, 2009; Pandian, Bose, *et al.*, 2014;	**QoL** is significantly lower for patients with a tracheostomy, likely due to a combination of	If ACV improves communication and swallowing function, there is a potential for improved QoL. Improving the patient's ICU experience may also help to reduce the incidence or severity of post-intensive care syndrome, post-

Rose *et al.*, 2014; Freeman-Sanderson *et al.*, 2018	different factors, including impaired **communication** and **swallowing.**	traumatic stress disorder, and long-term QoL. However, the EQ-5D may not be sensitive enough to capture positive changes in the QoL of these patients, and it may be necessary to employ other measures, such as the QOL-MV, which have been developed specifically for this population.
Safdar *et al.*, 2005; Cetto *et al.*, 2011; Freeman *et al.*, 2013; Speed and Harding, 2013; Young *et al.*, 2013; Blackwood *et al.*, 2014; NCEPOD, 2014	**LoS** is generally longer for patients with a tracheostomy and is impacted by the duration of tracheostomy weaning and **adverse events**. **VAP** may increase the **LoS** and associated **costs**.	If ACV improves swallowing function and oral secretion management, it may help reduce VAP incidence. This may lead to faster tracheostomy weaning, earlier decannulation, and reduced LoS. If ACV improves communication function, it may reduce the need for sedatives or anti-psychotics. It may contribute to reducing the risk of adverse events and expediting tracheostomy weaning, potentially reducing LoS. By reducing LoS, ACV could contribute to considerable cost savings.
Fernandez *et al.*, 2008; Martinez *et al.*, 2009	The **mortality** risk is higher for some patients with a tracheostomy managed in a ward-based setting.	If ACV accelerates tracheostomy weaning and decannulation before step-down to the ward, it may contribute to reduced LoS and mortality. If ACV helps to improve oral secretion management, it may also help to reduce the incidence of adverse events and potentially the risk of death.

Chapter 3 Evidence for Above Cuff Vocalisation in Patients with a Tracheostomy: A Systematic Review

This chapter evaluates the evidence base for ACV, reporting the findings of a systematic review of the literature. Section 3.1 describes similar work that has been conducted, explains the rationale for conducting the systematic review, and outlines the aims of the review. Section 3.2 outlines the study objectives. Section 3.3 presents the methods employed. Section 3.4 reports systematic review findings. The results are discussed in Section 3.5 and summarised in Section 3.6.

The work presented in this chapter has been published in *The Laryngoscope*:

Mills, C.S., Michou, E., King, N., Bellamy, M.C., Siddle, H.J., Brennan, C.A. and Bojke, C., 2022. Evidence for above cuff vocalization in patients with a tracheostomy: a systematic review. *The Laryngoscope*, *132*(3), pp.600-611.

This work presented in this chapter is also discussed in an invited paper published in *Intensive Care Medicine*:

Mills, C.S., Cuthbertson, B.H. and Michou, E., 2023. What's new in reducing the impact of tracheostomy on communication and swallowing in the ICU. *Intensive Care Medicine*, pp.1-4.

3.1 Introduction

When registering the systematic review with the International Prospective Register of Systematic Reviews (PROSPERO) in May 2019, there had been no systematic evaluation of the evidence for ACV despite this intervention being used since 1967 (Whitlock, 1967). Subsequently, a systematic review evaluated the feasibility, utility and safety of communication interventions in patients receiving mechanical ventilation, including some of the ACV literature (Zaga et al., 2019). The authors concluded that the quality of evidence for communication interventions in mechanically ventilated patients, including ACV, was low or very low. Despite this, these interventions are feasible, have utility, and are safe to use (Zaga et al., 2019). These conclusions were based on the evidence included in the review, and this may have overestimated the utility and safety. Three case studies reporting adverse events with ACV were not included in this study, despite other case studies and series being included in this review. Although these three studies are low quality, it suggests that there are more adverse events and, potentially, there could be safety issues with ACV.

In addition to Zaga's systematic review, a scoping review was published on the safety and effectiveness of ACV for speech (Petosic et al., 2021). A scoping review presents a broad subject overview (Peters et al., 2020). Many of the methodological approaches taken in the scoping review were appropriate for the remit of a scoping review.

However, this study's limitations highlight the need for a systematic review of this topic. This scoping review focused solely on speech, which allowed greater depth of reporting of speech outcomes and barriers to use. Nonetheless, to judge ACV's clinical utility, a review is needed which incorporates all relevant outcomes. Broad inclusion criteria and inclusion of conference abstracts allowed all relevant evidence to be incorporated. It also resulted in apparent double counting of the RCT data, with the conference abstract included presenting 25 patients from the published paper of 50 patients. The absence of a registered or published protocol, as typical for a scoping review, means that there is an increased risk of bias. One key study, a case report of an adverse event, was omitted from the review (Akhtar and Bell, 1993), perhaps due to the searches being conducted in only three databases. Risk of bias appeared to be conducted only for studies included in the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) analysis, which leads to a risk of bias and lack of transparency in the synthesis of the evidence.

In summary, despite its increasing use worldwide, there has been no systematic evaluation of the quality of evidence for ACV use, effectiveness, and acceptability for communication and swallowing. This systematic review aimed to identify methods of ACV implementation, current evidence on the efficacy, effectiveness and safety of ACV, and the acceptability of ACV to patients and HCPs.

3.2 Study objective

This study explored the following thesis objective:

- Objective 1: To examine the current evidence for the use of ACV in patients with a tracheostomy through a systematic review.

3.3 Methods

A systematic review protocol was developed, and a summary of this protocol was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 3rd May 2019 (Registration number: CRD42019133942). This systematic review is reported in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) reporting guidelines (Moher et al., 2010).

3.3.1 Study eligibility criteria

The criteria for study eligibility for this systematic review were designed according to the Population Intervention Comparators Outcomes Study (PICOS) design framework. The PICOS for the study is outlined in Table 5.

Table 5 Population, Intervention, Comparators, Outcomes, Study (PICOS) framework

Population
Adult patients
≥18 years old
Tracheostomy with the cuff inflated for any period during the day
Intervention
‘Above Cuff Vocalisation’ or ‘External Subglottic Air Flow’ or ‘Talking Tracheostomy’
Application of an external flow of air, or oxygen, via the subglottic port of a tracheostomy
Comparators
As the review included studies without comparators, this part of the framework did not form part of the criteria
Outcomes
Swallow function
Communication function
Safety of the intervention
Acceptability of the intervention for patients and healthcare professionals
Incidence of pneumonia
Time to decannulation
Length of stay in the ICU and hospital
Quality of life measures
Costs of the intervention
Cost benefits
Study
Qualitative and quantitative
Evaluating the intervention or the acceptability of the intervention
Including: randomised, non-randomised and observational studies (cohort, case studies and case series)

Peer-reviewed publications in English
No restrictions to the publication year
Studies in any setting, e.g., ICU, acute care, rehabilitation units, residential homes, nursing homes or long-term care facilities

3.3.2 Search strategy

In May 2019, the following electronic bibliographic databases were searched: Ovid MEDLINE(R), Embase, AMED, CINAHL, Cochrane Central Register of Controlled Trials, PsycINFO, Scopus and Web of Science Core Collection (Clarivate). The PROSPERO database, the trials registries ClinicalTrials.gov (U.S. NIH), and the International Clinical Trials Registry Platform (ICTRP-WHO) were also searched to identify unpublished studies. In June 2020, the searches were re-run on all databases except the ICTRP-WHO, which was closed to external users secondary to COVID-19. The candidate proposed the search strategy, which was discussed with supervisors and peer-reviewed by an Information Specialist (Appendix A outlines the search strategy for Medline and the breakdown of search results). Further relevant studies were sought by citation searching of the included studies. An Ovid MEDLINE(R) alert was established to allow the identification of any additional studies.

3.3.3 Study screening and selection

Retrieved studies were independently screened by two reviewers (the candidate and Assistant Professor Emilia Michou) to identify studies that met the *a priori* inclusion criteria. The candidate had no prior experience of systematic reviewing. Assistant Professor Emilia Michou had completed one systematic review and one systematic review with meta-analysis. Any disagreement was resolved through discussion between the two reviewers and, when necessary, with the wider review team. The reason for exclusion was documented for transparency.

3.3.4 Data extraction

Data extraction forms were formulated *a priori* and piloted with two studies to refine the forms and ensure inter-rater consistency. The two reviewers independently extracted the data for all eligible studies. Any discrepancies between the completed extraction forms were identified and discussed. Differences were resolved through discussion between the two reviewers and, where necessary, with the wider review team.

3.3.5 Risk of bias assessment

The Joanna Briggs Institute (JBI) recommendations for levels of evidence for effectiveness (Joanna Briggs Institute, 2013; Joanna Briggs Institute, 2014) were used to rate each study. These levels are described in Table 6. This was important to be able to describe the range of levels of evidence of included studies. Risk of bias assessment is an essential component in the process of conducting a systematic review, as it allows the systematic evaluation of the internal and external validity of studies and supports a robust interpretation of the included studies (Lundh and Gøtzsche, 2008). Consideration was given to a wide range of critical appraisal checklists to assess the risk of bias. These included Downs and Black (Downs and Black, 1998); the Specialist Unit for Review Evidence (SURE) checklists (Specialist Unit for Review Evidence (SURE), 2020); the ROBINS-I (Sterne et al., 2016); the Newcastle-Ottawa Scale (NOS) (Wells et al., 2000); the TIDieR checklist (Hoffmann et al., 2014); and the JBI Critical Appraisal checklists were selected (Joanna Briggs Institute, 2020). The criteria for choosing a checklist was based on whether the checklist(s) were specific for the study designs being evaluated, assessed the critical elements of bias, avoided the presentation of risk of bias as a numerical score, and were grounded in theory (Viswanathan et al., 2018).

Ultimately, the JBI Critical Appraisal checklists were selected. The variety of JBI checklists available was an important reason for this choice, with checklists including case reports, case series, text and opinion, qualitative research, quasi-experimental studies, and RCTs. Given the wide range of study types expected in this review, the JBI checklists supported critical appraisal specific to each study type, which could easily be compared with other study types. Additionally, these checklists are grounded in theory and do not include a numerical scoring system (Joanna Briggs Institute, 2020; Munn et al., 2020; Barker et al., 2023). The following JBI Critical Appraisal checklists were used: case reports, case series, quasi-experimental studies, and RCTs (https://jbi.global/critical-appraisal-tools).

Table 6 JBI Levels of Evidence for Effectiveness (Joanna Briggs Institute, 2013)

Level 1 – Experimental Designs
Level 1.a – Systematic review of RCTs
Level 1.b – Systematic review of RCTs and other study designs
Level 1.c – RCT
Level 1.d – Pseudo-RCTs
Level 2 – Quasi-experimental Designs
Level 2.a – Systematic review of quasi-experimental studies
Level 2.b – Systematic review of quasi-experimental and other lower study designs
Level 2.c – Quasi-experimental prospectively controlled study
Level 2.d – Pre-test – post-test or historic/retrospective control group study
Level 3 – Observational-Analytic Designs
Level 3.a – Systematic review of comparable cohort studies
Level 3.b – Systematic review of comparable cohort and other lower study designs
Level 3.c – Cohort study with control group
Level 3.d – Case-controlled study
Level 3.e – Observational study without a control group
Level 4 – Observational-Descriptive Studies
Level 4.a – Systematic review of descriptive studies
Level 4.b – Cross-sectional study
Level 4.c – Case series
Level 4.d – Case study
Level 5 – Expert Opinion and Bench Research
Level 5.a – Systematic review of expert opinion
Level 5.b – Expert consensus
Level 5.c – Bench research/single expert opinion

Two reviewers independently assessed each study's risk of bias using these checklists (Joanna Briggs Institute, 2020). Where applicable, this included assessment of

reporting bias, internal validity, external validity, measurement bias, selection bias, power, attrition bias, confounding bias, performance bias, and detection bias. The risk of bias assessment was planned to facilitate the evaluation of the quality of the evidence available; there was no intention to exclude studies from the analysis based on the risk of bias outcomes. Any discrepancies in risk of bias analysis were resolved through discussion, and a consensus decision was made. Application of GRADE (Ryan and Hill, 2016) to assess the overall evidence quality was planned, dependent on the suitability of the data.

3.3.6 Data analysis and synthesis

A narrative synthesis approach was used. This approach offers a flexible method to combine findings of different data types (e.g., qualitative and quantitative) from different study types with heterogeneous methodological approaches. The narrative synthesis comprised four stages, as per the guidelines produced by the Economic and Social Research Council (Popay et al., 2006): preliminary synthesis of findings, exploration of relationships in the data, development of the theory of the mechanism of intervention and for whom the intervention works, and assessment of the robustness of the synthesis. A meta-analysis was not possible due to the variability of the study design and outcome measures.

3.4 Results

3.4.1 Search results

The May 2019 database searches identified 3277 records, one study was added from the Ovid MEDLINE(R) alert, and June 2020 database searches identified an additional 99 records. After duplicate removal, there were a total of 1228 records. Citation searches did not identify any additional records. A PRISMA flow diagram (Moher et al., 2010) illustrates the selection process (Figure 6). The final review was conducted on 13 studies from the USA (Gordan, 1984; Leder and Astrachan, 1989; Leder and Traquina, 1989; Leder, 1990b; Pandian, Smith, et al., 2014; Pandian et al., 2020), the UK (Feneck and Scott, 1983; Akhtar and Bell, 1993; McGrath et al., 2016; McGrath et al., 2019), Japan (Naito et al., 1996), Denmark (Kothari et al., 2017), and Italy (Calamai et al., 2018) published between 1983 and 2019.

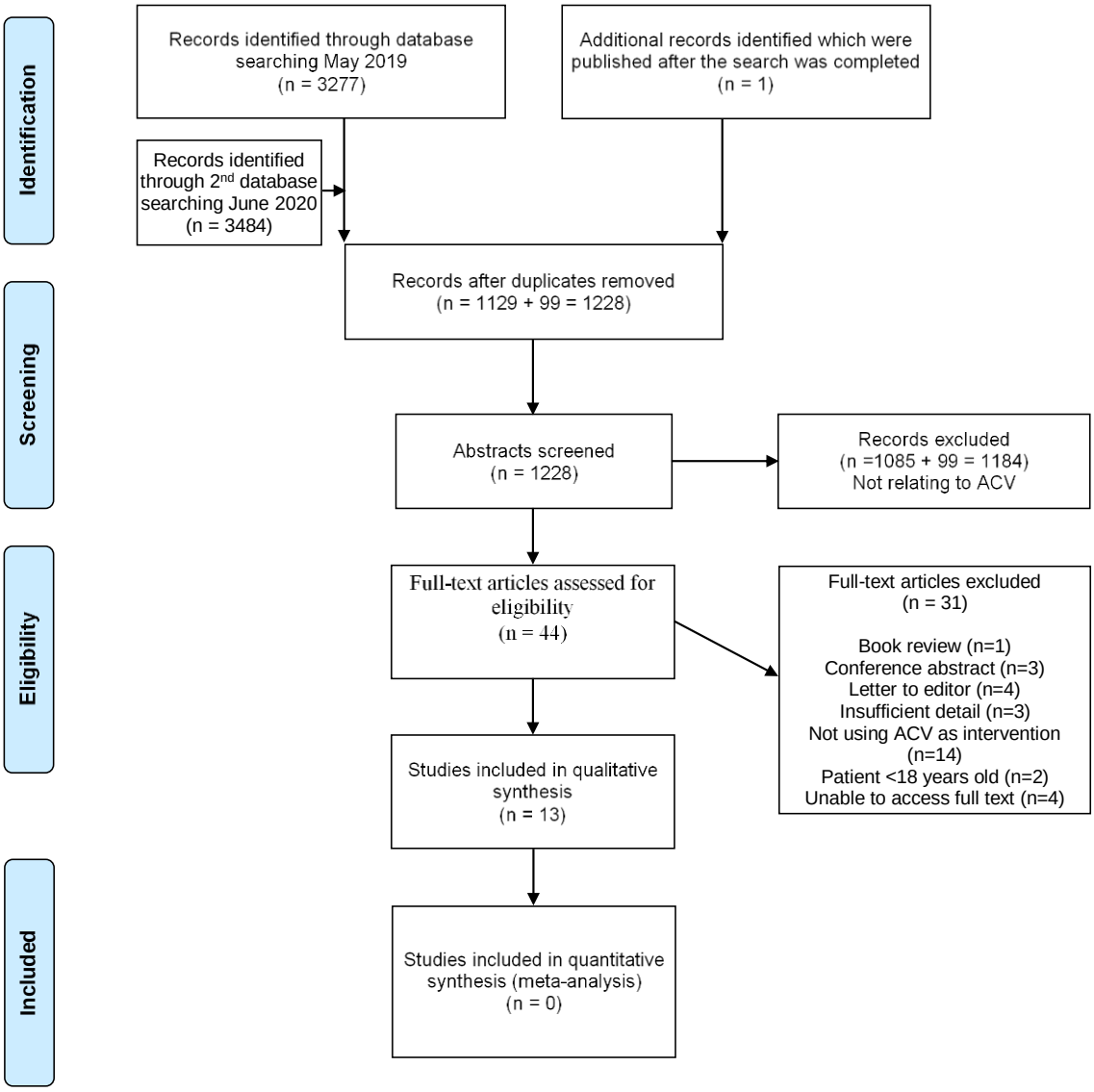

Figure 6 PRISMA flow diagram (Mills, Michou, King, et al., 2022)

3.4.2 Study characteristics

The study characteristics are outlined in Table 7. The PICOS are summarised in Table 8 and Table 9.

Table 7 Study Characteristics

Study	Funding Support and Conflicts of Interest	Country	Study Setting	Study Methodology	Sample size	Recruitment	Study Duration	Assessment Methods
Observational Descriptive†								
Akhtar & Bell (1993)	None reported	UK	ICU	Description of case.	1	N/A	N/A	Clinical examination, chest radiographs, physical examination of tracheostomy.
Calamai *et al.* (2018)	None reported	Italy	ICU	Description of case.	1	N/A	N/A	CT chest
Feneck *et al.* (1983)	None reported	UK	ICU	Description of case.	1	N/A	N/A	Clinical examination, chest x-ray, post-mortem examination, tests of six other tracheostomy tubes.
Leder & Astrachan (1989)	None reported	USA	ICU	Report of stomal complications and airflow line problems associated with Communi-Trach I® tracheostomy tube.	10	Consecutively admitted.	Four weeks	Visual observation of the stomal site and airflow line.
McGrath *et al.* (2016)	Unrestricted funding from Smiths Medical	UK	ICU	Describe a case series of using the subglottic suction port of tracheostomy tubes to facilitate communication.	5	Not described.	Unclear	Bedside evaluation and FEES in three cases.
Naito *et al.* (1996)	None reported	Japan	Not reported	Examination of aspiration under FEES with and without continuous positive subglottic airway pressure in one patient.	1	N/A	N/A	Laryngoscopy via the stoma and FEES via the nose. Evaluation of subglottic aspirates.
Pandian *et al.* (2014)	None reported	USA	ICU	Describe the types of talking tracheostomy tubes and present four case studies of who benefited from a talking tracheostomy.	4	Retrospective analysis of one year's worth of talking tracheostomy data.	One year retrospec-tively	Not reported

Observational Analytic†								
Kothari *et al.* (2016)	Funding from Regional Hospital, Hammel. Declaration of no conflicts	Denmark	Neurological ICU	Exploring the effectiveness of three sessions of External Subglottic Air Flow delivered over 150 minutes on patients with severe brain injury on swallowing frequency and subglottic residual volume.	10	Not described	Not described	Observation of swallowing frequency by Occupational Therapists. Quantities of subglottic secretions removed.
Leder (1990)	None reported	USA	ICU (cardiothoracic, medical, neurosurgical, surgical)	Investigation of voice intensity at different airflow rates using the Portex Talk Tracheostomy tube.	20	Consecutively treated, cognitively intact ventilator-dependent patients with a talking tracheostomy.	Unclear	Maximum voice intensity over 3-5 seconds using a sound level meter.
Leder & Traquina (1989)	None reported	USA	ICU	Investigation of ambient room noise levels, voice intensity at different airflow rates and whether audible, intelligible speech is produced by cognitively intact, ventilator-dependent patients with the Communi-Trach I®.	20	Consecutively treated, cognitively intact ventilator-dependent patients who received a talking tracheostomy.	Unclear	Maximum voice intensity over 3-5 seconds using a sound level meter.
McGrath *et al.*(2019)	Unrestricted grant from Smiths-Medical International Ltd. Primary author received expenses from Smiths-Medical and Ambu for attendance at educational events	UK	ICU (cardiothoracic and general)	Bedside trial of ACV. If vocalisation is achieved, FEES is performed (with and without ACV). Nursing staff are encouraged to use ACV with patients for up to 15 minutes every two hours.	10	Patients who required a tracheostomy were screened against the inclusion/ exclusion criteria.	Five months	Clinical bedside assessment and FEES.

Quasi-Experimental†								
Gordan (1984)	None reported	USA	Not described	Exploring the effectiveness of a talking tracheostomy tube in patients with and without neuromuscular disease.	10	Not described	Unclear	Subjective assessment of speech intelligibility by nurse/investigator.
Experimental†								
Pandian *et al.*(2019)	Partially funded by a Smiths Medical Research Grant, the Society of Otorhinolaryngology and Head-Neck Nurses Research Grant, and the Johns Hopkins Shirley Sohmer Research Grant. Primary author serves as coinvestigator for a sub-award from the University of Vermont and is funded by Sigma/American Nurses Credentialing Center Evidence-Based Implementation Research Award and is a multiple primary investigator for a study funded by the NIH/NINR.	USA	ICU	Patients were seen by SLT at 48 hours post tracheostomy tube insertion for trial with an OWV. If they could not tolerate an OWV, they were consented for the trial. Randomisation was conducted using Excel in a 1:1 ratio. Assessors were not-blinded as they could see the type of tube. Control group: pre-assessment data on day one and standard care from SLP (communication boards and iPads) and had post-assessment on day five. Intervention group: pre-assessment data on day one, BLUSA inserted, three treatment sessions with SLT to optimise voice with BLUSA. Airflow for optimal voice was handed over to ICU staff, and post-assessment data collected on day five.	50	All patients that met the inclusion/ exclusion criteria over the duration of the study.	Two years	Quality of life questionnaires completed by patients. Demographic data and LoS data were collected from electronic medical records. SIT completed post-assessment.

ACV – Above Cuff Vocalisation; APS – Airway Protection Scale; BLUSA – Blue Line Ultra Suction Aid; CT – Computed tomography; dB SPL – decibel sound pressure level; FEES – Fibreoptic Endoscopic Evaluation of Swallowing; FOIS – Functional Oral Intake Scale; GRBAS – voice scale of Grade, Roughness, Breathiness, Asthenia, and Strain; ICU – intensive care unit; ICU FCS – ICU Functional Communication Scale; LoS – Length of Stay; N/A – not applicable; NIH – national institute of health; NINR – National Institute of Nursing Research; OWV – one-way valve; PAS – Penetration Aspiration Scale; QOL-MV – quality of life in mechanically ventilated patients; SOFA – Sequential Organ Failure Assessment; SIT – speech intelligibility test; SLT – speech and language therapist; SSRS – Secretion Severity Rating Scale; voiceTOM – voice Therapy Outcome Measure; V-RQOL – voice-related quality of life. † Studies were allocated to a study design based on the Joanna Briggs Institute definitions (Joanna Briggs Institute, 2014)

Table 8 Population and Intervention Characteristics

Study	Gender	Age	Primary Diagnoses	Eligibility Criteria	Time from tracheostomy insertion to ACV	Type of Airflow Delivery	Rate of Airflow	Duration of ACV	Frequency of ACV	Number of days of ACV	Brand and Size of Tracheostomy
Observational Descriptive											
Akhtar & Bell (1993)	M	76	Post-laparotomy, ARDS	N/A	30 hrs (1st attempt); 50 hrs (2nd attempt)	Oxygen; unclear whether continuous or intermittent	6 L/min	30 seconds (1st attempt); not recorded for 2nd attempt	Not reported	Unclear	Portex Vocalaid #8.0
Calamai *et al.* (2018)	M	74	CAP	N/A	Six days	Air, continuous	3 L/min (starting at 2 L/min)	A few minutes	Not reported	Unclear	Not reported
Feneck *et al.* (1983)	F	58	Hypothermia, HoTN, acidosis	N/A	Vocalaid inserted eight days after the initial tracheostomy. Unclear whether ACV started the same day.	Oxygen; continuous	Not reported	Not reported	Not reported	Three days	30 FG Portex Vocalaid
Leder & Astrachan (1989)	5F 5M	Mean: 52.2; Range: 21-74	ARDS; C2 spinal injury; radiotherapy / chemotherapy induced cardiomyopathy + restrictive lung disease; CHF; Left cerebellar infarct; COPDx2; HIV+ pneumonia; recurrent uterine leiomyosarcoma + respiratory distress; SLE + quadriplegia.	Consecutively admitted over four weeks.	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Communi-Trach I®; size not reported

McGrath *et al.* (2016)	1F 4M	Mean: 52.8; Range: 30-76 (calculated from raw data)	Infective exacerbation of asthma + T2RF + PD + Influenza A; COPD + double lung transplant; COPD + left upper lobectomy for lung carcinoma; CAP + ARDS; burns	Not reported	Not outlined specifically but described for four patients (five days; approximately three weeks; five days; one week).	Not reported whether oxygen or air; implied use of intermittent airflow as discusses thumb port.	Not outlined specifically but described for three patients (5 L/min; 3 + 5 L/min; 6 L/min).	Not outlined specifically but described for two patients (5-minute spells; 5-minute spells).	Not outlined specifically but described for two patients (spells; every day for spells).	Not outlined specifically but described for two patients (three days; one month).	Portex BLUSA SGS
Naito *et al.* (1996)	M	65	SCI	N/A	Unclear. Argyle Aspiraid was 2nd tube inserted	Oxygen; continuous	1 L/min	Not reported	Not reported	Not reported	Argyle Aspiraid, Nihon Sherwood. Size not reported.
Pandian *et al.* (2014)	1F 3M	Mean: 41; Range: 25-54	Bilateral orthoptic lung transplant for progressive interstitial lung disease + respiratory failure; progressive lymphoproliferative disorder status post chemotherapy + bone marrow transplant + severe GVHD + ARDS; Type II neurofibromatosis + multiple vestibular schwannoma resections with residual left facial weakness, right facial nerve damage, right vocal fold paralysis, severe oropharyngeal dysphagia and severe GORD; ALS	Patients who received a Portex BLUSA SGS tracheostomy tube in 2010	Not reported	Air; state used intermittent airflow for two patients, not reported for the other two patients.	Not outlined specifically but described for two patients (5 L/min; 3 L/min and then 2-3 L/min when tracheosto-my tube upsized).	Not reported	Not reported	Not outlined specifically but described for one patient as ‘months’.	Portex Blue Line Ultra SGS; the tube size is not outlined specifically for all patients (one patient had a #8.0 changed to a #9.0; one patient had a change to a #8.0, but no information regarding the size of the 1st tube).

Observational Analytic											
Kothari *et al.* (2016)	2F 8M	Mean: 49.4 ± 5.12; Range: 19-78	Severe brain injury with low arousal levels	Inclusion criteria: FOIS=1, tracheostomised	Median: 20; Range 10-107	Air; intermittent	3 L/min (starting at 1 L/min)	5 min (total of 100 sec air application).	Three applications of 5 min during 150 min testing.	One	Portex Blue Line Ultra SGS; size not reported.
Leder (1990)	7F 13M	Mean: 61.2; Range: 24-80	COPD; ARDS; Aortic stenosis; CHF; HIV+; Tetralogy of fallot / pulmonary HTN; primary biliary cirrhosis + ARDS + liver transplant; CNS hypoventilation; C5-6 fracture; Duchenne's; Polycystic kidney disease + renal transplant; idiopathic pulmonary fibrosis; GBS, primary hypoventilation syndrome.	Consecutively treated, cognitively intact, ventilator-dependent, referred for talking tracheostomy	Not reported	Unclear whether oxygen or air; intermittent	5 L/min, 10 L/min, 15 L/min	Five seconds, three times at each airflow (unclear if having further trials between assessment sessions).	Unclear but stating daily rehab is needed to stimulate vocal fold adduction, synchronise with airflow, and use a thumb port.	Not reported	Portex “Talk” tracheostomy tube. 8mm and 9mm outer diameter with inner cannula removed.
Leder & Traquina (1989)	6F 14M	Mean: 59.1; Range: 21-78	C3-C4 fracture; C5-C6 fracture; left frontotemporopar-ietal subdural hematoma; muscular dystrophy; ARDS; Metastatic colon cancer; COPD; Lung cancer; GI bleeding; failed angioplasty; C2 fracture; radiotherapy /	Consecutively treated, cognitively intact, ventilator-dependent patients who had the Communi-Trach I®	No information was provided about the time from Communi-Trach I® being inserted to using ACV. Report the time from previous tracheostomy insertion to Communi-Trach I® being inserted – Mean: 11.9 days; SD	No information about oxygen versus air or intermittent delivery.	5, 10, 15 L/min	Five seconds at each airflow for measurem-ent purposes. Unclear if also had additional trials between assessment sessions.	Unclear but states daily rehab needed to support ACV use.	Unclear. Report number of days until voice intensity recordable – Mean: 5.6; SD: 2.0; Range: 2-13 (excluded outlier of 70 days).	Communi-Trach I®; no information about the size.

			chemotherapy induced cardiomyopathy + restrictive lung disease; CHF; left CVA; HIV+ pneumonia; respiratory distress		11.4; Range: 0-43						
McGrath *et al.* (2019)	3F 7M	Median: 60; IQR: 26; Range: 28-83	Cardiothoracic; general; pneumonia + left ventricular assist device; elective right lower lobectomy; emergency laparotomy for ischaemic gut; elective lobectomy complicated; respiratory syncytial viral pneumonitis requiring ECMO; double lung transplant for cystic fibrosis; biventricular heart failure due to hypertrophic cardiomyopathy + heart transplant; OHCA, severe interstitial lung disease + single lung transplant	Inclusion criteria: >16 years old, cuffed BLUSA tube for >72 hours, alert patients who can consent, participate and are suitable for FEES. Exclusion criteria: consent refused, potentially obstructed airway, or suspected to tolerate cuff deflation within 72 hours, FEES contraindicated.	Median: 8; IQR: 9; Range:3-46	Not reported whether oxygen or medical air; intermittent; implied non-humidified.	1-5 L/min	Median:15 minutes; IQR: 10; Range: 1-20	No report of daily frequency. Reports the number of episodes for all patients averaged throughout their treatment. Median: 9; IQR: 7; Range: 4-19.	Median: 3 days; IQR: 3; Range: 1-7.	Portex BLUSA SGS (nine percutaneous and one surgical); #7.0 (1), #8.0 (4), #9.0 (5).

Quasi-Experimental											
Gordan (1984)	2F 8M	Mean: 48.2; Range: 32-65 (calculated from raw data)	GBS; ALS; COPD + acute respiratory failure; bowel perforation + sepsis + acute respiratory failure; multiple trauma + acute respiratory failure; bronchopneumonia+ acute respiratory failure	Not reported	Not reported	Warm, humidified compressed air; no information on intermittent versus continuous.	4, 6, 7, 10, 12 L/min	Not reported	4-5 times per day or 'whenever indicated'.	5 days	Pitt speaking-cuffed tracheostomy; no information about the size.
Experimental											
Pandian *et al.* (2019)	25F 25M	Mean: 54.3 ±16.5	Medical pulmonary, medical neurological, surgical thoracic, surgical, non-thoracic	Inclusion criteria: adult ICU patients that were mechanically ventilated, awake, alert, attempting to communicate, English speaking, and could not tolerate an OWV on initial screening. Exclusion criteria: tracheostomy in the last 48 hours, laryngectomy, and delirium.	48 hours consideration of insertion of Portex BLUSA. Unclear exactly when the tube was inserted or treatment commenced.	Intermittent, no information on the type of air.	Mean optimal flow 4.7 ±1.3.	Not reported	Not reported	5 days	Portex Blue Line Ultra SGS; no information on the size.

ACV – above cuff vocalisation; ALS – Amyotrophic lateral sclerosis; ARDS – acute respiratory distress syndrome; BLUSA – Blue line ultra suction aid; CV – Cervical vertebrae; CAP – community acquired pneumonia; CHF – chronic heart failure; CNS – central nervous system; COPD – chronic obstructive pulmonary disease; CVA – cerebrovascular accident; CXR – chest x-ray; ECMO – extracorporeal membrane oxygenation; F – female; FEES – Fibreoptic Endoscopic Evaluation of Swallowing; FG – French Gauge; GBS – Guillain Barré Syndrome; GI – gastrointestinal; GORD – gastro-oesophageal reflux disease; GVHD – graft versus host disease; HIV – human immunodeficiency virus; HoTN – hypotension; HTN – hypertension; IQR – interquartile range; L/min – litres per minute; M – male; N/A – not applicable; OHCA – out of hospital cardiac arrest; OWV – one way valve; PD – Parkinson's disease; SCI – spinal cord injury; SGS – subglottic suction; SLE – systemic lupus erythematosus; T2RF – type II respiratory failure.

Table 9 Comparator and Outcome Characteristics

Study	Control Characteristics	Acceptability	Adverse Events and Complications	Outcome measure and follow-up time points
Observational Descriptive				
Akhtar & Bell (1993)	N/A	Not reported	Neck and facial emphysema. Resolved within six hours.	No outcome measures. Followed up to four days post-successful attempt.
Calamai *et al.* (2018)	N/A	Not reported	Subcutaneous emphysema of the neck and face.	No outcome measures. No follow-up.
Feneck *et al.* (1983)	N/A	Ability to talk to staff and visitors. Able to use the device easily. Happy with it.	Misconnection of the airflow line to the pilot tube leading to the cuff bursting and tracheal dilation.	No outcome measures. No follow-up. The patient died four days later from complications of the original condition.
Leder & Astrachan (1989)	No control	Adequate voice intensity.	Within three weeks of insertion stomal complications in 40% of patients and airflow line kinking in 80%. Reduced voice intensity, pressure necrosis, and wound extension.	Outcome measures not reported. Followed up over three weeks.
McGrath *et al.* (2016)	N/A	Ability to communicate with staff, family and visitors; ability to communicate effectively for four days; intelligibility of speech; ease of communication interaction; facilitated communication for one month; patient cooperation.	Burping; risk of air trapping with vocal folds fixed in paramedian position.	Outcome measures are not explicitly outlined but described for some patients (Case 1: appears to be pre-ACV and during the first trial of ACV; Case 2: no pre-ACV rating, voice TOMs appears to be completed during first trial of ACV; Case 3: not reported; Case 4: no pre-ACV rating, rating appears to have been completed during first ACV trial; Case 5: no pre-ACV rating, rating appears to have been completed during first ACV trial). Follow-up not reported.
Naito *et al.* (1996)	N/A	Not reported	Not reported	Unclear when the first FEES took place. 2nd FEES was conducted five days after the 1st. State 71 days post-injury free from mechanical ventilation. No repeat FEES/outcome measures at this point.
Pandian *et al.* (2014)	N/A	Ability to communicate meaningfully with family and staff with reduced anxiety; ability to express basic needs and emotions; ability to have short conversations with family and friends, comfort.	Strained voice quality from tensing vocal folds to control airflow; inability to achieve adequate phonation due to stomal leakage; air trapping due to vocal cord spasms.	No prescribed times for descriptive outcome measures to be recorded. Follow-up not reported.

Observational Analytic				
Kothari *et al.* (2016)	Patients were classed as their own control.	Not reported	Not reported	Over the course of 150 min. Swallow frequency included three pre-treatment, three during treatment, and three post-treatment. Subglottic aspirates included three pre-treatment and three just before the three treatment sessions. The last follow-up was 25 minutes after the final treatment session.
Leder (1990)	No control	One report from a patient of 'difficult initial nine days'. Speech was intermittent and frustrating, resulting in feelings of helplessness.	Not reported.	Patients were tested daily, but outcome measures were only taken once they could produce an audible voice. One patient followed up at one year; others had unclear follow-up.
Leder & Traquina (1989)	No control	Not reported	None reported. State "optimum speech…without significant patient discomfort", implying there is some discomfort.	Outcome measures taken daily until voice intensity recorded. Followed up until voice produced. Range from 2-70 days.
McGrath *et al.* (2019)	No control	72.5% of patients reported no complications.	Discomfort in 10/91 episodes; excessive oral secretions in 9/91 episodes; stomal air leak in 2/91 episodes; gagging in 2/91 episodes; nausea in 1/91 episodes; patient asked to stop in 1/91.	Initial ACV assessment and follow-up 3-7 days later.
Quasi-Experimental				
Gordan (1984)	Group with no neuromuscular disease.	Not reported	No complications were reported, including stomal leak or leak into paratracheal tissue. Reported airflows >8 L/min causing patient discomfort.	Assessed at every trial of ACV, which was repeated 4-5 times daily. Only one outcome measure was reported per patient. Followed up over five days.
Experimental				
Pandian *et al.* (2019)	Standard care includes OWV, communication boards, iPads, and writing. No extra tracheostomy change. No difference in SOFA scores.	Independence with intervention; satisfaction with intervention; ability to obtain strong voice/intelligible speech.	None reported	Outcome measures were taken at day one and day five. No further follow-up.

ACV – above cuff vocalisation; FEES – Fibreoptic Endoscopic Evaluation of Swallowing; N/A – not applicable; OWV – one way valve; SOFA – Sequential Organ Failure Assessment; voiceTOM – voice therapy outcome measure.

Patient population

The studies were conducted predominantly in ICUs, with 12 studies reporting ACV was commenced in the ICU and one study not reporting where ACV commenced. Most studies used ACV with ventilated patients, with 12 studies using ACV entirely with ventilated patients and one study using it with a mix of ventilated and non-ventilated patients (total ventilated patients: n=138; total non-ventilated patients: n=4; ventilation status not reported: n=1). ACV was used with patients with a wide variety of diagnoses, conditions, and after surgery (reported in column 'Primary Diagnoses' in Table 8). These were categorised as follows: burns, respiratory, spinal cord injury, haematology, neurology, general / thoracic / cardiac / cardiothoracic / neuro-surgery, progressive immune disorders, oncology, renal, hepatology, genetic conditions, and out-of-hospital cardiac arrest. A total of 143 patients were included in this review, with a median sample size of 10 (range: 1-50), an age range of 19-83, and a total of 53 females and 90 males.

Intervention delivery

Most studies did not report the time ACV commenced post-tracheostomy insertion. Of those that did, timing varied from 30 hours to 107 days post-tracheostomy insertion. Of those that stated the earliest time post-tracheostomy that the intervention would commence, this ranged from 48 hours (Pandian et al., 2020) to 72 hours (McGrath et al., 2016; McGrath et al., 2019).

Outcome Measures

The outcome measures varied considerably between studies, and the only outcome measure used by more than two studies was the subjective assessment of speech intelligibility or voice quality (Table 10).

Table 10 Outcome measures used

Outcome	Study
Aspiration	
Presence or absence of aspiration on FEES	Naito *et al.* (1996)
Aspirated material from the subglottic port	Naito *et al.* (1996)
Subglottic volume of secretions	Kothari *et al.* (2016)
Penetration Aspiration Scale	McGrath *et al.* (2019)

Swallowing function	
Functional Oral Intake Scale (FOIS)	Kothari *et al.* (2016)
Secretion Severity Rating Scale	McGrath *et al.* (2019)
Number of swallows	McGrath *et al.* (2019)
Airway Protection	
Number of coughs	McGrath *et al.* (2019)
Airway Protection Scale (APS)	McGrath *et al.* (2019)
Communication	
Time to audible voice production	Leder & Traquina (1989); Leder (1990)
Voice intensity in decibels sound pressure level (dB SPL)	Leder & Traquina (1989); Leder (1990)
voice Therapy Outcome Measure (voiceTOM)	McGrath *et al.*, (2016); McGrath *et al.*, (2019)
GRBAS scale (Grade, Roughness, Breathiness, Asthenia, Strain)	McGrath *et al.*, (2019)
Subjective assessment of speech intelligibility or voice	Gordan (1984); Leder & Traquina (1989); Leder (1990); Pandian *et al.*, (2014); McGrath *et al.* (2016); McGrath *et al*, (2019)
Speech Intelligibility Test (SIT)	Pandian *et al.*, (2020)
ICU Functional Communication Scale (ICU-FCS)	McGrath *et al.*, (2019)
Quality of life and acceptability	
Quality of life in Mechanically Ventilated patients	Pandian *et al.*, (2020)
Voice-Related Quality of life	Pandian *et al.*, (2020)
Satisfaction rating	Pandian *et al.*, (2020)
Independence rating	Pandian *et al.*, (2020)

Adverse events or complications	
Abnormality to tracheal or laryngeal mucosa	Naito *et al.* (1996)
Stomal complications or airflow line kinking	Leder & Astrachan (1989)
Length of Stay	
ICU length of stay	Pandian *et al.*, (2020)
Hospital length of stay	Pandian *et al.*, (2020)

All studies were unclear about data capturing time points, including repetition or reassessment, except for two studies that specified timings and captured outcome measures consistently. The follow-up periods were short: 150 minutes (Kothari et al., 2017) and five days (Pandian et al., 2020).

3.4.3 Study quality

The JBI levels of evidence were generally very low, 4.d to 2.d, with one Level 1.c RCT (Joanna Briggs Institute, 2013; Joanna Briggs Institute, 2014). The JBI level of evidence is provided for each study in Table 11. All studies had a moderate to high level of bias, with a risk of bias in multiple domains for most studies (Table 11). Bias was observed in the following domains: reporting bias (5/13 studies), internal validity (7/7 studies), external validity (5/7), measurement bias (6/9), selection bias (4/9), power (6/7), attrition bias (2/7), confounding bias (2/9), performance bias (1/9), and detection bias (4/9).

3.4.4 Study results

The results of the individual studies and recommendations for using ACV are outlined in Table 12.

Table 11 Risk of bias

Study	Joanna Briggs Institute Appraisal Tool					Reporting Bias	Internal Validity	External Validity	Measure-ment Bias	Selection Bias	Power	Attrition Bias	Confounding Bias	Performance Bias	Detection Bias
	Level of Evidence & Study Design	Bias	No Bias	Unclear	N/A										
Level 4: Observational-Descriptive															
Akhtar & Bell (1993)	Level 4.d Case study	2	6	0	0	+	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Calamai *et al.* (2018)	Level 4.d Case study	6	2	0	0	-	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Feneck *et al.* (1983)	Level 4.d Case study	3	5	0	0	+	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Leder & Astrachan (1989)	Level 4.c Case series	1	9	0	0	-	-	+	-	+	-	+	-	+	?
McGrath *et al.* (2016)	Level 4.c Case series	9	0	0	1	-	N/A	N/A	-	-	N/A	N/A	?	?	-
Naito *et al.* (1996)	Level 4.d Case study	2	6	0	0	+	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pandian *et al.*(2014)	Level 4.c Case series	1	8	0	1	-	N/A	N/A	-	+	N/A	N/A	?	?	?
Level 3: Observational-Analytic†															
Kothari *et al.* (2017)	Level 3.e Observational study without a control group	0	6	4	0	+	-	-	-	-	-	+	?	?	?

Leder (1990)	Level 3.e Observational study without a control group	1	9	0	0	+	-	-	+	?	-	+	?	+	+
Leder & Traquina (1989)	Level 3.e Observational study without a control group	2	8	0	0	+	-	-	+	?	-	+	?	+	+
McGrath *et al.*(2019)	Level 3.e Observational study without a control group	2	7	1	0	+	-	-	-	+	-	-	?	?	-
Level 2: Quasi-Experimental															
Gordan (1984)	Level 2.d Quasi-experimental	7	2	0	0	-	-	-	-	-	-	+	?	-	-
Level 1: Experimental															
Pandian *et al.* (2019)	Level 1.c RCT	5	7	1	0	+	-	+	+	-	+	-	-	?	-

+ = low risk of bias; - = high risk of bias; ? = unclear risk of bias. The numbers in the Joanna Briggs Institute columns are the number of questions in the tool that were positive for bias, negative for bias, or unclear or not applicable. †The case series critical appraisal checklist was used for these studies as one does not exist for observational studies without control groups

Table 12 Study Findings

Study	Key Findings	Statistics	Suggested Mechanisms of ACV Action	Suggested Recommendations for ACV use
Observational Descriptive				
Akhtar & Bell (1993)	Surgical emphysema can occur with poorly positioned tubes.	None	No hypothesis of intervention action. No leak or manufacturing defect on the tracheostomy tube on physical examination. Hypothesise that the reactionary oedema following tracheostomy insertion increased the distance between the skin and the tracheal lumen and displaced the Vocalaid so that the distal end of the airline was positioned into the neck's soft tissues.	They question whether the Vocalaid tracheostomy tube should not be used for ACV in the first 48 hours post-insertion.
Calamai *et al.* (2018)	Subcutaneous emphysema of neck and face.	None	No hypothesis of intervention action. The mechanism of the adverse event was suggested to be a result of the suction port being outside the tracheal lumen allowing gas to spread through surrounding tissues.	None made
Feneck *et al.* (1983)	Misconnection of oxygen to the pilot tube can result in the tracheostomy cuff bursting and tracheal dilation. The different colours of the pilot tube and the subglottic tube ends, the difference in diameter of the connection tubing, and the pilot balloon presence did not prevent misconnection. With continuous oxygen flow at 2-4 litres, there would only be 5-15 seconds to identify misconnection and correct it.		No hypothesis of intervention action. The mechanism of the adverse event was due to the mistaken connection of continuous flow oxygen to the pilot tube. This resulted in the cuff rupturing. The need for over-inflation of the replacement tube was likely a result of tracheal dilation. CXR and post-mortem confirmed this.	Modifying the tube and the connector to deliver intermittent flow directed by the patient should improve safety. Safety could be improved by: • Modifying the tube so that the pilot tube connector is a different type and diameter to the subglottic port connector • Using a connector to allow an intermittent rather than continuous flow • Patient-operated intermittent flow wherever possible

Leder & Astrachan (1989)	8/10 (80%) of patients had airflow line kinking. 4/10 (40%) had stomal complications within three weeks of tube insertion.	None	No hypothesis of the mechanism of action of intervention. They reported that the complications' mechanism is that the airflow line's position at six o'clock results in kinking of the tube causing pressure necrosis and wound extension. They hypothesise that placing the airline at 3-5 or 7-9 o'clock would resolve the issues.	Suggest redesigning the tracheostomy tube so that the airflow line enters between the 3- and 5-o'clock or the 7- and 9-o'clock positions to prevent airflow line kinking and stomal complications.
McGrath *et al.* (2016)	Case 1: voiceTOM improved from 0 to 2 with ACV, intelligible speech, improved laryngeal sensation on FEES with silent aspiration of secretions and fluids becoming overt. Case 2: voiceTOM of 4 with ACV, communicating effectively for four days. Case 3: limited voice likely due to fixed vocal cords. Case 4: voiceTOM of 5 with ACV, strong, loud voice for next month, swallow function improved more quickly than expected. Case 5: voiceTOM of 0 with ACV, cough and swallow stimulated, limited cooperation. No clear predictors of early, successful voicing.	None	ACV facilitates vocal fold vibration enabling voice and improved glottic closure reflexes. Postulate that airflow re-sensitises the larynx, improving airway protection and swallowing strength. They state that success with ACV depends on intact laryngeal function and patient cooperation. Any leak from the stomal site will limit the air available for speech. Less likely to observe a stomal leak with a percutaneous tracheostomy. Dry airflow or high concentrations of airflow are likely to have a drying effect on the laryngeal mucosa or hyperadduction of the vocal folds. Hypothesise that several days of ACV use may be needed to develop voice production. State there are no clear predictors of early, successful voicing.	Upper airway obstruction should likely be a contraindication for ACV. Complications should be minimised by appropriate bedside supervision of experienced multi-disciplinary team and trained SLTs. Using the subglottic port for secretion clearance should minimise blockage of the port with secretions. Guidelines should be developed.

Naito *et al.* (1996)	With continuous 1 L/min applied via the subglottic port, there were no food or liquid residue particles in the subglottic aspirates. Conclude that this abolished aspiration. FEES assessment five days later revealed no side-effects to subglottic or tracheal mucosa.	None	Increasing the subglottic airway pressure using ACV facilitates glottic closure during swallowing and prevents aspiration.	Suggest that prolonged use of non-humidified gas might be harmful to airway mucosa.
Pandian *et al.* (2014)	Case 1: meaningful communication with staff and family for months, hoarse vocal quality and strained vocal quality. Increasing the tube size to a #9.0 reduced airflow needed. Case 2: too weak to occlude thumb port, improved QoL, able to express basic needs and emotions, e.g., pain, anxiety, thirst, discomfort during terminal days. Case 3: unable to achieve adequate phonation because of stomal leakage. Case 4: able to speak but needing a larger tube for suction. When upsized to #8.0, less airflow was needed to produce voice, and the patient reported increased comfort. Air trapping below vocal cords over time because of vocal fold spasm. Vocal function exercises helped to reduce laryngeal spasticity and improve voice quality. Able to use ACV for short conversations with family and friends.	None	They report the advantages of the BLUSA over specially designed talking tracheostomies (larger subglottic port lumen, no corrugated inner cannula, thumb port can be disconnected, and subglottic port flushed with saline). Other advantages of ACV include no interruption to mechanical ventilation, the patient can speak whenever they wish, easy to use, there is no requirement for frequent follow-up or extensive training, reduction in anxiety, increase in autonomy and participation in care decisions, improvement to QoL as a result of improved verbal communication. State there is a risk of vocal fold injury from dry air and hyperadduction of the vocal folds in response to high flow. Potential issues if poor thumb port connection. Swallowing of air could result in abdominal distention. Risk if the airflow is connected to the pilot tube. Risk of subcutaneous emphysema if used in a patient with a freshly formed stoma.	Outline criteria for ACV: • Needing prolonged mechanical ventilation but unable to have cuff deflated • Awake, alert and attempting to communicate • Able to manipulate thumb port or have a communication partner who can assist • Sufficient motor speech/language to produce functional communication • No upper airway obstruction • Established tracheostomy stoma Other recommendations: • Communication partners occluding thumb port may need education • Suggest humidification of air to reduce the risk of vocal fold injury from dry air • Use minimum airflow that elicits voice to avoid hyperadduction of the vocal folds • Never use in patients with upper airway obstruction • If non-optimal voice quality, assess vocal folds and upper airway patency to identify laryngeal pathology • Poor thumb port connection can be an issue • Turn off the air if the patient is not speaking to reduce the risk of abdominal distention from aerophagia • Ensure thumb port is unoccluded when not in use • Label pilot and subglottic ports to avoid misconnection of the airflow to the pilot balloon

				• Use BLUSA as the first tracheostomy change to avoid application to a freshly formed stoma and reduce the risk of subcutaneous emphysema
Observational Analytic				
Kothari *et al.* (2016)	Significant increase in swallowing frequency during ESAF and reduction in subglottic residual secretion volume over time.	Mean (±SEM) change in swallowing frequency = from 0.60 ± 0.30 at baseline to 2.10 ± 0.70 during the intervention (p<.001). Mean (±SEM) change in subglottic residual secretion volumes = 3.10 ± 0.31 mL at baseline to 0.50 ± 0.30 mL post intervention (p<.001). Spearman's correlation analysis showed no relationship between the increase in swallowing frequency and the reduction in subglottic secretion volume (−0.108 < δ < 0.357; p = .311).	Intervention stimulates subglottic mucosa innervated by the internal branch of the superior laryngeal nerve, which may assist in brief vocal fold closure creating subglottic pressure and increasing the probability of laryngeal adductor reflex triggering. Stimulation of laryngeal mechanoreceptors could regulate swallowing function.	The intervention could be beneficial for patients with increased subglottic residual secretion volumes.
Leder (1990)	Significantly greater voice intensity than ambient room noise at all airflows. Significantly greater voice intensity as flows increased. Shorter time to produce audible voice than with Communi-Trach I®. No significant difference between voice intensity produced compared to Communi-Trach I®. Optimal voice intensity and speech intelligibility were produced between 10-15 L/min. A mean of 2.1 days before consistently adequate voice intensity for intelligible speech was produced.	Mean time to talk = 2.1, SD = 2.3, Range = 0-9. Student's *t* tests comparing time to talk with the Communi-Trach I® revealed significantly shorter for the Portex "Talk" tube (p<.001). Mean voice intensity (dB SPL) at 5 L/min = 69.8, SD = 6.5, Range = 59-82, (n=17); Mean voice intensity at 10 L/min = 75.3, SD = 5.2, Range = 65-89 (n=20); Mean voice intensity at 15 L/min = 80.4, SD = 6.2, Range 69-98 (n=20). Two-tailed Student's *t* tests comparing means of voice intensity with the ambient room were p<.001 at each airflow, with voice intensity greater than ambient room noise. Student's *t* tests comparing voice	The type of tube can impact on ease of voicing. The number of openings on the tube does not appear to affect voice intensity. The single opening does not get clogged with secretions. No stomal complications when the subglottic port is in the 9 o'clock position. Potential reasons for the delay in voicing are hypothesised to be: poor adduction of the vocal folds due to localised trauma, prolonged vocal fold abduction, and non-use of the voice.	Poor connection from the airflow tubing to the connector could be solved by reducing the size of the valve tip. To reduce patient and staff frustration, daily rehabilitation and reinforcement is needed to train patients to: • synchronise vocal fold adduction with the airflow • emphasise articulation • reduce anxiety • coordinate speech production with ventilator support • self-use the thumb port

		intensity as airflow increased showed that voice intensity was greater with greater airflow ($p<.001$) for 5 L/min versus 10 L/min and 10 L/min versus 15 L/min.		
Leder & Traquina (1989)	Significantly greater voice intensity than ambient room noise at all airflows for 18/20 patients. Significantly greater voice intensity as flows increased. 18/20 patients demonstrated subjective adequate conversational speech intelligibility. Of 18, nine could not voice at 5 L/min, and one could not vocalise at 10 L/min. Two patients had no voicing at any intensity due to laryngeal pathology. Optimal speech intelligibility at 10-15 L/min. A mean of 5.6 days before adequate voice intensity for intelligible speech is produced.	Mean time to talk = 5.6, SD = 2.9, Range = 2-13 (this excluded one patient who took 70 days). Mean voice intensity (dB SPL) at 5 L/min = 71.6, SD = 7.3, Range = 60-85, $p<.01$ compared to ambient room noise (n=9); Mean voice intensity at 10 L/min = 77.3, SD = 7.6, Range = 66-94, $p<.001$ compared to ambient room noise (n=17); Mean voice intensity at 15 L/min = 83.0, SD = 4.9, Range 74-93, $p<.001$ compared to ambient room noise (n=18). Comparisons between voice intensity and ambient room noise were made using Two-tailed *t*-tests of difference. Two-tailed *t*-tests were also used to compare voice intensity as the airflow increased, showing voice intensity was greater with higher airflows ($p<.01$) for 5 L/min versus 10 L/min and ($p<.001$) for 10 L/min versus 15 L/min.	Prolonged endotracheal intubation, and the associated vocal fold trauma and disuse, can result in poor vocal fold adduction and a delay in the successful use of ACV. They hypothesise that the eight fenestrations of this tube might affect the amount of flow needed for adequate speech intensity and patient comfort levels. They postulate that patients cannot vocalise during the inspiratory cycle of the ventilator due to the normal breathing-speaking cycle.	Daily rehabilitation is needed to: • Train the patient to use the thumb port • Work on stimulating vocal fold adduction and synchronising adduction with airflow • Eliminate anxiety and reduce frustration • Promote coordination of vocalisation with the ventilator • Train the patient to use the airflow line themselves. Techniques to help achieve audible speech: • Cough/throat clear can help to stimulate vocal fold adduction, which can then progress to sustained vowels and then onto speech • Use light finger pressure on the ventilator hosing to position the tube optimally and reduce air leak at the stoma site • Train the patient to speak during expiration • Provide 50cm of extra airflow tubing so the patient/staff can locate the thumb port more easily • Maintain the perpendicular insertion of the airflow line to prevent kinking of the tubing, which can lead to reduced airflow for vocalisation Other recommendations: • Rule out laryngeal pathology using FEES if no voice is elicited • Check for other causes of lack of voicing, e.g., airflow line kinking, tubing blocked with secretions, poor tube position from loose neck straps or pulling of ventilator tubing)

McGrath *et al.* (2019)	Audible voice/whisper in 8/10 patients during 66 of 91 attempts (72.5%). Audible voice (37/91), audible whisper (29/91). Significant improvement in the SSRS. No significant difference in the APS. No significant difference in the PAS. Significant improvement in the voiceTOM. Significant improvement in the ICU FCS. Significant increase in the number of dry swallows per minute. Significant improvement in the number of coughs per minute. No short-term evidence of drying of the laryngeal mucosa or other complications.	Median of three days of ACV use (IQR: 3; range:1-7). Median of nine episodes of ACV (IQR:7; range 4-19). SSRS median difference without versus with ACV=0.5, five patients improved, five patients showed no change, Wilcoxon signed rank p 0.04 (n=10). APS median difference without versus with ACV=0, two patients improved, six patients showed no change, Wilcoxon signed rank p 0.18 (n=8). PAS median difference without versus with ACV=0, four patients improved, one patient was worse, four patients showed no change, Wilcoxon signed rank p 0.28 (n=9). voiceTOM median difference without versus with ACV=1, eight patients improved, two patients showed no change, Wilcoxon signed rank p 0.01 (n=10). ICU FCS median difference without versus with ACV=1, six patients improved, four patients showed no change, Wilcoxon signed rank p 0.02 (n=10). Frequency of dry swallow per minute median difference without versus with ACV=2, eight patients improved, one patient was worse, one patient showed no change, Wilcoxon signed rank p 0.02 (n=10). Frequency of unstimulated cough per minute median difference without versus with ACV=0.5, five patients improved, five patients showed no	Suggest that improvements in cough, swallow and saliva management observed were due to increased laryngeal sensitivity or afferent neural activity due to restored laryngeal airflow. Hypothesise that the airflow results in upward ejection of secretions from the larynx. Suggest that stomal leakage may be less of an issue with tracheostomies inserted percutaneously.	Suggest that ACV could be attempted earlier if the stomal site is healing well.

		change, Wilcoxon signed rank p 0.04 (n=10).		
Quasi-Experimental				
Gordan (1984)	No patient in the neuromuscular disease group achieved intelligible speech at any flow rate. Non-neuromuscular disease group could attain intelligible whisper at flows of 4-6 L/min.	They found a significant difference between the two groups using chi-square, but no details were provided.	The success of ACV depends on the patient having functional vocal cord vibration and the ability to use their articulators effectively. This is likely to be reduced in patients with neuromuscular disease.	Advice against using ACV in patients with neuro-muscular disease.
Experimental				
Pandian *et al.* (2019)	No significant difference in the baseline characteristics between the control and intervention groups for SOFA scores, QOL-MV score, V-RQOL score, age, sex, race, and indication for tracheostomy. There was a significant difference between the groups in the indication for admission (with more pulmonary in the intervention groups and more neurological patients in the control group). There was a significant difference between groups in change in V-RQOL score, with more improvement in the intervention group. V-RQOL repetition scores (needing to repeat to be understood) and outgoing scores (how outgoing the person feels) also improved significantly in the intervention group. When the 10 patients in the control group that tolerated the OWV were excluded, the changes to QOL-MV and V-RQOL scores were better in the intervention group. The SIT scores decreased as the SOFA scores increased. 73% could	Baseline QOL-MV 44 ± 14. Baseline V-RQOL 27 ± 17. Mean post-intervention SIT score: 53.1% ± 25.8%, Range: 7.69 - 95.45, (n=18/25 intervention group). Stepwise regression analysis found that the SIT scores decreased by 6.4 points for each 1-point increase in SOFA score (p = 0.04). Mean flow rate for optimal phonation: 4.7 ± 1.3. Median days from initiation of BLUSA to discharge from the ICU: 19 days, IQR: 11, 37 days. Median days from initiation of BLUSA to discharge from hospital: 29 days, IQR:15, 64 days. ICU LoS (control: 29 intervention: 49). Hospital LoS (control:35; intervention: 60) was significantly longer for the intervention group. Moderate correlation between the overall QOL-MV and V-RQOL	Restoring phonation helps to improve QoL.	None made

	use the BLUSA with some level of independence (n=22/25). 41% reported somewhat or very satisfied with BLUSA, 36.4% were neutral, and 22.7% were somewhat or very dissatisfied with use (n=22/25).	(Spearman correlation coefficient = 0.59). Weak correlation between QOL-MV and V-RQOL and the SOFA scores (Spearman correlation coefficient = -0.19 and -0.08, respectively). The speech item on QOL-MV correlated moderately with overall V-RQOL (Spearman correlation coefficient = 0.56). High levels of internal consistency in the QOL-MV for the measurement of the construct of 'overall QOL whilst mechanically ventilated" (reliability: Cronbach alpha = 0.71).

ACV – Above Cuff Vocalisation; APS – Airway Protection Scale; BLUSA – Blue Line Ultra Suction Aid; CXR – chest x-ray; dB SPL – decibel sound pressure level; ESAF – External Subglottic Air Flow; FEES – Fibreoptic Endoscopic Evaluation of Swallowing; ICU FCS – ICU Functional Communication Scale; IQR – interquartile range; L/min – litres per minute; LoS – length of stay; MDT – multi-disciplinary team; PAS – penetration aspiration scale; QoL – quality of life; QOL-MV – quality of life in mechanically ventilated patients; SD – standard deviation; SIT – speech intelligibility test; SLT – speech and language therapist; SOFA – Sequential Organ Failure Assessment; SSRS – Secretion Severity Rating Scale; voiceTOM – voice Therapy Outcome Measure; V-RQOL – voice-related quality of life

Acceptability of ACV

Six of the 13 studies described ACV acceptability for patients or staff. Signs of acceptability for patients included the ability to use ACV with ease and independence; satisfaction with ACV; lack of frustration with ACV; ability to communicate with staff; family and visitors; effective and meaningful communication; the intelligibility of speech; sustained ability to communicate; reduced anxiety; ability to express basic needs and emotions; comfort; adequate voice intensity; and minimal adverse events or symptoms. Overall, these comments suggested that ACV was generally acceptable to patients. Pandian and colleagues reported patient satisfaction levels, 41% stated they were somewhat or very satisfied with ACV, and 23% said they were somewhat or very dissatisfied (Pandian et al., 2020). Additionally, they reported that 74% of participants could use ACV with some level of independence (Pandian et al., 2020). Signs of acceptability for staff included patient cooperation (McGrath et al., 2016).

Adverse events and complications

Nine studies reported adverse events or complications. Various adverse events were reported in the literature, including subcutaneous emphysema of the neck and face directly after the application of airflow (Akhtar and Bell, 1993; Calamai et al., 2018) and dilation of the trachea in one patient following the application of airflow to the pilot balloon resulting in the tracheostomy cuff bursting (Feneck and Scott, 1983). Complications and side-effects reported included granulation and pressure necrosis at the stomal site with Communi-Trach I® in 40% of patients (Leder and Astrachan, 1989); air trapping in two patients (Pandian, Smith, et al., 2014; McGrath et al., 2016); discomfort (Gordan, 1984; Leder and Traquina, 1989; McGrath et al., 2019) in 11% of patients in one study (McGrath et al., 2019); aerophagia resulting in burping/abdominal distension in one patient (McGrath et al., 2016); excessive oral secretions in 10% of patients (McGrath et al., 2019); stomal air leak in three patients (Pandian, Smith, et al., 2014; McGrath et al., 2019); gagging in 2% of patients (McGrath et al., 2019), nausea in 1% of patients (McGrath et al., 2019); and hoarse and strained voice quality in two patients (Pandian, Smith, et al., 2014).

Communication

Seven studies reported positive effects of ACV on communication, including voice intensity being greater than ambient room noise in 45-100% of patients at flows from 5 L/min to 15 L/min (Leder and Traquina, 1989; Leder, 1990b); ability to produce an intelligible whisper or speech in 50-80% of patients (Gordan, 1984; McGrath et al., 2016; McGrath et al., 2019); more effective communication (McGrath et al., 2016); more meaningful communication (Pandian, Smith, et al., 2014); improved ability to communicate basic needs and discomfort (Pandian, Smith, et al., 2014); ability to participate in short conversations (Pandian, Smith, et al., 2014); reduction in the need

to repeat to be understood (Pandian et al., 2020); improvements to the voice Therapy Outcome Measure in 60-80% of patients (McGrath et al., 2016; McGrath et al., 2019); and improvements to the ICU Functional Communication Scale in 60% of patients (McGrath et al., 2019). Some studies also reported difficulties with ACV, including difficulty producing intelligible speech at lower flows (Leder and Traquina, 1989); the inability to produce voice with laryngeal pathology in 10% of patients (Leder and Traquina, 1989); inability of 100% of patients with neuromuscular disease to produce intelligible speech (Gordan, 1984); and delay to intelligible speech from 2.1 to 5.6 days and need for training from an SLT (Leder and Traquina, 1989; Leder, 1990b). Optimal voice intensity and speech intelligibility were found to be between 10-15 L/min for the Communi-Trach I® (Leder, 1990b) and the Portex “Talk”® Tracheostomy Tube (Leder and Traquina, 1989). The mean flow rate for optimal voicing with the Portex Blue Line Ultra SuctionAid (BLUSA) was reported by one study as 4.7 (±1.3) L/min (Pandian et al., 2020).

Swallowing

Positive benefits for swallowing were reported by four studies, including subjective reports, such as the elimination of aspirated food or drink particles in the subglottic port (Naito et al., 1996); swallowing improving more quickly than expected (McGrath et al., 2016); stimulation of swallowing (McGrath et al., 2016); and improved laryngeal sensation (McGrath et al., 2016). Quantitative measures included an increase in spontaneous swallowing frequency with a mean increase of 1.5–2 swallows per minute (Kothari et al., 2017; McGrath et al., 2019), reduction in subglottic secretion volume from a mean of 3.10 ± 0.31 mL to 0.50 ± 0.30 mL (Kothari et al., 2017), and improvements in the Secretion Severity Rating Scale in 50% of patients by 0.5 (scale of 0 to 3) (McGrath et al., 2019). ACV did not affect the Penetration-Aspiration Scale (McGrath et al., 2019).

Airway protection

Two studies reported positive effects on cough (McGrath et al., 2016; McGrath et al., 2019), with subjective statements of cough being stimulated (McGrath et al., 2016) and an increase in the number of spontaneous coughs per minute of 0.5 in 50% of patients (McGrath et al., 2019). ACV did not affect the Airway Protection Scale (McGrath et al., 2019).

Quality of life

Pandian and colleagues subjectively stated that QoL was improved (Pandian, Smith, et al., 2014). The RCT reported greater improvements in the V-RQOL score with ACV (26.59 ± 16.81 to 42.50 ± 17.69 versus 26.67 ± 16.72 to 32.26 ± 24.90; $P = .001$) and greater improvements in the QOL-MV score (data not provided) $P = .04$ when

excluding 10 patients in the control group who received an OWV for speech (Pandian et al., 2020).

Length of stay

One study examined the impact of ACV on LoS and found that both ICU and hospital LoS were greater in the ACV group (49 days ICU; 60 days hospital) than in the control group (29 days ICU; 35 days hospital) (Pandian et al., 2020). They suggested this was due to the severity of the illness, but there was no significant difference between the sequential organ failure assessment scores presented.

Mechanism of action

To fully understand complex interventions, it is important to understand the mechanism of action, and early-stage research for new interventions should provide this information (Craig et al., 2013). Therefore, studies were reviewed for any information about ACV's mechanism of action. McGrath and colleagues hypothesised that ACV enables vocal fold vibration to facilitate voicing (McGrath *et al.*, 2016) and that to successfully produce speech, functioning vocal folds and articulators are required (Gordan, 1984). Pandian and colleagues stated that the restoration of vocalisation facilitated improved QoL (Pandian et al., 2020). It was hypothesised that delay in voice production or the inability to produce voice is caused by poor vocal fold adduction due to laryngeal pathology (Leder and Traquina, 1989; Leder, 1990b), prolonged vocal fold abduction and disuse (Leder and Traquina, 1989; Leder, 1990b), prolonged endotracheal intubation (Leder and Traquina, 1989), or poor ventilator-phonatory timing with phonation attempts occurring during the inspiratory cycle (Leder and Traquina, 1989). Leder and Traquina hypothesised that tracheostomy tubes with multiple openings for subglottic airflow would increase patient comfort and reduce the airflow needed (Leder and Traquina, 1989).

Various mechanisms of action for improving swallow function were suggested, including increasing subglottic airway pressure, which facilitates glottal closure during swallowing (Naito et al., 1996; Kothari et al., 2017); stimulation of subglottic mucosa and the superior laryngeal nerve facilitating vocal fold closure (Kothari et al., 2017); stimulation of laryngeal mechanoreceptors regulating swallowing function (Kothari et al., 2017); increase in afferent neural activity (McGrath et al., 2019); re-sensitisation of the larynx (McGrath et al., 2016; McGrath et al., 2019); improving swallowing strength (McGrath et al., 2016); improving airway protection (McGrath et al., 2016); and providing airflow to eject secretions from the trachea and larynx (McGrath et al., 2019).

Recommendations for ACV delivery

Several studies made suggestions regarding the earliest that ACV should commence post-tracheostomy insertion, with one stating 48 hours (Akhtar and Bell, 1993) and two

saying 72 hours (McGrath et al., 2016; McGrath et al., 2019), with the caveat that it could be started earlier if the stomal site is adequately healed (McGrath et al., 2019). Recommendations for airflow delivery included using intermittent airflow wherever possible (Feneck and Scott, 1983); avoiding prolonged use of non-humidified air (Naito et al., 1996; Pandian, Smith, et al., 2014; McGrath et al., 2016); using minimal airflows to prevent laryngeal drying or hyperadduction of the vocal folds (Pandian, Smith, et al., 2014; McGrath et al., 2016); switching off airflow or unblocking the thumb when not speaking to reduce aerophagia (Pandian, Smith, et al., 2014); and labelling the pilot balloon and subglottic port to prevent misconnection of the airflow (Pandian, Smith, et al., 2014). The only contraindication suggested was upper airway obstruction (Pandian, Smith, et al., 2014; McGrath et al., 2016). Criteria for suitable patients for ACV included not suitable for cuff deflation (Pandian, Smith, et al., 2014); awake and attempting to communicate (Pandian, Smith, et al., 2014; McGrath et al., 2016); adequate speech and language function (Pandian, Smith, et al., 2014); intact laryngeal function (McGrath et al., 2016); and established tracheostomy stoma (Pandian, Smith, et al., 2014). Kothari and colleagues suggested that there is benefit to using the ACV in patients with severe subglottic aspiration (Kothari et al., 2017). Gordan stated that ACV should be avoided in patients with neuromuscular disease, as there are no speech benefits (Gordan, 1984).

Two studies asserted that daily rehabilitation with an SLT is required for patients to synchronise vocalisation with the airflow and the ventilator cycle and to avoid or resolve negative side-effects, such as hoarse or strained vocal quality (Leder and Traquina, 1989; Leder, 1990b). Pandian and colleagues stated that some patients need vocal fold exercises to reduce vocal fold spasms or laryngeal spasticity and to prevent air trapping (Pandian, Smith, et al., 2014). They also advocated for education and training for communication partners (Pandian, Smith, et al., 2014). McGrath and colleagues emphasised that an experienced multi-disciplinary team (MDT) and trained SLTs should supervise ACV to minimise complications (McGrath et al., 2016). Two studies suggested using nasendoscopy to exclude laryngeal pathology in patients unable to vocalise with ACV (Leder and Traquina, 1989; Pandian, Smith, et al., 2014).

3.5 Discussion

A comprehensive systematic literature search and a narrative synthesis were conducted to evaluate the evidence for using ACV in patients with a tracheostomy. This review has identified considerable variation in how ACV is implemented and a lack of evidence for how it should be implemented in clinical practice. There was limited and low-quality evidence to show the efficacy or effectiveness of ACV for the various outcome measures in question, including communication, swallowing, airway protection, QoL, LoS, and acceptability to patients and HCPs. There was no published

evidence for other outcomes, such as incidence of pneumonia, time to decannulation, mortality, intervention costs, and cost benefits. This review demonstrated reported safety issues with ACV, with both adverse events and minor complications described. The extent of these safety issues is unclear.

The 13 included studies were a mixture of case reports, case series, observational, quasi-experimental, and one RCT. Levels of evidence were low, and there was a high risk of bias in more than two domains for every study. Additionally, sample sizes were small, with one study having 50 participants and all others having ≤ 20. The studies examined different aspects of the effects of ACV, including adverse effects (n=4); communication (n=4); swallowing (n=2); communication and swallowing (n=2); and QoL and communication (n=1). The studies can be split into two cohorts. The first, published pre-1996, used tracheostomy tubes specially designed for airflow application to facilitate speech: the Portex Vocalaid, the Portex "Talk" Tracheostomy, the Communi-Trach I®, and the Pitt-speaking cuffed tracheostomy. The second cohort, published from 1996 onwards, used tubes with a subglottic port designed to remove secretions: the Portex BLUSA and the Argyle Aspiraid.

3.5.1 Summary of evidence

Both cohorts of studies evaluated ACV in a wide range of diagnoses. Some studies advised against use in specific populations, such as people with neurological conditions (Gordan, 1984) or people unable to communicate or cooperate with the intervention (McGrath et al., 2016). However, these recommendations appear to be attributable to a lack of observed benefits for communication, whereas other studies have demonstrated swallowing benefits even in patients with reduced consciousness (Kothari et al., 2017). It is unclear whether ACV benefits any particular patient group more than another, and this determination is made more difficult because all possible benefits are not evaluated in each study.

In contrast to the findings of the scoping review by Petosic in 2021, which reported *'..detailed descriptions of the ACV technique which was regarded as very similar…'* that *'…adds to the replicability of ACV both in research and clinical settings…'* (Petosic et al., 2021), this systematic review found considerable variability in terms of intervention delivery. The first cohort of studies (pre-1996) tended to use higher flows of ≤15 L/min, whereas the second cohort of studies (post-1996) used ≤6 L/min. There was variability in whether humidified oxygen, non-humidified oxygen or medical air was used. Airflow was mainly applied intermittently using a thumb port, but some studies used continuous airflow.

Intervention delivery information was incomplete for all studies. Only one study provided information about the planned frequency and dosage of the intervention (up to

15 minutes every two hours) and the dose delivered (McGrath et al., 2019). There was limited information on the interval between tracheostomy insertion and intervention commencement. The RCT that implemented ACV within 48 hours did not specify precisely when the Portex BLUSA tubes were inserted and ACV commenced. This lack of detail in ACV application and delivery is problematic. Firstly, it makes comparing studies difficult, as determining the relative benefits of the intervention is challenging when there is a lack of transparency in the application. Secondly, there are no clear protocols for ACV use which may render translation into clinical practice more complex for HCPs. This could result in confusion and uncertainty for clinicians, and may increase the frequency of complications or patient safety incidents if ACV is misapplied.

There was marked variation in outcome measures used, supporting the findings of a recent systematic review which explored the use of outcome measures for communication in mechanically ventilated individuals (Zaga et al., 2019). The subjective judgement of speech intelligibility was the only consistent measure used, but how this was performed was unclear for most studies. As discussed in Chapter 2, there are potential issues with reliance on subjective outcome measures – particularly when there is no blinding of treatment allocation – as clinicians have been shown to tend to exaggerate positive findings (Wood et al., 2008). Furthermore, the lack of consistency in using outcome measures makes comparison of the studies problematic. This highlights the need for a core outcome set for both swallowing and communication in the critical care setting, and research has commenced developing core outcome sets for both of these areas (Zaga, Cigognini, et al., 2020; Duncan et al., 2023).

All studies that outlined who performed the initial assessment of the intervention used either an SLT (Leder and Astrachan, 1989; Leder and Traquina, 1989; Leder, 1990b; Pandian, Smith, et al., 2014; McGrath et al., 2016; McGrath et al., 2019; Pandian et al., 2020) or an occupational therapist (OT), as per local guidelines (Kothari et al., 2017). Four studies specified that speech and language therapy input for ACV introduction is essential to maximise effectiveness and minimise complications (Leder and Traquina, 1989; Leder, 1990b; Pandian, Smith, et al., 2014; McGrath et al., 2016).

Only one study explored patient satisfaction with ACV, with fewer than half reporting satisfaction. A single study examined patient-reported complications, finding that <30% had complications. Patient or staff acceptability was reported descriptively and focused predominantly on communication, ability to use ACV, and comfort. No studies explored acceptability or satisfaction from a dysphagia perspective. Various studies reported adverse events and complications from the serious, such as subcutaneous emphysema and tracheal dilation, to the mild, for example, stomal air leak and discomfort. No studies reported bleeding as a complication. Several studies mentioned concerns regarding the potential for drying of the laryngeal and tracheal mucosa.

However, no studies reported any symptoms or signs of this during or post-ACV. There was also no follow-up of patients in any study, which might have identified possible long-term adverse effects of ACV, such as laryngo-tracheal drying or dysphonia. Four of the studies did not mention adverse events or complications, and most of the studies provided minimal detail of adverse events or complications and often appeared to lack a systematic approach to capturing this data. It is unclear whether the limited reporting of complications is a sign of an absence of issues, a lack of consideration, difficulty with identification, or dismissal as unimportant. Severe adverse events are possible, but the nature, duration, and frequency of minor complications are uncertain.

All studies exploring effects on communication (n=7) or swallowing (n=4) reported qualitative or quantitative benefits for patients. Although two studies reported positive effects on cough sensitivity with increased spontaneous initiation of cough, there was no evidence of improved cough effectiveness or airway protection. Patients' QoL was said to improve in one study using two QoL measures. Only one of these measures – a scale evaluating QoL solely related to voice – demonstrated improvements with the entire sample. The other measure considered broader aspects of QoL, including comfort, airway comfort, the comfort of breathing, activity, bedside recreation, swallowing, speech, saliva control, mood, anxiety, sleep, and autonomy. Significant improvements were found in this measure in the intervention group only when almost half the control group was excluded, leading to a risk of bias and reduced study power. Although there is a signal of potential QoL benefits with ACV, these currently appear to be primarily related to voice and communication.

The finding of increased ICU and hospital LoS with ACV is challenging to interpret in light of different protocols applied to the intervention and control arms (40% of the control group, but not the intervention group, underwent cuff deflation trials). The authors suggested that the increased LoS in the ACV group was related to differences in the severity of illness between groups (Pandian et al., 2020). Nevertheless, there was no significant difference between the Sequential Organ Failure Assessment (SOFA) scores – a severity of illness measure – for the control or ACV groups. There are other potential explanations for this unexpected outcome. Firstly, there was a significantly greater number of patients in the ACV group with a primary reason for admission of medical pulmonary impairment and fewer with a medical neurological impairment. It might be that this cohort of patients takes longer to recover, and as such, have a greater ICU and hospital LoS. However, research suggests that primary diagnosis is not a critical factor in LoS in critically ill patients, with the severity of illness tending to have a more significant impact on LoS (Higgins et al., 2003). Secondly, the different approaches in weaning between the control group and the ACV group could explain the difference in LoS. It appears that the control group were allowed to continue with the weaning process, with 10 of the 25 patients able to proceed to cuff deflation

and OWV trials. In contrast, none of the ACV group proceeded to cuff deflation trials during the 5-day RCT. One study has shown that early cuff deflation can accelerate the decannulation process (Martin et al., 2021). Even though this study did not find a reduction in ICU or hospital LoS (Martin et al., 2021), it is possible that early cuff deflation could affect this change. Researchers may have inadvertently delayed decannulation and discharge by denying the ACV group the opportunity to proceed with cuff deflation trials. Thirdly, personal communication with one RCT research team member revealed that most of their local hospitals do not accept patients with the Portex BLUSA tracheostomy tube. This means that patients with these tubes usually require an alternative tube to be placed before transfer to another hospital. This potentially could delay discharge and subsequently increase LoS.

Several studies advanced hypotheses for the mechanism of action of ACV, but none were mechanistic studies. The studies proposed that airflow elicits vocal fold vibration to facilitate vocalisation. Airflow is vital for vocalisation, with airflow for normal speech ranging from 6-18 L/min (mean: 11 L/min) for males and 5-13 L/min (mean: 8 L/min) for females (Holmberg et al., 1988). Researchers have suggested that a minimum phonation threshold flow is required (Jiang and Tao, 2007). However, it is likely that subglottic pressure also plays a vital role in facilitating phonation. Researchers have also postulated that a minimum phonation threshold pressure is required to elicit vocalisation (Chan and Titze, 2006). Both the minimum phonation threshold flow and pressure vary from person to person. They depend on factors such as the visco-elasticity of the vocal fold tissue, laryngeal pathology, and the glottal shape and size (Chan and Titze, 2006; Jiang and Tao, 2007).

Some authors have suggested that swallowing benefits observed in ACV result from increased subglottic pressures. Positive subglottic pressure is essential for a normal functioning swallow and is usually determined by lung volumes at the time of swallowing (Gross et al., 2006; Gross et al., 2012). In healthy individuals, apnoea occurs during the swallow, and this subglottic pressure does not continue to build whilst the vocal folds are adducted. Application of a 7 L/min airflow via a subglottic catheter has been shown to increase subglottic pressures in tracheostomised patients with a deflated cuff and an OWV in situ (Clarett et al., 2014). They reported pressures of 2-10 centimetres of water (cmH_20) (median 4.5 cmH_20) during swallowing without air insufflation (Clarett et al., 2014). These figures are similar to that found in two studies evaluating subglottic pressures during speech in healthy individuals: 6.3-10.9 cmH_20 (mean: 8.65 cmH_20) (Murry and Brown, 1971) and 4.4-9.6 cmH_20 (Holmberg et al., 1988). Once air insufflation was added, the pressures increased to 3-22 cmH_20 (median 5.5 cmH_20) (Clarett et al., 2014). Hess states there may be ‘excessive expiratory resistance’ when tracheal pressures are greater than 5 cmH_20 during passive exhalation (Hess, 2005). The period of apnoea during swallowing has been

shown to range between 0.86 and 1.41 seconds for saliva and 0.83 and 1.14 seconds for a 20 mL bolus in male and female healthy individuals of a range of ages (Hiss et al., 2001). Comparatively, the period of apnoea is greater in individuals with dysphagia and those who aspirate, with a mean of 1.59 seconds and 2.30 seconds, respectively, for a 20 mL bolus (Butler et al., 2007). Therefore, continuous air insufflation with an inflated cuff – with the air unable to disperse into the lung or escape during the period of apnoea when the vocal folds are adducted – may result in the formation of excessive resistance in the subglottic space. In dysphagic and aspirating patients, any excessive resistance generated by accumulating subglottic pressure during ACV is likely more pronounced due to the extended apnoeic period. None of the studies in this systematic review mentioned any possible negative impact of increasing or excessive build-up of subglottic pressures, e.g., with continuous flow or high flow rates. Neither did any study suggest that airflow should be paused during swallowing. Some of the patient discomfort reported in these studies could result from attempting to swallow against an increasing build-up of subglottic pressure. Excessive build-up of subglottic pressure may even prevent patients from swallowing altogether. The potential long-term impact of excessive resistance in the subglottic space is unknown.

Another suggestion proposed in various studies was that airflow increased laryngopharyngeal stimulation eliciting positive effects on swallowing function. This theory has merit, as air pulse stimulation of the oropharynx has been shown to improve saliva swallowing frequency (Theurer et al., 2005; Theurer et al., 2009) and, in younger adults, increase the urge to swallow (Theurer et al., 2005). Furthermore, neurological studies using functional magnetic resonance imaging have demonstrated that air pulse stimulation to the oropharynx activates critical areas of the cortex and brainstem involved in the sensorimotor control of oral and pharyngeal stages of swallowing (Sörös et al., 2008; Lowell et al., 2008). Similarly, research evaluating various tracheostomy manipulations found improvements to the penetration-aspiration scale when airflow was redirected through the vocal folds with cuff deflation and an OWV (Suiter et al., 2003). They hypothesised that this improvement was due, in part, to improved laryngopharyngeal sensation as a result of restored trans-laryngeal airflow (Suiter et al., 2003).

3.5.2 Facilitators and barriers to implementation of ACV

The studies reviewed suggested various factors facilitating the effective use of ACV, including involvement of an SLT in ACV assessment and introduction with patients; appropriate patient identification; waiting 48-72 hours post-tracheostomy insertion before commencing ACV to minimise the risk of subcutaneous emphysema; and optimising airflow delivery. Potential barriers to implementation may include lack of access to speech and language therapy; inadequate staff training in the appropriate

use of ACV; lack of clear evidence for optimal timing and delivery of ACV; and lack of access to nasendoscopy to identify laryngeal pathology and verify safety. Since the publication of these studies, the COVID-19 pandemic has become a significant barrier to ACV implementation. This will be explored further in Chapter 5.

3.5.3 Strengths and Limitations

This review synthesised the key evidence for ACV and included various qualitative and quantitative data. The strengths of this review include the use of a systematic approach and registered protocol, reducing the risk of bias. Data extraction and risk of bias analysis were carried out independently by two reviewers, improving the reliability and accuracy of the findings. Sample sizes were small, and the levels and quality of the evidence were low. A meta-analysis and completion of GRADE were not possible due to the heterogeneity of the studies. All studies lacked detail on the prescribed and delivered intervention, contributing to a lack of clarity regarding optimal timings, airflow type, airflow limits, frequency, and duration of ACV. The English-language eligibility criteria may have resulted in the omission of relevant studies that may have added to the findings.

3.5.4 Implications for clinicians and researchers

This review reveals serious potential complications if ACV is delivered too early (Akhtar and Bell, 1993), the tube is in the incorrect position (Calamai et al., 2018), or is carried out incorrectly or with inadequate training (Feneck and Scott, 1983). Misapplication of the intervention or inadequate support for the patient can lead to adverse events and complications, such as strained vocal quality. Given the limited and low-quality evidence available, the findings suggest cautious implementation of ACV in patients with a tracheostomy. The research findings indicate that SLTs, or other voice specialists, should be involved in assessing and introducing ACV to minimise laryngeal complications. Developing guidelines, competencies and education packages is essential to ensure staff have the appropriate skills to assess or deliver ACV. Given the limited and low-quality evidence, making specific recommendations regarding ACV delivery is impossible.

The evidence suggests ACV has potential benefits for swallowing, communication, cough and QoL; however, many unanswered questions remain. Future studies must ensure a detailed description of ACV prescription and delivery to enable replicability and evaluation of optimal intervention delivery. Developing a core outcome set to include QoL, communication, swallowing, and airway protection would ensure that research is comparable.

Various similarities and differences are noted when comparing this systematic review with the recent scoping review, which studied the safety and effectiveness of ACV for

speech (Petosic et al., 2021). While this systematic review had a broader scope – exploring all relevant outcome measures – it had narrower inclusion criteria, excluding conference abstracts, studies with patients <18 years old, studies using other interventions in addition to ACV, or not providing clear or precise data. This resulted in the inclusion of fewer studies than the scoping review. As a result of conducting a risk of bias assessment on each study, this systematic review reported low quality of evidence overall for ACV. In contrast, the scoping review, which conducted risk of bias assessment on three outcome measures, reported moderate quality of evidence for communication, low quality for QoL and complications, and very low quality for adverse events (Petosic et al., 2021). Both studies highlighted the need for staff training in conducting and implementing ACV, further research, and the use of standardised outcome measures.

3.6 Summary

This is the first systematic review of ACV evaluating the evidence for acceptability and effectiveness for all identified potential benefits. Limited and low-level evidence is available for using ACV in patients with tracheostomy. The research suggests potential benefits for communication, swallowing, cough and QoL. However, other vital outcome measures – incidence of pneumonia, time to decannulation, intervention costs, and cost benefits – were not evaluated. There were reported safety issues and complications with ACV, but the extent of these issues is unclear. The data require cautious interpretation because of the small sample sizes and methodological issues. There was considerable variation in the application of ACV, and the current evidence is insufficient to provide recommendations for optimal intervention delivery. There is a need for more high-quality and larger studies. Future research could benefit from a core outcome set and the accurate recording of the prescribed and delivered intervention.

Chapter 4 explores how ACV has been translated into clinical practice via an international survey of HCPs. It will ascertain ACV implementation and application practices, frequency of adverse events and complications, and explore staff opinions of ACV.

Chapter 4 Determining the Prevalence, Implementation Approaches, and Opinions of Above Cuff Vocalisation: A Survey of Healthcare Professionals

This chapter investigates the current ACV and tracheostomy weaning practices in the UK and internationally, reporting the results of an online survey. Section 4.1 describes the rationale and background for this study. Section 4.2 outlines the study objectives. Section 4.3 reports the methods used, and the results are presented in Section 4.4. Finally, the study findings are discussed in Section 4.5 and summarised in Section 4.6.

The work presented in this chapter has been published in the *Archives of Physical Medicine and Rehabilitation*:

Mills, C.S., Michou, E., Bellamy, M.C., Siddle, H.J., Brennan, C.A. and Bojke, C., 2022. Determining the Prevalence, Implementation Approaches, and Opinions of Above Cuff Vocalization: A Survey of Health Care Professionals. *Archives of physical medicine and rehabilitation*, *103*(3), pp.394-401.

The work presented in this chapter is also discussed in an invited paper published in *Intensive Care Medicine*:

Mills, C.S., Cuthbertson, B.H. and Michou, E., 2023. What's new in reducing the impact of tracheostomy on communication and swallowing in the ICU. *Intensive Care Medicine*, pp.1-4.

4.1 Introduction

Little is known about the prevalence of Above Cuff Vocalisation (ACV) use or implementation approaches in clinical practice, despite its availability as an intervention for over 50 years (Whitlock, 1967). As Chapters 2 and 3 described, there is limited and low-quality evidence to support the use of ACV (Mills, Michou, King, et al., 2022). There are reports of various benefits of ACV, including communication (Gordan, 1984; Leder and Traquina, 1989; Leder, 1990b; Pandian, Smith, et al., 2014; McGrath et al., 2016; McGrath et al., 2019); swallowing (Naito et al., 1996; McGrath et al., 2016; Kothari et al., 2017; McGrath et al., 2019); QoL (Pandian et al., 2020); and cough (McGrath et al., 2019). Specifically, ACV has been found to improve cough frequency, an important sign of improved laryngeal sensation. The cough reflex is an important mechanism for preventing materials such as saliva, food, or drink from entering the lungs and clearing them after they have passed below the vocal folds (Haji et al., 2013). Complications range from serious, such as subcutaneous emphysema and tracheal dilation (Feneck and Scott, 1983; Akhtar and Bell, 1993; Calamai et al., 2018) to minor, including discomfort, strained voice quality, and nausea (Gordan, 1984; Leder

and Astrachan, 1989; Pandian, Smith, et al., 2014; McGrath et al., 2016; McGrath et al., 2019).

The considerable variability of tracheostomy management and weaning approaches were described in Chapter 2. These variations in practice may influence the implementation and use of ACV in clinical practice. For example, early use of cuff deflation and one-way valves (OWVs) may result in limited use of ACV as it will not be necessary for patients who succeed with this approach. Whereas, delaying cuff deflation until patients are weaned from the ventilator creates more of a need for an intervention such as ACV, as patients will have prolonged periods of cuff inflation with an absence of airflow through the vocal folds and upper airway, which is likely to lead to desensitisation and atrophy of the musculature. Thus far, no studies have explored HCPs' opinions of ACV or investigated implementation practices. The study aimed to provide information about tracheostomy management, current ACV practice, opinions about ACV use, and identify gaps for further research.

4.2 Study objectives

This study explored the following thesis objectives:

- Objective 2: To investigate current ACV and tracheostomy weaning practices in the UK and internationally using an online survey.
- Objective 3: To understand HCPs' experiences with ACV via an online survey.

4.3 Methods

This descriptive observational study utilising a cross-sectional, online, single-event survey investigated ACV prevalence, practice and opinions. Ethical approval was obtained from the School of Medicine Research Ethics Committee at the University of Leeds (05/02/2019/MREC 18-037).

4.3.1 Survey development

A novel, open, online survey was developed in English using *Jisc Online Surveys*. The target population was any HCP involved in ACV and tracheostomy weaning. The HCPs involved vary across the UK and internationally. They may include advanced critical care practitioners (ACCPs), doctors, nurses, occupational therapists (OTs), physiotherapists (PTs), respiratory therapists (RTs), tracheostomy specialist nurses, and SLTs.

The survey design process included: 1) planning the content and objectives; 2) survey layout; 3) specific questions; 4) survey piloting; and 5) dissemination of adverts or letters (Kelley, 2003). There were no existing psychometrically tested questionnaires available for this topic. Therefore, questions were developed by the study team.

Questions were based on knowledge gained from a systematic review (Mills, Michou, King, et al., 2022), described in Chapter 3, and individuals from various professional groups to ensure content validity, as per best practice (Kelley, 2003; Burns et al., 2008). The study team reviewed the draft survey and piloted it with eight external HCPs from four professional groups in the UK. Piloting of the survey included verifying: understanding of terms and questions, time for completion, items for reduction, and technical issues. The final refined survey included 73 questions covering participant information (n=6), tracheostomy management (n=9), the prevalence of ACV use (n=3), practicalities of using ACV (n=30), resource use (n=4), personal experiences and opinions (n=20), and barriers to ACV (n=1). The question types included closed questions (binary, nominal, ordinal, Likert scales, interval measurements) and open questions (free-text qualitative responses). Most closed questions included 'other' and 'not known' response options to avoid 'floor' and 'ceiling' effects and allow for uncertainty (Burns et al., 2008). The survey was routed, with participants directed in various paths through the survey, dependent on their responses. This reduced the number of questions for participants and maximised survey completion. Appendix B presents the survey questions.

4.3.2 Data sampling

The survey was disseminated internationally from 24 May to 30 November 2019. Convenience sampling was used – a type of non-probability sampling where data is collected from an easily accessible population – with distribution via readily available networks. Survey completion was voluntary, with no provision of incentives. To ensure responses were received from relevant HCPs, the survey was distributed via social media and professional, tracheostomy, and critical care networks. Thirty professional networks and societies were approached, and 17 agreed to disseminate the survey. Dissemination approaches of these networks varied from social media posts, emails, and newsletter adverts. Most networks adopted a multifaceted approach, using a combination of social media, emails and adverts, and initiated multiple reminders during the dissemination period. The survey was also advertised at two multi-disciplinary conferences: the European Society for Swallowing Disorders and the UK Critical Care Research Forum. Appendix C lists the professional networks that disseminated the survey.

4.3.3 Data analysis and reporting

Responses were exported into Microsoft® Excel® 2016 and analysed for each respondent; data from incomplete responses were included. Omissions of questions were recorded as 'no response'. Quantitative data were reported descriptively. Qualitative content analysis was conducted using QSR International's NVivo 12

software. This survey was reported in accordance with the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (Eysenbach, 2004)**,** including reporting the participation and completion rate as preferable to the response rate (Eysenbach, 2004).

4.4 Results

A total of 243 responses were included in the analysis, with one response excluded as the survey was terminated immediately after consent. Five respondents terminated the survey early, and these were analysed up until the point of termination since many questions were stand-alone. This factor, along with survey routing design which leads to bypassing of questions, resulted in a varying denominator. The participation rate (the percentage of visitors to the online survey webpage who participated in the survey) was 9%. The completion rate (the percentage of those who participated in the survey that completed the survey in full) was 98%.

The survey was completed by respondents from 25 countries (Figure 7). The highest number of respondents came from the UK (n=131/243; 54%), followed by Australia (n=26/243; 11%) and the USA (n=25/243; 10%). Table 13 describes the respondent characteristics.

The survey results were grouped into the following sections: tracheostomy management, availability of speech and language therapy services, the prevalence of ACV use, ACV implementation, ACV safety, ACV benefits, and barriers to ACV use.

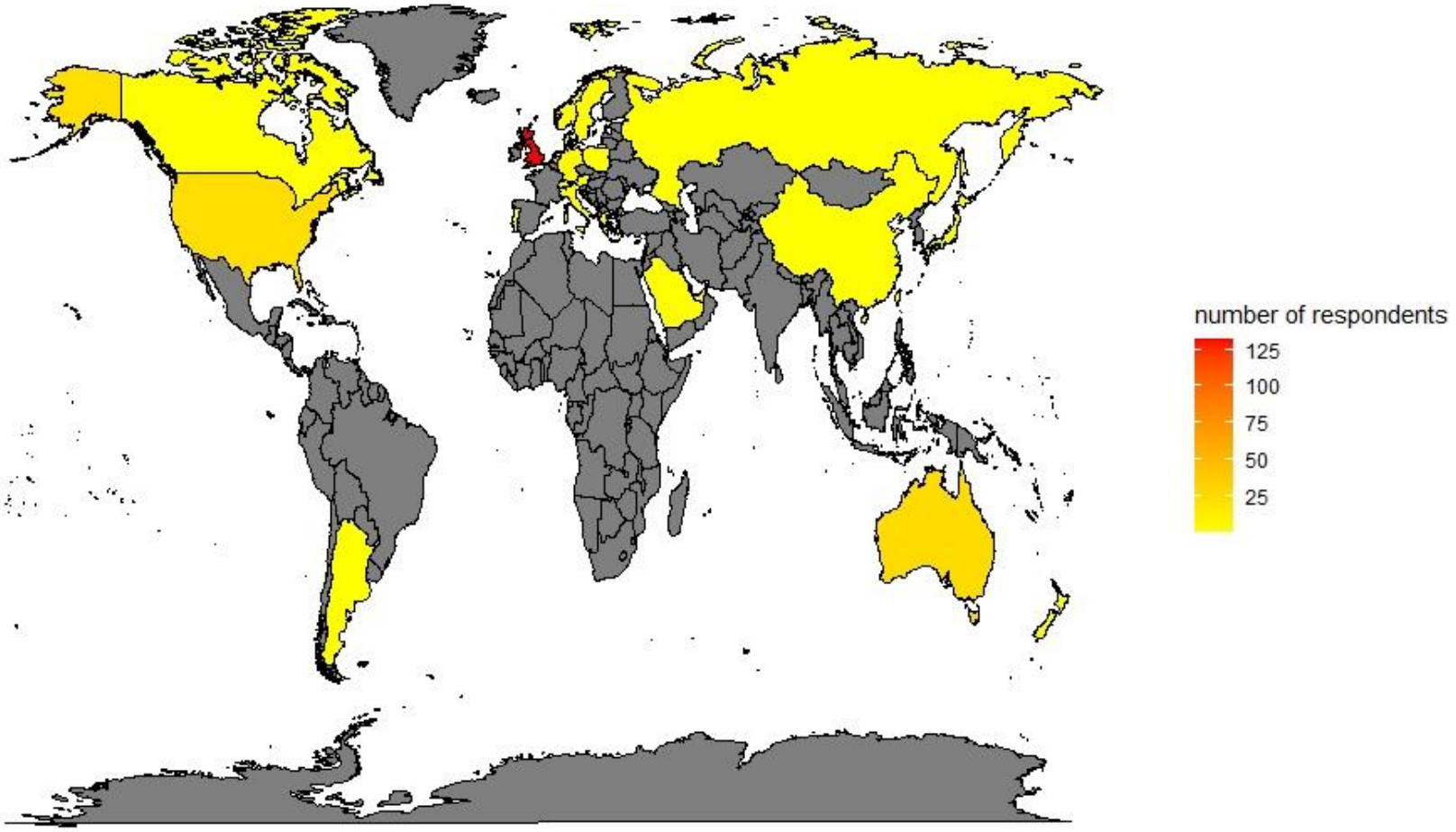

Figure 7 Map of respondents

Table 13 Characteristics of respondents

	n	%
Professional Group		
Speech and Language Therapists	134	55.1%
Doctors	38	15.6%
Nurses	31	12.8%
Physiotherapists	27	11.1%
Advanced Critical Care Practitioners	8	3.3%
Occupational Therapists	2	0.8%
Advanced Nurse Practitioners	1	0.4%
Respiratory Therapists	1	0.4%
Tracheostomy Specialist Nurses	1	0.4%
Total number of responses (N)	**243**	
Clinical areas		
Critical Care	205	84.4%
Acute	111	45.7%
Rehabilitation	51	21%
Long-term care	12	4.9%
Community	10	4.1%
Total number of responses (N)	**243**	
Direct involvement in ACV		
Yes	83	89.3%
No	10	10.8%
Total number of responses (N)	**93**	
Duration of involvement in ACV		
<6 months	10	12.1%
6-12 months	17	20.5%
1-2 years	28	33.7%
3-4 years	9	10.8%
≥5 years	19	22.9%
Total number of responses (N)	**83**	
Number of patients involved with ACV		
<10	50	60.2%
10-50	23	27.7%
51-100	3	3.6%
>100	4	4.8%
Don’t know	2	2.4%
No response	1	1.2%
Total number of responses (N)	**83**	

4.4.1 Tracheostomy management

Tracheostomy use and management approaches, which are likely to impact ACV use, varied widely. Many respondents estimated their critical care units or wards treated ≤10 patients with a tracheostomy per month (n=151/243; 62%), with 28% (n=67/243) treating approximately 11-40 patients per month, and 4% (n=9/243) caring for ≥50 patients per month. The top five types of patients with a tracheostomy seen were: respiratory (n=209/243; 86%), neurological (n=196/243; 81%), general (n=180/243; 74%), cardiothoracic (n=113/243; 47%), and spinal (n=103/243; 42%). There was no consistency for the earliest or typical time the first tracheostomy cuff deflation occurred or the highest level of positive end-expiratory pressure (PEEP) or pressure support (PS), at which cuff deflation was considered (Table 14). Twenty percent of respondents (n=48/242) stated that all of their patients received a subglottic tracheostomy tube as their first tube. In contrast, 31% (n=76/242) reported that none of their patients' first tracheostomy tubes had a subglottic port, and of those using ACV, 24% (n=22/93) stated that a tracheostomy change was required to facilitate ACV use. A similar variation in tracheostomy management and weaning approaches was observed within the UK data.

4.4.2 Availability of speech and language therapy services

Sixty percent (n=145/242) had speech and language therapy input five days per week, while 36% (n=87/242) had less frequent input, and 4% did not know their level of speech and language therapy input (n=9/242). These proportions were similar for those services that were using ACV: 65% (n=61/94), 33% (n=31/94), and 2% (n=2/94), respectively. Fibreoptic endoscopic evaluation of swallowing (FEES) was available for 62% of respondents (n=150/242), with 34% (n=82/242) having no access and 4% (n=10/242) unsure of their FEES access. In those respondents using ACV, there was a higher proportion (n=69/94; 74%) able to access FEES.

4.4.3 Prevalence of ACV use

Thirty-nine percent (n=94/242) used ACV in their clinical services. The demographics of respondents using ACV were: UK (n=55/94; 59%), Australia (n=14/94; 15%), USA (n=8/94; 9%), Sweden (n=3/94; 3%), and other countries (n=14/94; 15%). The professional groups represented included: SLTs (n=58/94; 62%), PTs (n=13/94; 14%), doctors (n=10/94; 11%), ACCPs (n=5/94; 5%), nurses (n=4/94; 4%), OTs (n=2/94; 2%), and other (n=2/94; 2%). Most services used ACV with small numbers of patients; 95% (n=88/93) used it with ≤10 patients in the previous month. A small proportion had been using ACV for >10 years (n=7/93; 8%), 71% (n=66/93) had used it for 1-10 years, and 24% (n=22/93) had used it for <1 year.

Table 14 Variation in tracheostomy weaning approaches

Tracheostomy weaning approaches		N	%
Earliest cuff deflation is considered	<1 hr post-insertion	3	1.2%
	1-24 hrs post-insertion	14	5.8%
	25-48 hrs post-insertion	25	10.3%
	49-72 hrs post-insertion	9	3.7%
	>72 hrs post-insertion	7	2.9%
	Dependent on patient	73	30.0%
	Dependent on consultant on duty	21	8.6%
	No defined earliest time	76	31.3%
	Don't know	15	6.2%
	Total number of responses	**243**	
Typical number of days post-insertion that cuff deflation is first trialled	<1 day	3	1.2%
	1-5 days	51	21.1%
	6-10 days	19	7.9%
	11-20 days	3	1.2%
	21-30 days	0	0%
	>30 days	1	0.4%
	Dependent on patient	122	50.4%
	Dependent on consultant on duty	23	9.5%
	Don't know	19	7.9%
	No response	1	0.4%
	Total number of responses	**242**	
Highest level of Positive End Expiratory Pressure (PEEP) at which cuff deflation is considered	0 cmH_2O	4	1.6%
	1-5 cmH_2O	42	17.3%
	6-10 cmH_2O	51	21.0%
	11-15 cmH_2O	1	0.4%
	Dependent on patient	37	15.2%
	Dependent on consultant on duty	18	7.4%
	No defined highest level of PEEP	54	22.2%
	Don't know	36	14.8%
	Total number of responses	**243**	
Highest level of pressure support (PS) at which cuff deflation is considered	0 cmH_2O	9	3.7%
	1-5 cmH_2O	12	5.0%
	6-10 cmH_2O	28	11.6%
	11-15 cmH_2O	11	4.5%
	16-20 cmH_2O	9	3.7%
	21-25 cmH_2O	0	0%
	26-30 cmH_2O	2	0.8%
	Dependent on patient	52	21.5%
	Dependent on consultant on duty	22	9.1%
	No defined highest level of PS	53	21.9%
	Don't know	44	18.2%
	Total number of responses	**242**	

4.4.4 ACV implementation

Thirty-seven percent were using ACV guidelines, protocols or patient-specific guidelines in their services (n=34/93). Figure 8 outlines the implementation of these and competency documents. Of those using documents, 74% (n=25/34) stated they were extremely or very beneficial. The top benefits reported were: providing clarity on

the approach to ACV (n=32/34; 94%) and minimising risk (n=31/34; 91%). Of those not using documents, 92% (n=47/51) thought it would be beneficial to introduce them.

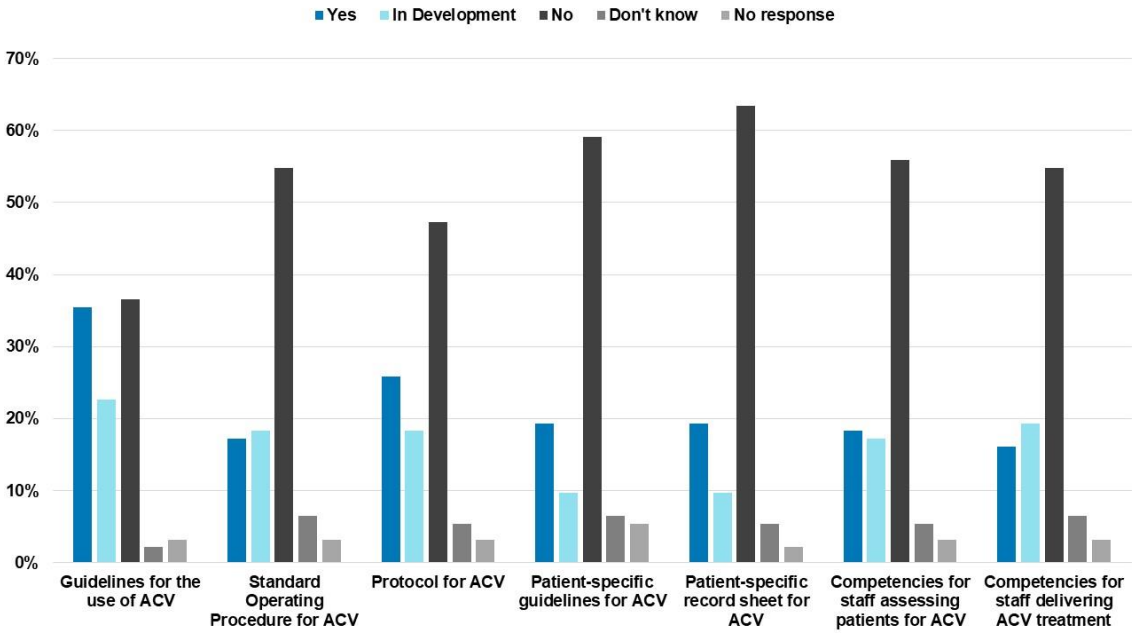

Figure 8 Percentage of respondents that have implemented various documents for ACV delivery (N = 93)

A contraindications list was used by 50% (n=46/93), but there was considerable variability in content (Table 15). This variability in procedural ACV implementation was apparent even in the responses of those who had been using ACV for more than five years.

Few respondents reported using competencies for staff assessing for suitability for ACV (n=17/93; 18%) or delivering ACV (n=15/93; 16%). However, most respondents thought competencies were needed for staff assessing patients for ACV (n=73/93; 78%) and for delivering ACV (n=74/93; 80%). The relative importance of different elements included in competencies was generally similar for staff assessing and delivering ACV (Figure 9). Training for staff delivering ACV was in place for 47% (n=44/93) and for staff carrying out ACV initial assessments in 35% (n=33/93). Most respondents stated that staff should receive training for ACV assessment (n=86/93; 92%) and delivery (n=92/93; 99%).

Table 15 Contraindications included in contraindications lists

Contraindications	n (N=46)	%
Known upper airway patency issues	38	82.6
Issues at the tracheostomy stomal site (e.g., bleeding)	34	73.9
Altered upper airway	27	58.7
Low levels of alertness/too drowsy	24	52.2
Tracheostomy not in the optimal position	21	45.7
Requiring continuous subglottic suction	21	45.7
Unwell	19	41.3
<72 hours post tracheostomy insertion	18	39.1
Not attempting to mouth to communicate	14	30.4
Patients with a disorder of consciousness	12	26.1
<24 hours post-tracheostomy insertion	11	23.9
Tracheostomy tube not licensed for ACV use	10	21.7
Fluctuating levels of alertness	9	19.6
<48 hours post-tracheostomy insertion	9	17.4
Sepsis	8	17.4
Other	5	10.9
Tubes without subglottic port	1	2.2
Informal list based on National Tracheostomy Safety Project guidance	1	2.2
Cognitive status (e.g., attention and command following)	1	2.2
Surgical Emphysema	1	2.2
Specialty tubes (e.g., extended-length tracheostomy)	1	2.2
Inability to mouth clearly (e.g., dysarthria)	3	6.5
Don’t know	2	4.3
Surgical tracheostomy	0	0

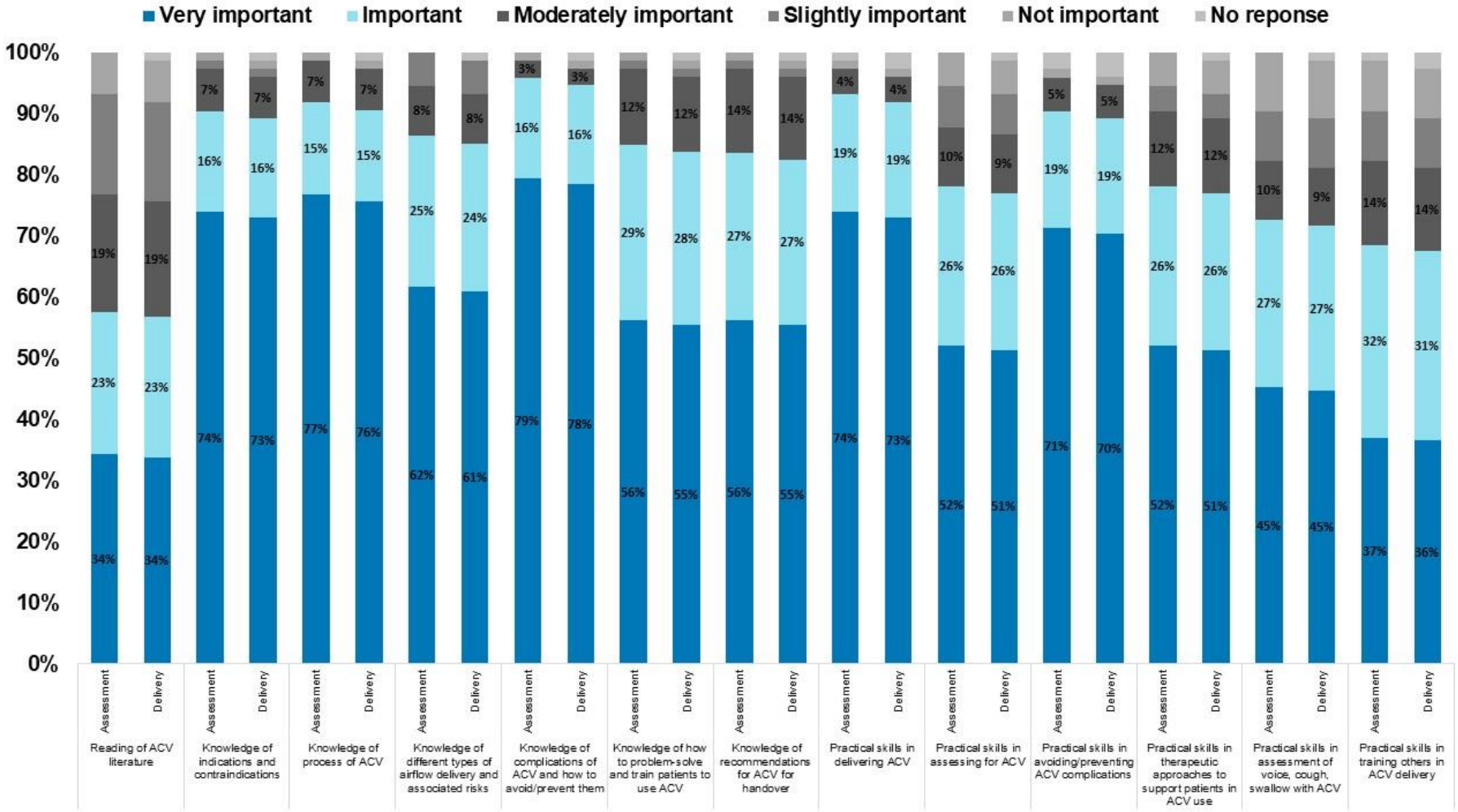

Figure 9 Importance of the inclusion of each element in competencies for staff assessing for and delivering ACV

There was a wide range of ACV implementation approaches (Table 16). The most common reasons given for not introducing ACV earlier included: patient alertness levels (n=32/93; 34%), lack of available staff to assess (n=29/93; 31%), and concerns regarding the risk of subcutaneous emphysema (n=25/93; 27%). Some of the 'other' reasons given included: lack of appropriate tracheostomy tube with a subglottic port (n=8/93; 9%), ACV considered a last resort (n=6/93; 6%), and early cuff deflation achieved (n=5/93; 5%). The main reasons for using non-humidified oxygen were: ease of access or availability (n=28/45; 62%) and no access to humidified oxygen for ACV (n=19/45; 42%). In contrast, the main reasons for using humidified oxygen for ACV were: reduced risk of drying of laryngeal mucosa (n=10/14; 71%) and improved comfort for patients (n=9/14; 64%). Some respondents reported there should be defined upper limits for flow rate (n=51/93; 55%), total time of ACV (n=26/93; 28%), and number of ACV episodes (n=13/93; 14%). However, there was no agreement about these optimal approaches (Table 17).

SLTs most commonly determine patient suitability for ACV assessment (n=64/93; 68%), followed by doctors (n=48/93; 51%), and PTs (n=30; 32%). Most services conduct assessments to verify that patients are safe and appropriate for further ACV sessions (n=70/93; 75%), and these are most commonly completed by SLTs (n=59/71; 83%), PTs (n=26/71; 37%), and doctors (n=18/71; 25%). Respondents stated the following groups are best placed to carry out ACV assessments: SLTs (n=88/93; 95%), PTs (n=46/93; 49%), nurses (n=32/93; 34%), doctors (n=29/93; 31%), and ACCPs (n=29/93; 31%). Various reasons were given for why certain professional groups were thought to be better placed to carry out these assessments. The most common skills or knowledge reported as essential for ACV assessment were: voice, speech and communication, upper airway anatomy and physiology, tracheostomy, and saliva management.

ACV is most commonly delivered by SLTs (n=56/93; 60%), PTs (n=18/93; 19%), and nurses (n=7/93; 8%). The typical time spent by staff delivering ACV with a patient over the course of the day is <15 minutes for 6% (n=6/93), 15-30 minutes for 25% (n=23/93), 31-60 minutes for 33% (n=31/93), 61-90 minutes for 12% (n=11/93), and >91 minutes for 3% (n=3/93). Nineteen percent of respondents (n=18/93) did not know how long staff spent daily delivering ACV. Family participation is limited; 49% (n=46/93) stated they never or rarely involved families, 17% (n=16/93) reported families were sometimes involved, and 13% (n=12/93) that families were very often or always involved.

Table 16 ACV implementation approaches

		N	%
Earliest introduction of ACV	0-24 hrs	3	3.2%
	25-48 hrs	10	10.8%
	49-72 hrs	14	15.1%
	>72 hrs	45	48.4%
	Don't know	21	22.6%
	Total number of responses (N)	**93**	
Typical timing of introduction of ACV	0-24 hrs	0	0%
	25-48 hrs	3	3.2%
	49-72 hrs	9	9.7%
	>72 hrs	55	59.1%
	Don't know	25	26.9%
	No response	1	1.1%
	Total number of responses (N)	**93**	
Type of air used	Humidified oxygen	14	15.1%
	Non-humidified oxygen	45	48.4%
	Medical air	25	26.9%
	Don't know	9	9.7%
	Total number of responses (N)	**93**	
Airflow delivery	Intermittent	28	30.1%
	Continuous	34	36.6%
	Both intermittent and continuous (with equal frequency)	3	3.2%
	Both intermittent and continuous (with intermittent used more frequently)	9	9.7%
	Both intermittent and continuous (with continuous used more frequently)	9	9.7%
	Don't know	10	10.8%
	Total number of responses (N)	**93**	
Upper airflow limit	2 L/min	1	1.1%
	3 L/min	3	3.2%
	5 L/min	30	32.3%
	6 L/min	11	11.8%
	7 L/min	2	2.2%
	8 L/min	13	14.0%
	9 L/min	1	1.1%
	10 L/min	10	10.8%
	15 L/min	4	4.3%
	No upper limit	4	4.3%
	Don't know	14	15.1%
	Total number of responses (N)	**93**	

		n	%
Upper limit of airflow duration per day	<15 mins	7	38.9%
	15-30 mins	3	16.7%
	31-60 mins	4	22.2%
	61-90 mins	0	0%
	91-120 mins	1	5.6%
	>120 mins	0	0%
	Don't know	2	11.1%
	No response	1	5.6%
	Total number of responses (N)	**18**	
Typical daily duration of airflow per day	<15 mins	27	29.0%
	15-30 mins	21	22.6%
	31-60 mins	9	9.7%
	61-90 mins	3	3.2%
	91-120 mins	2	2.2%
	>120 mins	4	4.3%
	Don't know	27	29.0%
	Total number of responses (N)	**93**	
Usual advice on the number of ACV episodes per day	No advice given	10	10.8%
	Hourly	1	1.1%
	1-2 times daily	8	8.6%
	3-4 times daily	14	15.1%
	5-6 times daily	1	1.1%
	>6 times daily	2	2.2%
	When requested by the patient	40	43.0%
	Whenever staff communicate with the patient	31	33.3%
	When relatives visit	34	36.6%
	Don't know	11	11.8%
	Other	16	17.2%
	Total number of responses (N)	**93**	
Typical number of days duration having ACV	≤1 day	1	1.1%
	2-5 days	19	20.4%
	6-7 days	4	4.3%
	1-4 weeks	13	14%
	>1 month	3	3.2%
	Ongoing (e.g. long-term tracheostomy)	18	19.4%
	Don't know	33	35.5%
	No response	2	2.2%
	Total number of responses (N)	**93**	

Table 17 Optimal approaches to ACV

		n	%
Optimal airflow delivery	Intermittent for a certain number of episodes each day	25	26.9%
	Intermittent with continual access during the day	21	22.6%
	Continuous for a certain number of episodes each day	4	4.3%
	Continuous applied throughout the day	1	1.1%
	Patient dependent	19	20.4%
	Don't know	23	24.7%
	Total number of responses (N)	**93**	
Optimal upper airflow limit	4 L/min	1	2.0%
	5 L/min	15	29.4%
	6 L/min	6	11.8%
	7 L/min	1	2.0%
	8 L/min	9	17.6%
	9 L/min	1	2.0%
	10 L/min	5	9.8%
	15 L/min	2	3.9%
	Don't know	11	21.6%
	Total number of responses (N)	**51**	
Optimal upper limit of airflow duration per day	<30 minutes per day	3	11.5%
	30-60 minutes per day	3	11.5%
	1-2 hours per day	3	11.5%
	3-4 hours per day	6	23.1%
	11-12 hours per day	1	3.8%
	Don't know	10	38.5%
	Total number of responses (N)	**26**	
Optimal upper limit of the number of ACV episodes per day	4 episodes	1	2.0%
	5 episodes	2	3.9%
	10 episodes	1	2.0%
	12 episodes	1	2.0%
	Don't know	8	15.7%
	Total number of responses (N)	**13**	

4.4.5 ACV safety

More than two-thirds of respondents stated they would stop treatment if observing: excessive coughing (n=72/93; 77%), lack of evidence of air passing through the upper airway (n=72/93; 77%), subcutaneous emphysema (n=76/93; 82%), or patient discomfort or pain (n=82/93; 88%). There was less agreement for the signs or symptoms which would result in discontinuing any further ACV trials, with the highest

being subcutaneous emphysema (n=58/93; 62%) and achieving cuff deflation (n=47/93; 51%).

Most respondents reported that ACV delivery and complications were recorded (n=90/93; 97%). Safety monitoring was most commonly conducted by SLTs (n=42/93; 45%), followed by nurses (n=12/93; 13%). Eighteen percent (n=17/93; 18%) did not know if any measures had been introduced to avoid or reduce the risk of complications. Of those with strategies in place, the top two were: only trained or competent staff delivering ACV (n=52/93; 56%) and all patients being assessed by a trained or competent assessor (n=51/93; 55%).

Respondents observed a wide variation of complications, with the most common being discomfort (n=54/93; 58%), strained vocal quality (n=39/93; 42%), air escape via stoma (n=32/93; 34%), and drying of the laryngeal mucosa (n=23/93; 25%). More serious complications were less common: 8% (n=7/93) reported 1-4 incidences of subcutaneous emphysema, 11% (n=10/93) reported 1-6 occurrences of air trapping, and 10% (n=9/93) reported 1-4 incidences of bleeding. A substantial proportion of respondents (n=27-29/93; 29-31%) did not know if patients had suffered any of these complications.

The frequency of the replacement of ACV airflow tubing and thumb ports was not known by 59% (n=55/93) and 65% (n=60/93), respectively (Figure 10).

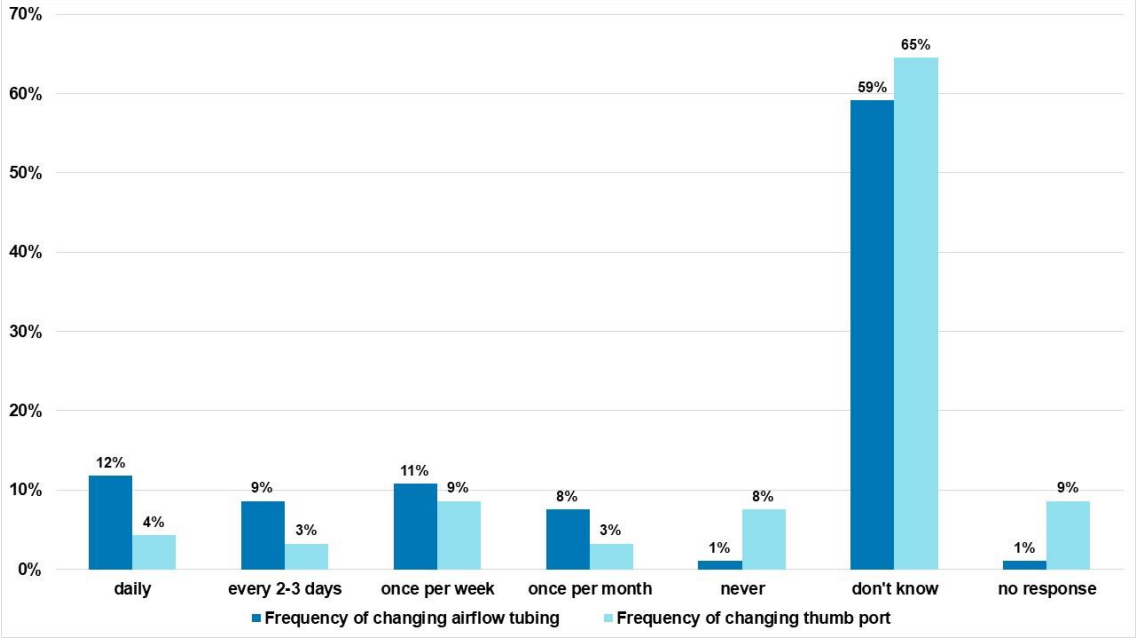

Figure 10 Frequency of changing of airflow tubing and thumb port

4.4.6 ACV benefits

Few respondents collected outcome measures to evaluate the effect of ACV (n=10/93; 11%), and there was considerable variation in outcomes used. Thirteen percent (n=12/93) often or always used FEES to monitor outcomes or safety, 49% (n=46/93) never or rarely used FEES, 26% (n=24/93) sometimes used FEES, and 12% (n=11/93) did not know. The top five perceived benefits reported were: improved communication (n=76/93; 82%); improved mood (n=62/93; 67%); improved laryngeal sensation (n=49/93; 53%); increased frequency of swallowing (n=43/93; 46%); and reduced volume of subglottic secretions (n=39; 42%). The extent of this perceived effectiveness is outlined in Figure 11.

There was a lack of clarity regarding which types of patients benefited most from ACV (Figure 12). Techniques used to improve the effectiveness or success of ACV included: adjusting the position/posture of the patient (n=58/93; 62%); an SLT training the patient (e.g., vocal exercises) (n=46/93; 49%); and manually adjusting the tracheostomy position (n=37/93; 40%).

4.4.7 Barriers to ACV use

Respondents reported a variety of barriers to ACV implementation (Figure 13). The most extreme barriers reported were: lack of access to staff with the knowledge to implement (n=92/238; 39%), lack of access to training (n=73/238; 31%), and not using tracheostomy tubes with subglottic ports (n=74/238; 31%).

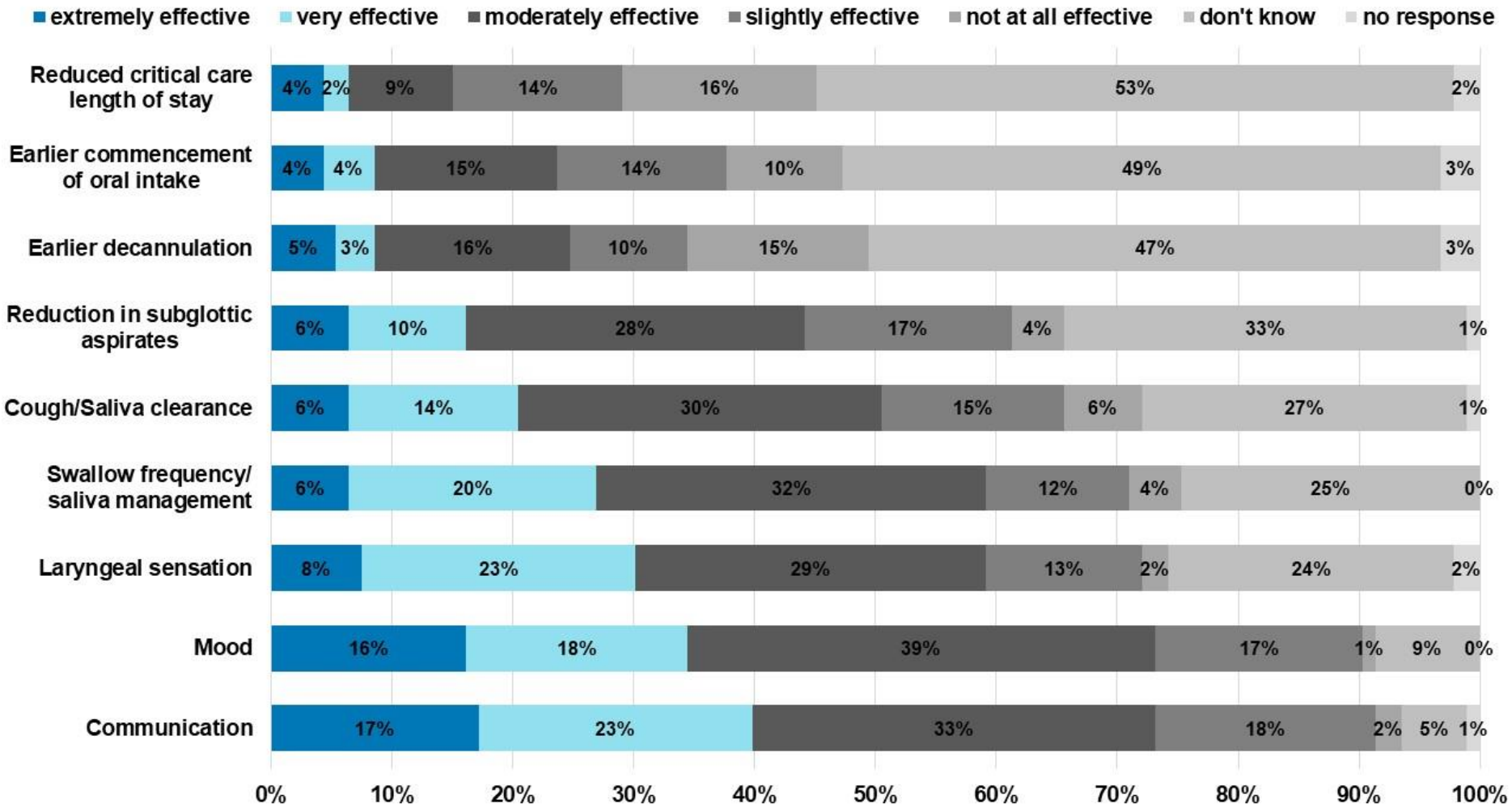

Figure 11 Perceived effectiveness of ACV for different domains

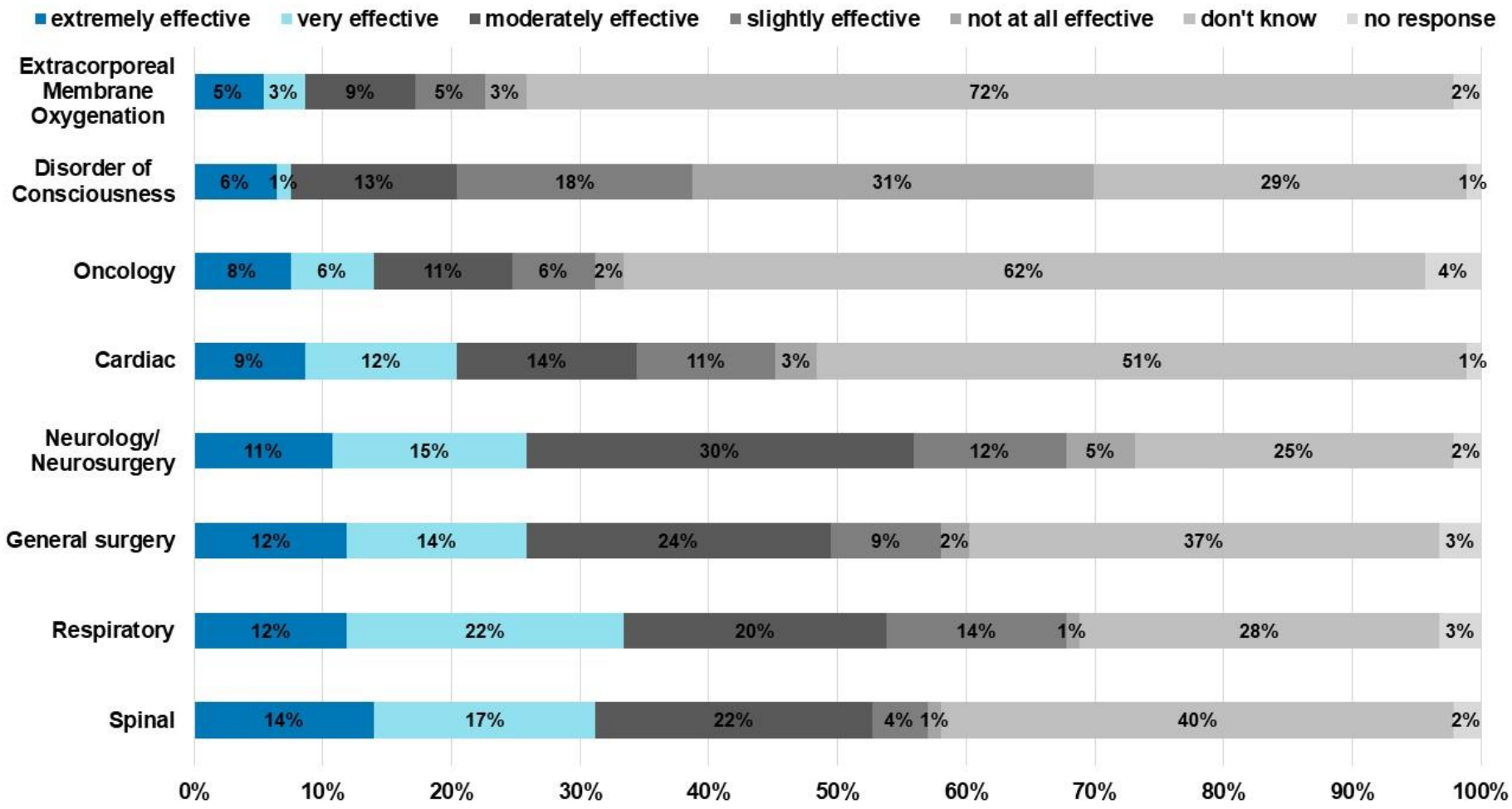

Figure 12 Perceived effectiveness of ACV in different patient groups (N=93)

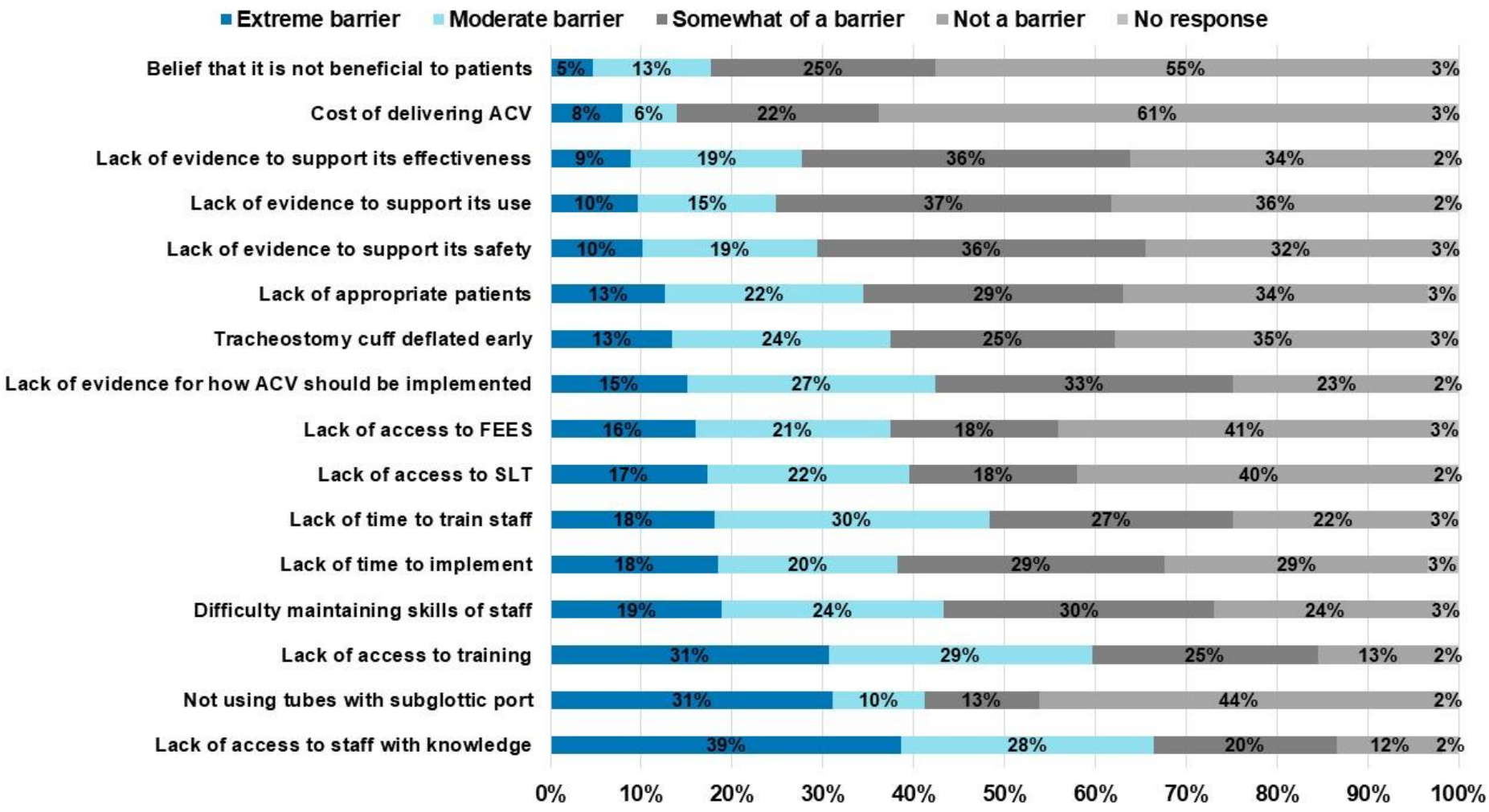

Figure 13 Barriers to ACV implementation

4.5 Discussion

This is the first study to report HCPs' opinions and experiences of ACV. Despite this technique being first reported in 1967 (Whitlock, 1967), many centres are still not using ACV. Those using ACV have limited experience in time and patient numbers compared to similar procedures, such as cuff deflation and an OWV. More than three-quarters of respondents stated their services had started using ACV in the past six years. A potential reason for this could be improved awareness brought about by the recent increase in research since 2014 (Pandian, Smith, et al., 2014; McGrath et al., 2016; Kothari et al., 2017; McGrath et al., 2019; Pandian et al., 2020). The results demonstrate huge variability in ACV implementation regarding safety processes and procedures, training, competencies, staff involvement, and the approach to assessment and delivery.

4.5.1 Tracheostomy management

The findings of this study support previous research demonstrating that tracheostomy management and weaning vary internationally and may even vary within hospitals (Pierson, 2005; Liu and Gropper, 2008; Mitchell et al., 2013; de Lima Zanata et al., 2014; Smith et al., 2014; Cohen et al., 2016; Welton et al., 2016). The variability in tracheostomy management may contribute to the variability in ACV use; centres practising early cuff deflation are less likely to observe benefits from an intervention generally delayed until 72 hours post-tracheostomy insertion. Furthermore, if tracheostomies with subglottic ports are not routinely used and a tracheostomy tube change is required, some centres may question the costs and benefits of ACV. Services caring for fewer numbers of patients with a tracheostomy may be less inclined to consider techniques such as ACV, given the training needs and potential burden to staff.

4.5.2 Availability of speech and language therapy services

The finding of limited access to speech and language therapy in some services is similar to that found by a recent international survey evaluating dysphagia management in ICUs; they reported that 66% of services had access to speech and language therapy, and just 4% had a dedicated speech and language therapy service (Spronk et al., 2022). This inconsistent access to speech and language therapy may contribute to the variability in ACV uptake and implementation approaches. Many respondents highlighted that SLTs are crucial team members in ACV implementation, involved in producing guidelines, training, delivering ACV, assessing patients for suitability, and monitoring safety. This aligns with the research literature which emphasises the importance of speech and language therapy involvement in ACV

introduction, for example, in providing daily rehabilitation to prevent complications such as strained or hoarse voice quality or air trapping (Leder and Traquina, 1989; Leder, 1990b; Pandian, Smith, et al., 2014; McGrath et al., 2016), and using FEES to ensure safety (Leder and Traquina, 1989; Pandian, Smith, et al., 2014). Over one-third of services had inconsistent speech and language therapy presence or access to FEES, which may impact the ability to safely, effectively and consistently introduce ACV. A large proportion of the day-to-day delivery of ACV appears to be supported by speech and language therapy, suggesting patients in some settings may receive ACV less frequently than needed. This is evidenced by more than half stating that the typical daily ACV duration is less than 30 minutes. The benefits received from such a short duration of therapy are unclear, particularly since communication is a function needed throughout the day.

4.5.3 Prevalence of ACV use and implementation

Less than half of respondents were using ACV, and use was limited, with most respondents using it with fewer than ten patients per month. There were limited use of documentation and contraindications lists, and less than one-fifth of respondents reported using staff competencies. However, up to half of respondents stated that staff training was in place. The limited uptake of ACV and the variability in approach to ACV implementation is predictable, given the scarcity of evidence supporting any one approach and the lack of national or international guidance (Mills, Michou, King, et al., 2022). Perhaps less predictable is the lack of agreement amongst respondents about their opinions on the optimal approaches for ACV. Several possible explanations exist for this finding, including limited experience, variability in tracheostomy weaning approaches, or variable caseloads or settings. SLTs were identified by most respondents, regardless of profession, as the professional group best placed to conduct ACV assessment due to their skills and knowledge in speech, voice, communication, swallowing, upper airway, and tracheostomy. SLTs were also the group most commonly involved in both the assessment and delivery of ACV. Therefore, the limited access to SLTs in some services may contribute to the restricted uptake of ACV and the variability in implementation approaches.

Respondents reported minimal involvement of family members in ACV delivery. Research has shown that families want to be part of the healthcare team in the ICU, with motivations including ‘wanting to help’ and ‘wanting the best’ for their relatives (Wong et al., 2020). Specifically, one study reported that 36% of family members wanted to be actively involved or have shared involvement in physical tasks in the ICU (Wong et al., 2021). Improving the involvement of family in the delivery of ACV might be one way to help ensure regular use and may help to compensate for any staffing issues. There are known benefits of family participation and patient- and family-centred

care. These can include improved patient experience, family satisfaction, the mental health status of patients and relatives, goal achievements, ICU LoS, and ICU costs (Goldfarb et al., 2017). Exploring the reasons for the lack of family involvement is essential, as safety concerns may contribute.

4.5.4 ACV safety

Safety monitoring was conducted in most services, and SLTs were most frequently involved. The most common approach to reducing risk to patients was to ensure that only trained or competent staff were involved with ACV. Many respondents observed minor complications, but more serious complications were observed infrequently. Given that the respondents are unlikely to have conducted all episodes of ACV in their service, it is likely that reports of complications are underestimated. Notably, bleeding was reported to occur more frequently than subcutaneous emphysema. This is the first study to identify bleeding as a potential risk of ACV. Research has shown that turbulent jets of air, or the application of airflow in a more constricted space, can increase the wall shear stress – the frictional stress applied to the airway surface – with the potential for epithelial cell damage of the airways (Nucci et al., 2003; Lin et al., 2007). Therefore, applying a turbulent airflow via the narrow subglottic port may lead to increased tracheal wall stress and the potential for epithelial cell damage and bleeding. This may have significance for patient selection for ACV, as potentially more cautious use is required in patients at higher risk of bleeding, e.g., individuals receiving Extracorporeal Membrane Oxygenation (ECMO). Bleeding will usually be identified around the tracheostomy stoma site or via the subglottic port, with the bleeding site likely to be internal and difficult to visualise. Further research is needed to determine whether ACV can cause bleeding or whether these reports of bleeding are incidental and unrelated to ACV. There is considerable variation in the frequency that airflow tubing and thumb ports were changed for infection control, and no guidance in the literature on this topic (Mills, Michou, King, et al., 2022). This is a potential hazard for patients and requires further investigation to provide evidence for recommendations for infection control and the safe use of ACV.

4.5.5 ACV benefits

This study demonstrates minimal use of outcome measures. This may be due to the inconsistent use of outcome measures in the ACV research and a heavy reliance on descriptive, subjective measures (Mills, Michou, King, et al., 2022). It may also result from the lack of consensus on core outcome measures for dysphagia or communication in critical care (Dinglas et al., 2020; Zaga, Cigognini, et al., 2020). The lack of use of FEES to monitor outcomes and safety is potentially related to many respondents having limited access to FEES and staffing issues. Many respondents

reported benefits for communication, mood, and certain aspects of swallowing. However, few stated that these improvements translated into functional gains, such as earlier commencement of oral intake, decannulation, or critical care step-down. The perceived effectiveness of ACV for different groups was highly variable, but ACV was believed to be slightly more effective with spinal and respiratory patients. The lack of objective outcome measures means the subjective reports of the benefits of ACV must be interpreted cautiously, as research has highlighted that clinicians more commonly overestimate the benefit of treatment (Hoffmann and Del Mar, 2017), particularly when outcomes are subjective (Wood et al., 2008). This highlights the need to develop specific core outcome sets appropriate for ACV. The potential benefits and the extent of the positive effects of ACV remain unclear, and more research in this area is needed. The reasons for this variability in perceived benefits are also uncertain but could include differences in ACV application, equipment used, staff experience, staff training, and patient groups. More explicit guidance for patient selection – and which patient groups are most likely to benefit – may improve ACV uptake and effectiveness. Similarly, a compilation of troubleshooting methods to facilitate improved ACV effectiveness would also benefit HCPs.

4.5.6 Barriers

There were many reported barriers to the successful implementation of ACV, the most important being staff proficiency and the ability to train staff. The development of internationally acceptable standardised training would be beneficial to promote more widespread and safe adoption of ACV. However, the wide variety of implementation approaches, combined with the lack of agreement on optimal approaches and the limited evidence base, indicates that achieving an expert consensus on a standardised ACV approach may be challenging. Further investigation of these themes with HCPs would be beneficial to explore whether consensus is possible and understand individuals' opinions of and experiences with ACV in more depth.

4.5.7 Study strengths and limitations

The survey development and piloting were thorough, dissemination was widespread, and a satisfactory number of responses were received. A high survey completion rate (98%) indicates that the survey was acceptable to participants. Although the participation rate was low (9%), this measured those individuals visiting the initial survey page. The survey was disseminated widely on social media but was not designed to be completed using a mobile telephone. The low participation rate is potentially due to people clicking on the survey link on mobile devices to ascertain relevance before completing later on a computer.

There appears to be a sample bias, with responses predominately from the UK. Various potential reasons include more support for distributing the survey from societies and networks within the UK, varying terminology between countries, and varying usage and interest in the intervention between countries. Additionally, the survey was conducted in English, which may have limited responses from non-English speaking countries, or made it more difficult for accurate completion. Some of the networks contacted to request dissemination of the survey did not respond; others would only distribute surveys of members or had a rule to refrain from disseminating surveys. More than half of the respondents were SLTs, which may be reflected in the current findings. A greater number of responses from SLTs were expected, given that the benefits of ACV are predominantly for communication and swallowing, which are the specialist fields of SLTs. Differences in roles between countries can account for the limited response from some professional groups; for example, OTs in Denmark are involved in dysphagia and tracheostomy management. There was a lack of agreement for most of the questions regarding implementation, both between and within professional groups.

Certain questions were excluded to make the survey an acceptable length for participants. A question on the brand of tracheostomy tubes used for ACV was not included. This information would have been helpful to ascertain if there were differences in opinions related to variations in the features and mechanics of the tubes and whether individuals perceive specific tubes to be more effective for ACV than others.

4.5.8 Implications for clinicians and researchers

This survey confirms the finding of the systematic review (Chapter 3) that adverse events and complications can occur and that a cautious approach may be needed. For the first time, bleeding has been identified as a possible complication, and clinicians and researchers need to monitor and record bleeding incidence. Extra caution may also be needed when using ACV with patients at high risk of bleeding. The survey also supports the systematic review findings that an SLT, or voice specialist, involvement in ACV assessment and delivery is critical for reducing the risk of complications. The implementation of guidelines and competencies, with an education programme, may also help to improve the safety and effectiveness of ACV.

Most respondents reported benefits for communication, swallowing, and mood. However, opinions on optimal patient groups and the effectiveness of ACV were variable. The cause of this variability is unknown, and further research in this area is needed to maximise the benefits and ensure that positive effects can be achieved consistently.

Like the systematic review, the survey also identified issues with outcome measures, with minimal and inconsistent use. Clinicians and researchers must use validated outcomes consistently; developing a core outcome set for dysphagia and communication in the critical care population may facilitate this (Zaga, Cigognini, et al., 2020; Duncan et al., 2023).

Staff proficiency and training were identified as critical barriers to successfully implementing and using ACV. The development of standardised, international training resources might help increase ACV uptake and maximise safe practice. Future research should focus on exploring the potential benefits and feasibility of family involvement in ACV; exploring HCPs' opinions of ACV; exploring the potential to reach a consensus on an optimal approach to ACV delivery and implementation; evaluating the risk of bleeding from ACV; investigating optimal infection control processes for ACV; determining optimal patient groups for ACV; exploring the impact of different brands of tracheostomy tube on the effectiveness of ACV; and evaluating the cost-effectiveness of ACV.

4.6 Summary

This online survey successfully investigated the current ACV and tracheostomy weaning practices in the UK and internationally. There is no standardised approach to delivering ACV, and there is variability in implementation approaches and uptake. The disparity in tracheostomy management may also contribute to the extent of this variation. The limited access to speech and language therapy staff reported by many respondents may further compound these issues and impact the frequency of use and uptake. These results suggest that a consensus on an optimal or standardised approach to ACV delivery is needed. This chapter has reported on the first research exploring HCPs opinions and views of ACV. Chapter 5 explores these opinions in more depth and reports on interviews with HCPs about their experiences and perceptions of best practice for ACV.

Chapter 5 Worth a try or a last resort: Healthcare professionals' experiences and opinions of Above Cuff Vocalisation

This chapter explores HCPs' experiences and opinions of ACV and their perceptions of the impact of COVID-19 on the intervention through individual interviews. Section 5.1 outlines the rationale and background for this study. Section 5.2 reports the study objectives and research questions, and Section 5.3 describes the methods. The study findings are presented in Section 5.4 and discussed in Section 5.5. Section 5.6 summarises the chapter.

5.1 Introduction

Chapter 4 presented the findings of an international online survey. This study highlighted the limited uptake and lack of a standardised approach to the implementation and use of ACV. Many respondents reported various benefits of ACV, but there was variability in the perceived degree of benefit and variations in ACV implementation and practice. Chapter 3 documented the systematic review findings, revealing limited and low-level evidence available for using ACV in patients with a tracheostomy. It also emphasised the variability in application evident in the literature. The lack of supporting evidence for ACV and the variation in application approaches is probably contributing to the clinical variations in practice observed in the survey. The study aimed to explore HCPs' experiences and opinions of ACV. It was undertaken during the COVID-19 pandemic when restrictions on the use of ACV were being advised in the UK and many other countries due to potential transmission risk. For this reason, additional questions were added to explore the impact of the pandemic on ACV use.

5.2 Study objectives and research questions

This study explored the following thesis objectives:

- Objective 4: To explore the opinions of HCPs regarding the use of ACV using one-to-one online interviews.
- Objective 5: To describe the impact of COVID-19 on ACV use via HCP interviews.

The research questions for this study were:

- How do the experiences of HCPs with ACV impact their opinions of ACV?
- How do HCPs' opinions of ACV influence their use of ACV?
- Why do HCPs have particular opinions about ACV?
- Why do HCPs think ACV should be used or implemented in certain ways?
- How has COVID-19 impacted ACV use?

5.3 Methods

5.3.1 Research design

This study employed a qualitative interview design.

5.3.2 Ethical considerations

Ethical approval was obtained from the School of Medicine Research Ethics Committee at the University of Leeds (05/02/2019/MREC 18-037). Ethical considerations for this research included ethical research conduct and ethical participant representation. Ethical research conduct included ensuring that participants were fully informed of the purpose of the study and how data would be used. Participants were provided with a participant information sheet and given the opportunity to ask any questions before the interview. They were also informed of the potential risks with the research and their right to withdraw, thus ensuring that informed consent was obtained for all participants (Elliott et al., 1999). Ethical research conduct also involved ensuring that the research was conducted sensitively, particularly when discussing upsetting incidents and experiences. Participants were given the time they needed and the option to pause or stop the interview. The privacy and confidentiality of participants were maintained at all times, and quotes from participants were de-identified (Tolich and Tumilty, 2020). There were no incentives for participating in an interview.

Ethical participant representation was important during data analysis and report writing. Honouring participants' experiences and opinions was essential to ensure they were represented accurately, honestly, and fairly in the research analysis and outputs (Braun and Clarke, 2013). Part of this included the candidate reflecting on their position and opinions and how this might have influenced the interpretation of the data and the potential consequences of that interpretation (Clarke and Braun, 2021). The analysis was performed with integrity and endeavoured to ensure that in representing participants, no harm was caused to them or the professional groups to which they belonged.

The interviews were conducted with HCPs working in critical care during the COVID-19 pandemic, many of whom were under considerable pressure and stress. For this reason, to ensure participant safety, interviews were paused during the height of COVID-19 'waves' when pressures were heightened. It also resulted in greater flexibility in the timing and duration of interviews. Participants and potential participants were also only sent one follow-up email if there was a lack of response to communication.

5.3.3 Participants

Target participants were HCPs with direct experience in the assessment or delivery of ACV. Participants with various backgrounds and experiences were sought, specifically from a range of countries, with differing experience levels, from different professional groups, and with experience with different patient groups. Participants were recruited in three ways: 1) respondents from the international online survey (Chapter 4) who stated they would be interested in participating in an interview, 2) critical care networks, and 3) an advertisement on social media.

5.3.4 Sampling

Purposive sampling was employed, a type of sampling where participants are intentionally selected based on specific characteristics, to facilitate the inclusion of a range of participants who could provide detailed information about their experiences and opinions of ACV (Bhardwaj, 2019). Interview criteria were created to ensure the inclusion of a range of participants. The primary criterion was that participants had to have direct experience with ACV. Following this, various factors were prioritised to maximise the range of participants. These factors were prioritised in the following order: patient population, professional group, country, and experience level. The aim was to ensure representation for each patient group: disorders of consciousness, general medical, respiratory, neurology and spinal, cardiac, and long-term tracheostomy. A minimum of one participant of each of the following professional groups was sought: advanced critical care practitioner (ACCP), doctor, nurse, occupational therapist (OT), physiotherapist (PT), respiratory therapist (RT), SLT, and tracheostomy nurse specialist. The aim was for one participant from each of the following countries: the USA, the UK, Australia, Ireland, two mainland European countries, and one other country. Level of experience was divided into three categories with the aim for at least two participants from each category: < 1 year, 1-5 years, and >5 years.

Initially, the 34 survey respondents who had experience with ACV and stated that they were willing to participate in interviews were reviewed according to these criteria and were grouped into tiers of priority for interview. As 17 of the respondents were from the UK, and a large proportion were SLTs, it was not possible to use all volunteers from the survey respondents. Another limiting factor was emails bouncing and non-response by some volunteers. Therefore, recruitment expanded using critical care networks and social media, employing the same criteria. Targeted advertising of these groups was employed when it was impossible to meet the criteria; for example, when recruiting specific professional groups was challenging. Where this was unsuccessful, the available and consenting participants were interviewed.

Unlike sample size decisions for quantitative research and so-called ‘small q’ qualitative research, sample size decisions for reflexive thematic analysis should be based on the richness and depth of the data (Clarke and Braun, 2021). Data saturation, where no additional codes or themes are found, and there is redundancy in the data, is sometimes proposed as a sample size approach for qualitative research. However, increasingly qualitative researchers are moving away from data saturation, which focuses on the number of participants, to focus on the dataset itself and ensuring that it has sufficient depth and breadth to allow for a comprehensive analysis (LaDonna et al., 2021). In particular, data saturation is not appropriate for reflexive thematic analysis because the codes and themes are developed by the researcher and not found in the data (Braun and Clarke, 2021b). Therefore, data saturation and redundancy may never be achieved because new meanings and interpretations of the data are always possible (Clarke and Braun, 2021). Thus, the sample size was determined based on ongoing and iterative analysis of the data and pragmatic decisions about the richness and depth of the dataset and its sufficiency to allow the research questions to be answered (O’Reilly and Parker, 2013; Braun and Clarke, 2021b).

5.3.5 Participant recruitment

Participants meeting the sampling criteria, who had stated they were interested in participating, were emailed a participation information sheet and a consent form. Participants who consented were invited to an online interview at their chosen time.

5.3.6 Data generation

5.3.6.1 Topic guide development

The topic guide (Appendix D) was developed from the information gathered from the systematic review of the literature (Chapter 3) and the international survey (Chapter 4) (Mills, Michou, King, et al., 2022; Mills, Michou, Bellamy, et al., 2022). Topics included: experiences with ACV, management of ACV, opinions about ACV, the impact of COVID-19, and future directions for ACV. Other topics, such as the effect of ACV on LoS, were also included, where the information gathered might prove useful for the early-stage health economic decision-analytic model (DAM) (Chapter 6). The topic guide was piloted with four participants; minor revisions were made after each interview. These revisions included the addition of additional topics such as laryngeal mucosal drying, LoS, and the future of ACV.

5.3.6.2 Interview procedure

Individual interviews were conducted, rather than the focus groups originally planned, because of feedback from the research patient, carer, and public involvement (PCPI)

group. The original focus groups had been planned for health care professionals and separate groups for patients and relatives. The PCPI group expressed concerns that patients would want to talk about their ICU experiences, which are often distressing, as part of a group. They also felt that it was essential to speak to patients while they were in the ICU with memories of ACV fresh in their minds. Despite the COVID-19 pandemic resulting in the abandonment of plans to interview patients and relatives, it was still felt best to continue with the intent to conduct individual interviews for two reasons. Firstly, the dataset could be combined for further analysis if it is possible to conduct patient and relative interviews in the future. Secondly, given the evidence for ACV to date with the variation in approach, it was crucial to gain individual experiences and opinions rather than group discussions where participants might feel constrained in the debate by other individuals' beliefs.

The candidate underwent focus group training in preparation for conducting the planned focus groups, but much of the training received was directly applicable and transferrable to individual interviews. Interviews were semi-structured using the topic guide. Adherence to the topic guide was pragmatic, with the focus of questions adapting and deviating from the guide according to the responses and priorities of the participant to focus on what was meaningful to them. The interviews were conducted on Microsoft Teams or Zoom. Interviews were audio recorded and, subsequently, transcribed. Interviews were conducted over 16 months, from December 2020 to March 2022. During the interview, all participants consented to further email contact for any additional information. An email was subsequently sent to a selection of participants to request additional background information on the brand of tracheostomy tubes used for ACV, the type of airflow used, and the method of airflow delivery. This information was elicited as it became apparent during data analysis that it might be pertinent to the experiences and opinions of the participants.

5.3.7 Good research conduct

Good clinical practice was adhered to throughout the planning, conduct, and analysis of this research. The candidate endeavoured to conduct and report the research openly, transparently, honestly, and with integrity. This included ensuring reflexivity and consideration of the position and experiences of the researcher and how this impacted the conduct of research and the interpretation of the findings. The study was conducted rigorously to ensure the reliability of the research. The candidate treated the research participants with care and respect to ensure their safety and well-being.

5.3.8 Data analysis and reporting

Interviews were transcribed orthographically and included indications of non-verbal communication, hesitations, repetitions, pauses, and overlapping speech. All

transcripts were checked and verified by the candidate. The data were analysed using a reflexive thematic analysis, using the six-phase process outlined by Braun and Clarke (Braun and Clarke, 2006). These six phases included: 1) data familiarisation, 2) initial code generation, 3) generating themes, 4) reviewing potential themes, 5) defining and naming themes, and 6) producing the report (Braun and Clarke, 2006; Braun and Clarke, 2012). This was not a strictly linear process, and the six phases were used iteratively throughout the analysis and report-writing process. This type of analysis accepts and embraces the influence of the researcher's experience and position on a particular topic on their analysis of the data (Braun and Clarke, 2019). Reflexive thematic analysis is, therefore, considered a subjective approach that incorporates the view and position of the researcher, the data, and the broader context of the research (Braun and Clarke, 2021a). The meaning and meaningfulness of participants' experiences and opinions of ACV are central to the analysis (Byrne, 2022).

For good practice and to aid analysis, the candidate kept a research journal throughout the study. Interview transcripts were scrutinised, which involved listening to the audio recordings, reading the transcripts multiple times and making observations in a research journal about the participants' experiences concerning the research questions (Phase 1) (Ryan and Bernard, 2003). Data relevant to the research questions were coded inductively using descriptive and latent codes (Phase 2). Codes were continually reviewed, merging and refining codes where necessary as the analysis proceeded (Phases 2, 3, 4, and 5). Similar codes were grouped into themes (Phase 3), which are a pattern of shared meaning that is underpinned by a central concept, to facilitate the development of a unified data story (Clarke and Braun, 2021). The candidate developed and refined the key themes, with wider consultation with the research team (Phases 4 and 5). Themes were designated as key, dependent on a combination of different factors, including the frequency of occurrence and the importance of the information they captured about the research questions (Ryan and Bernard, 2003; Braun and Clarke, 2006). This facilitated careful consideration of how the candidate's viewpoint and experiences influenced and shaped the data analysis and interpretation (Holloway and Todres, 2003). The final stage of the analysis process was writing the report, which involved integrating the themes into a comprehensive and coherent data story and incorporating these reflexive considerations (Phase 6).

NVivo ® version 1.6.1 (QSR International) was used to manage the data and support analysis. The extracts included in the results have been edited to omit hesitations and repetitions. Sections of irrelevant text have also been edited (indicated with […]). These edits have not altered the meaning of the quotes. Explanatory statements have also been inserted with square brackets. Data is reported according to the consolidated criteria for reporting qualitative studies (COREQ) (Tong et al., 2007).

5.4 Results

Twenty-four HCPs were interviewed about their experiences and opinions of ACV. Data generation ceased after the 24th participant; at this point, a relatively diverse group of participants had been recruited, and the dataset was rich enough to facilitate reflexive thematic analysis (Braun and Clarke, 2021b). Participants were from seven countries and five professional groups (Table 18). Participants used ACV with a range of patient populations and with varying application approaches (Table 19). The purposive sampling criteria were partially met (Table 20). Interviews ranged from 17 to 61 minutes (mean: 35 minutes).

Table 18 Sample characteristics (N = 24)

Professional group	Speech and Language Therapist (SLT) (13), Physiotherapist (PT) (8), Advanced Critical Care Practitioner (ACCP) (1), Nurse/Tracheostomy Specialist Nurse (1), Occupational Therapist (OT) (1)
Country	UK (12), Australia (5), Norway (2), USA (2), Denmark (1), Greece (1), Ireland (1)
Gender	Female (20) Male (4)
Number of years practising clinically	Median: 19.5 years Range: 8 – 30 years
Number of years using ACV	Mean: 5 years Range: 0.5 – 16 years

Table 19 ACV approach of participants (N = 24)

Patient population	The majority of participants used ACV in the ICU population. Some participants also used ACV in other patient populations, e.g., neurology, neurosurgery, respiratory, spinal, cardiothoracic, long-term/home ventilation and weaning, stroke, medical, post-surgical, and general acute. Two participants only used ACV with the non-ICU population.
Brand of tracheostomy tube used for ACV	Portex® Blue Line Ultra® Suctionaid (15), TRACOE® twist (3), Portex® Blue Line Ultra® Suctionaid and TRACOE® twist (5), Shiley Evac (1)
Type of airflow used	Oxygen (8), oxygen or humidified oxygen (1), medical air (4), oxygen or medical air (7), humidified medical air (2), unknown (2)
Method of airflow delivery	Intermittent using a thumb port (14), using a thumb port but holding the port closed continuously (1), continuous (6), both continuous and intermittent but predominantly intermittent (1), both but predominantly continuous (2)

Table 20 Purposive sampling criteria

Patient groups included: disorders of consciousness, general medical, respiratory, neurology and spinal, cardiac, long-term tracheostomy	Criteria achieved
Professional groups included: advanced critical care practitioner (ACCP), doctor, nurse, occupational therapist (OT), physiotherapist (PT), respiratory therapist (RT), speech and language therapist (SLT), and tracheostomy nurse specialist.	At least one representative of each professional group, except doctors and respiratory therapists.
Countries included: USA, UK, Australia, Ireland, two mainland European countries, one other country	At least one representative from each target country, except 'other'.
Number of years' experience in using ACV included: <1 year, 1-5 years, >5 years	At least two representatives for each category, except '<1 year', where there was only one representative.

Five interconnected themes were developed from the reflexive thematic analysis of the data, with three sub-themes related to the fourth theme (Figure 14). The five interconnected themes were:

Theme 1: Moral distress amplifying the need to fix patients

Theme 2: Uncertainty and subjectivity leading to variations in practice and purpose

Theme 3: Knowledge and experience leading to control and caution

Theme 4: Worth a try or a last resort

Theme 5: Limited consideration of COVID-19 or starting from scratch

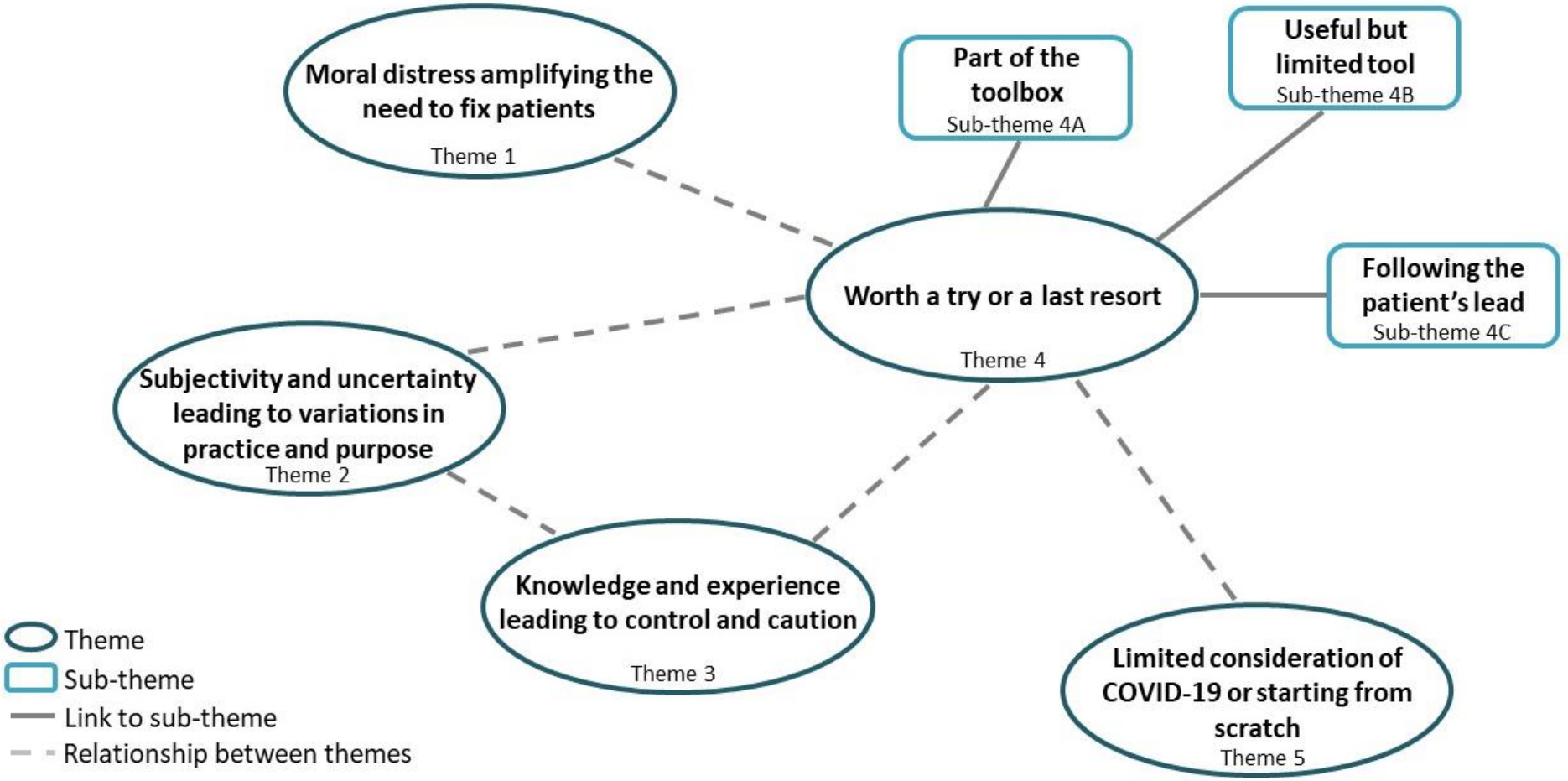

Figure 14 Thematic map illustrating the relationships between themes and sub-themes

5.4.1 Theme 1: Moral distress amplifying the need to fix patients

In this study, some participants described their experiences of moral distress. Moral distress is the psychological unease experienced by HCPs when they cannot provide patients with appropriate care because of factors outside of their control. The moral distress experienced by participants appears to have amplified their underlying feeling of needing to fix their patients:

> "…it's so hard because you're just like: "I wish I had a fix. […] I feel…like I've let patients down a lot, but not through any fault of not trying […] I hate feeling like we can't make a difference purely because we don't have a magic wand sometimes." [SLT 7]

There are various drivers for the need to fix patients; some of these are intrinsic to the HCP. Some participants described feeling helpless in their efforts for patients, with a willingness to try anything rather than feeling like they are doing nothing:

> "So what can we do? That's mostly the feeling 'what can we do?' and using the ACV well, then we try to do something…it might not help all patients, but we try and do something." [OT 1]

Most participants wanted to use ACV with patients. However, a variety of barriers exist. One of the barriers is issues around potential side-effects. Many participants expressed concern about the potential risk of laryngeal mucosal drying and described their approach to limiting the frequency and duration of ACV to minimise this risk. When ACV was successful for communication, some participants felt responsible and guilty for restricting the patient's access to ACV because of these laryngeal drying concerns. These participants appeared distressed over denying patients unrestricted opportunities to verbalise using ACV. This seems to lead to HCPs being more persistent in their desire to provide ACV and contribute to improving the patient's QoL.

Participants reported various structural or process barriers to the use of ACV, which, in some circumstances, led to moral distress. For example, one participant stated that many hospitals in the USA do not accept patients with a subglottic tracheostomy tube. This meant that before transfer to another hospital, most patients using ACV require a tracheostomy tube change, which results in them losing their means of communication. This leads to deep levels of frustration and distress for staff, but a determination to change processes to improve things for patients:

> "…so we have to be like strategic as to like when we place it [consider the likelihood of patient transfer when deciding whether to insert a subglottic tube]. And sometimes they make us like take it [subglottic tube] out! Which is […] it's cruel and horrible and I think just stupid. But that's, you know, we're trying to deal with that." [SLT 5]

Some pressures to fix patients come from extrinsic rather than intrinsic sources. Managers may pressure staff to progress patients, by any means, because of bed or cost pressures. This can lead to altered approaches to ACV application as it is viewed as a potential method to progress patients. Another extrinsic pressure can be the patients themselves; patient behaviours and desires can have a marked impact on the behaviour of HCPs and may augment this need to fix. In the example below, the patient is so desperate to speak it influences one HCP's urgency to use ACV, whilst the participant demonstrates aspects of moral distress with feelings of guilt over the provision of an inadequate service:

> "And I work with people who really want to give it a go now because their patients are dying to speak and I work with people, and probably my own practice is, [sigh] actually if in a couple of days we're gonna get this cuff down this is quite a big time commitment for us to go and do this and supporting the nurse to do it […] So then I feel like maybe we don't need to do this now. But then I also feel a bit bad about that as well...sometimes. I think if we were better resourced, we'd have a different take on it for sure." [SLT 1]

This quote also highlights the uncertainty and doubt over ACV's benefits relative to the time and effort required from staff. Most participants highlighted staffing issues, high turnover of staff, and over-stretched staff as major factors in limiting ACV use. The moral distress caused by the resultant inadequate service provision due to poor staffing is illustrated here:

> "I think it's unfortunate we don't have the capacity here to do it as much for rehab. That infrequency of it for a person. And I think they then get…denied the opportunity to possibly get to the point of decannulation. […] there are things out of my control cos I'm not in a senior position and our staffing is quite grim here!" [SLT 6]

These staffing issues can also create a potential burden for specific staff members or professional groups. Many participants expressed protective instincts and not wanting to pass this burden on to nursing or junior staff:

> "I think resource is difficult. And it's unfair to ask the nurses to do it because they're so busy. And they've got so many other things that they need to do with the patient. […] So yes, it's probably staff resource is the most difficult thing." [PT 4]

This burden, which seems to primarily fall on physiotherapy staff, who often seem to have to compensate for the lack of speech and language therapy staff, appears to affect other aspects of their work adversely or leads to the deprioritisation of ACV in some circumstances. This appears to lead to feelings of guilt:

> "...But from all the other things I have to do as a physio on ICU, that is probably, comes a bit down the list, down the priority ladder, I guess…which may be right or wrong? But I need a speech and language therapist!" [PT 5]

Despite the staffing issues and the burden placed on HCPs, the need to fix often wins out and potentially results in staff becoming even more over-stretched and over-burdened:

> "I sometimes think: "Oh. For the effort that I'm putting in maybe using it for a week?...Yeah. I'm like: Nah." But I think, in the end, often it's just they're just so desperate that anyone is really willing to try anything so – and if there is some success with it, it's like: "Oh great! Let's keep going."" [SLT 8]

It is important to note that at the other extreme of moral distress, positive experiences with ACV can also influence the need to fix patients, with one positive experience of using ACV incentivising the team to implement ACV more widely:

> "…when we put the air in, they both communicated. They both cried. They both shared their end-of-life wishes. And that really touched both of our hearts because we stood there and we observed what happened in front of us. And the next day, the patient passed away. But there was so much closure for his life partner, that he had that opportunity to speak. […] But then there were three other instances where we had to do something to help with communication. So, we trialled it." [Nurse 1]

These complex factors and the need to fix patients, and make a difference in their ability to communicate, can result in feelings of obligation to use ACV:

> "So, I think that we have an obligation to offer this for patients who do have the ability to use it as a communication." [OT 1]

5.4.2 Theme 2: Subjectivity and uncertainty leading to variations in practice and purpose

Participants reported subjectivity in various aspects of ACV, including implementation, application, and effectiveness. Some participants also recognised that their opinions of ACV were subjective and formed from their experiences rather than data or evidence. Training of staff and the use of competencies for ACV reported by staff also appear to be largely informal and subjective. In addition to the reported subjectivity surrounding ACV, participants stated there is considerable uncertainty about various aspects of ACV, including application, risks and harms, effectiveness, impact on the LoS, and the need for FEES. The subjectivity and uncertainty encompassing ACV appear to contribute to the wide variations in ACV implementation and application in clinical practice reported by participants and variations in the purpose for which ACV is used.

Participants recognised that their opinions of ACV tended to be based on their experiences and subjective observations of its effectiveness when used with patients. These observations seemed to vary widely between professionals and were dependent on their level of experience, knowledge, and patient group:

> "Like, I can say I did this, and it was brilliant but…the only thing that I kind of was looking at was…kind of subglottic load. […] and it's really tricky with anything, tracheostomy related, you know even the kind of saliva scales. They're not…they're very subjective aren't they? You know what I think is a lot after 10 years would be different to what like a new band 5 thinks is a lot!" [PT 1]

Participants stated that the application of ACV is subjective because of the variability in how patients respond to and cope with ACV, both within sessions and from day to day. One participant suggested that this subjectivity was more difficult for less experienced staff to manage, as it was impossible to follow a protocol. For this reason, many participants reported restricting the involvement in ACV to certain members of staff to maintain safety for patients and staff:

> "And because it's quite subjective…you know you can't say oh she's going to be absolutely fine for those 10 minutes, 5 minutes, because you don't know how fatigued she was from the day before and stuff. So, it's not just as simple as…you can't follow a protocol as such and go oh we're going to do it for this. […] and that's where we felt that the staff with […] their registration, they've got that bit of extra knowledge. They'd be in a better position to make that call. Although, you know, just from a safety perspective, and just also then not to put too much of a burden on our support staff." [PT 7]

Few participants seemed to use a standard competency framework for ACV, but many spoke of competencies in a subjective way using terms like 'feeling competent' and 'feeling comfortable':

> "…and then it'll be us handing over to nurses. And if a nurse has had that one-to-one demonstration and is feeling competent with how it works, then they can trial it." [SLT 2]

Some participants reported that competencies did exist but that staff were signed off as competent to use ACV purely based on theoretical knowledge because of the limited use of ACV in their setting:

> "…more often than not be deeming someone competent in all other areas of the competency and sort of have ACV as like a 'not-observed'. But, you know make sure that the person is familiar with the theoretical aspects […] if we were to…hold-off on deeming someone competent in management then you know

there'd be a lot of people who wouldn't be competent because they haven't actually seen ACV routinely." [SLT 13]

As there is little consensus on application approaches for ACV, participants reported uncertainty around factors such as patient selection, the timing of use, frequency of use, and airflow rates. This appeared to lead to a highly variable approach reliant on individual clinical judgement:

> "When I did that presentation for the ODN [Operational Delivery Network] there was a few people on there and they're saying you know we use like 10 or 15 litres and then there's loads of hands going up! And I was like "Oh no, no! I'm not sure. We don't do that though!" I think that might be a bit much, but I don't know again if there's any…strict guidance on that…" [PT 1]

Much ACV research highlights the potential risk of laryngeal drying due to the airflow. However, there is a lack of guidance regarding what rate and duration of airflow are safe for patients. Many participants expressed their uncertainty on this topic, and some stated that arbitrary numbers were selected for frequency and duration of use, and these varied substantially between participants. Despite the uncertainty regarding application, some centres have developed standardised approaches to delivery. For some, this uncertainty about how to best put ACV into practice resulted in the decision to try to consider ACV for all patients with a tracheostomy.

Some participants highlighted the growing evidence base but stated that there is ongoing uncertainty about the potential risks and harms of ACV. This uncertainty seemed to influence how some participants applied ACV in their practice. Some participants expressed uncertainty about when and how to use ACV; this could be making them anxious about undertaking ACV with certain patients:

> "…when you go to do it, there's always, with that excitement, there's also that little piece of anxiety of…you know "have we covered all the bases here? Are we making sure that we have no contra-indications here? Is this safe for the patient?"" [SLT 9]

Along with the lack of certainty about the application of ACV amongst participants, there was uncertainty about the effectiveness of ACV and whether positive effects are a result of ACV, spontaneous improvement, or something else:

> "Because that person also might improve their swallow because they might bump up their neurology a little bit and they might have just started swallowing anyway." [SLT 6]

There is an interplay of uncertainty and subjectivity; uncertainty exists about the application and the effectiveness of ACV because of the subjectivity and limited objective methods to measure change:

> “Does it work, or does it not work? Because of course I have patients where I use it, but I can't see changes from day to day. But it's difficult to set up a study because it's difficult to measure the sensitisation in the pharynx. Does it change when you give the ACV? Does it change for a short while or for longer terms?” [OT 1]

The uncertainty over the effectiveness of ACV means that some participants reported difficulty knowing whether to persist with the intervention or give up when there is no immediate, tangible or functional benefit for communication:

> “And is this…this is obviously maybe not really beneficial from a communicative perspective for them, but they might be enjoying it, because they are now verbal where they haven't been before. But also, as you might be thinking there are other benefits here in terms of upper airflow stimulation, so should we just keep going with it?” [SLT 1]

This lack of certainty about the effect – combined with the lack of tangible benefit – was also reported to lead to the deprioritisation of ACV by nursing staff. Nonetheless, some participants held a strong belief that ACV must work, even if they did not see that objectively for themselves, and that they needed to keep persevering or adapt their approach to finally achieve success.

There was uncertainty amongst most participants about the impact of ACV on ICU and hospital LoS. Various mechanisms were proposed as to how ACV might extend or reduce LoS. Factors that might increase LoS included delaying cuff deflation, over-fatiguing the patient and delaying progress, and an adverse event making the patient more unwell. Factors that might facilitate a reduction in LoS included earlier rehabilitation, improved swallowing and secretion management leading to accelerated weaning and decannulation process, improved engagement and participation, restoration of communication reducing frequency of adverse events and delirium, and reduction in aspiration of secretions and pulmonary complications. However, most participants were uncertain of any LoS effect, except a few who thought that ACV could not increase LoS:

> “…so, if anything it would be the opposite. But definitely not increase length of stay. No, no, definitely not.” [PT 6]

The uncertainty surrounding ACV is partly due to the limited and subjective evidence available – with much of the evidence reliant on subjective outcome measures. However, the uncertainty also appears to be related to how the evidence is interpreted and applied, which can lead to variability in ACV application. One participant described an incident with a junior member of their team who had used high airflows for ACV and suggested that one of the potential causes was related to a lack of integration of

knowledge with clinical experience:

> "…and I said "oh why did you go up to 15?" and she said "oh because I remembered that you had said about that you know really old [name of author] article where he had used a super..." you know and that had obviously stuck in her head […] People had – who were you know prolific publishers – had used a really high flow rate in the past. And that's the thing I think that's always a bit of the concern for me that […] when that literature is out there and people can access it and people are referring to it and then reading it independently but perhaps not integrating it with expert clinical experience, that's when things I think get a bit hairy and you're a bit like oh gosh you know and how long did she leave that running for?" [SLT 1]

Some participants reported a lack of confidence in using ACV due to a lack of experience, uncertainty because of the limited evidence available, and a lack of resources and protocols. Subsequently, many participants reported that ACV becomes a learning process, a process of experimentation and 'trial and error':

> "I feel okay about it. I wouldn't say I feel overly confident I think because there isn't a lot of research available compared to other methods and I don't have that breadth of anecdotal experience. You know I sort of think, well I think I know what I'm doing but maybe I could be doing something differently that could enhance the outcomes?" [SLT 13]

Some participants tried to minimise uncertainty by looking closely at all the research to develop guidelines and processes and carrying out local benchmarking to make decisions about ACV application approaches. Some participants reported a lack of support from their MDT to use ACV, which they suggested was due to the uncertainty and limited evidence for ACV. Most participants were emphatic in their opinion of the need for more research to prove the case for ACV, which they thought would help to engage the MDT, standardise practice, and make it easier for staff to use:

> "…that's the bit we need to try and prove with ACV and then throw that evidence at them. The same way that we've done with Passy Muir valves. […] And I think we need really good research that just can't…explain away!" [ACCP 1]

There were varying opinions amongst participants about how ACV should be applied and what the primary purpose of ACV is. This appears to be due to the underlying uncertainty and subjectivity surrounding ACV. Many participants were focused on communication and consequently used ACV later in the patient's journey. By not embracing the full potential of ACV they may have missed some of the non-communicative benefits and further limited the small window of opportunity for ACV

and the number of patients that could benefit:

> “I know that in some hospitals, they try to put this as the first trache tube of choice. […] So, in this situation, sometimes, it just sits there and helps with suctioning secretions. But it’s really not helpful until the patient is awake and interactive and can really use that in a meaningful way.” [Nurse 1]

There also appeared to be a disparity within professional groups about the purpose of ACV, with several participants describing that the medical and nursing perspective was focused on communication. This focus on communication by some HCPs may be because communication is much more tangible than swallowing and sensation. As well as being more tangible and visible to members of the MDT, improved communication from ACV can also bring about direct benefits to staff, which can result in its prioritisation:

> “So, it's not always the first priority [of other members of the MDT]. Often it gets the first priority when the patient can communicate. Then it's easier because “oh when I use this, I get an answer and then it's easier to help the patient.”” [OT 1]

It appeared that those participants who were mainly focused on communication seemed to have fewer patient candidates for ACV and tended not to hand over ACV delivery to nursing staff or train nursing staff. Participants expressed that the limited number of potential candidates for ACV meant they struggled to justify training large numbers of staff in using ACV. Some participants reported that as they experimented with ACV and the evidence base evolved, their experience changed their focus of purpose. Most often, this shift in purpose was away from communication and towards swallowing. Those participants that focused purely on swallowing generally reported it was due to a lack of success in communication or related to their particular patient group (e.g., patients in a disorder of consciousness). Some clinicians felt strongly that other people were not using ACV enough to focus on swallowing and saliva management and that this was due to the uncertainty and limited evidence available:

> “I know we always go: “Yes! Let’s use it for voicing.” But I think convincing people that actually it is about restoring function and does improve secretion management, that, you know, if there was more research…” [SLT 8]

5.4.3 Theme 3: Knowledge and experience leading to control and caution

All participants discussed that the implementation and application of ACV needed some level of control and that there was a need for caution. The amount of control and caution thought to be required was heavily influenced by the level of knowledge that the individual had about ACV and their personal experiences with ACV. Often negative

experiences – including adverse events such as subcutaneous emphysema, burst cuffs, and gastric distension – had such a profound impact on staff and teams that it resulted in feeling that there was a strong need for caution to keep staff and patients safe:

> "What happened to our last patient was very, very, very important for me. We are supposed to take care of our patients so…it was something that stuck with me. […] I'm trained to do my best, but you know enough is enough. And you have to know when to stop. So, yes, I think that it's dangerous. That somehow if you don't know how to use it, it's…just don't use it if you don't know how to use it." [SLT 3]

These adverse events, as well as instigating a need for caution to protect patients, also created a need to protect staff and hospitals from the potential of litigation. In some instances, these adverse events resulted in the prohibition of ACV:

> "They put air into […] the pilot balloon instead of the suction port. And so, that burst, and it did not affect the patient but just that it was a near miss. Something bad could have happened. And they wanted us to explore it further and so right now we're still in that phase of trying to figure out if we should reinstate or not." [Nurse 1]

In contrast, when there were no adverse events, there was more support from the wider team to use ACV and less focus on control and caution. However, these places also tended to have strict rules and processes in place for how to use ACV safely:

> "I think it's because we haven't quite seen anything sort of really detrimental happen that most people are like: "Alright, yeah, we'll follow the rules, yeah, you start it off, come back and help us do it again."" [SLT 8]

Some participants reported that they thought there was a general perception amongst HCPs that ACV is a benign and harmless intervention. Many participants reported instances of misuse of ACV and potential patient harm, which they felt were a result of a lack of understanding of the potential risks with ACV and how to deliver it safely:

> "One of the […] physios came to see me […] and said "I walked in the room and the nurse was doing 10 litres! The cuff was down. She had no idea what she was doing!" […] But you do tend to find with nurses, it just gets passed on, word of mouth, rather than through the formal process of training or competency based…learning." [PT 3]

Most participants highlighted that training of staff, particularly nursing staff, was problematic due to the large numbers of staff and the high staff turnover, combined with staffing pressures and limited numbers of potential patients. Some participants expressed concern about the possible indiscriminate use of ACV without sufficient

training or the necessary guidance. Most participants stated that these concerns led to a desire to set up safety processes and governance structures and designate responsibility of ACV to specific individuals:

> "…you've got to get the balance right of … educating clinicians, of using good clinical reasoning for how to use it and who with. And you don't want uneducated clinicians who haven't really researched it and understood all the ins and outs of it, just having a go! Like the have-a-go mentality has its uses but also its risks!" [SLT 2]

Many participants from different professional groups who were prescribing the treatment for ACV – and other interventions – stated there was a need for control in how any interventions are delivered because of patient safety concerns. Some participants also expressed a lack of trust that interventions will be carried out appropriately, with one participant describing anxiety that other members of the MDT would 'go a little bit rogue' with ACV. Again, participants suggested that this was due to issues with training staff and insufficient staffing:

> "…I think some of the crit care nurses have used it…shall we say, kind of…guided…medically, maybe just, you know "let us try this and see if they can speak to us kind of thing?" Not like…as controlled as maybe we would trial it." [PT 1]

One participant spoke about the potential damage to their professional reputation if something went badly with ACV. There was a general sense of anxiety amongst many participants that there is potential for things to go wrong and an entrenched need to do everything possible to 'get it right':

> "You know, these are vulnerable patient groups. So, that's always in the back of your mind […] that small anxiety and your own competency then as well to ensure that I'm doing this as it should be done and we're considering all things, we've done our homework, as best we can." [SLT 9]

Many participants wanted standardised processes and procedures to ensure safety. Most participants thought the need for training, support and good communication with MDT members was vital to reducing risk and maintaining safety for patients and staff:

> "…if you're handing that over to staff who are unfamiliar with the technique and making sure that you've got very good signage or education with the staff. […] Making sure you do have good handover processes. Good education. Because of you know such high activity area and such a big turnover of staff. That that's probably the biggest risk I think" [PT 8]

This need for caution resulted in participants describing various approaches to reduce risk and maximise safety. These included only carrying out ACV in the ICU

environment, careful patient selection, discussing patient selection with the medical team, and having two staff members present at initial assessments. The need for caution seems to be heightened for particular patient groups, such as those in a disorder of consciousness:

> "I think it's not really reluctance with the nursing staff in using it. I think with the low arousal patients, I just think the observation's a bit different isn't it?...Of whether they're tolerating it? […] you probably just feel a little bit more cautious around those patients." [PT 1]

It is clear that for many participants, as their knowledge and experience of ACV developed, their opinions on the need for caution grew stronger:

> "I think…over the…gosh 11, 11 years of using it, my approach has very much changed. […] And I think I probably was one of the "oh you just stick a bit of oxygen on don't you? There's no problems!" […] it used to be that we were quite happy to – after we'd done the initial assessment – go "oh anyone can do that now, we know that they're okay." But we've had some patients that have been really variable, where sometimes they're brilliant and other times they're terrible." [SLT 10]

Despite experiencing multiple serious adverse events, one participant expressed the need for caution in some aspects of management, in other aspects, there continued to be a belief that ACV is a simple intervention that all can use with a minimum of training and no need for competencies:

> "But usually I just expect the nurse that I've handed over to or shown her how to do it, to then hand over with a…the next nurse coming on to show them how to do it! It takes…two, if everything's set up and ready to go, well not even that! 30 seconds doesn't it? To show someone how to do it. And that's kind of the beauty of it, I think" [ACCP 1]

Some people viewed ACV as a safer option to support the restoration of airflow through the upper airway – compared with cuff deflation and the use of an OWV – particularly when there was a lack of trust that other members of the team would follow the recommended treatment prescriptions:

> "…your only alternative is to do very, very small pockets of cuff down, isn't it? And it's very hard to control that on a ward environment, isn't it? Cos unless it's you doing it, and you've got complete control, you come in the next day and they're like "oh no, the cuff was down for an hour." You're like "No!" […] But I think the patient that ACV is useful for are equally probably the patients that you would do really micro-cuff deflations for. […] and it just provides you, almost a safer way of doing that but maybe as a once or twice a day session." [PT 4]

With some individuals, as knowledge and experience grew, and in the absence of adverse events, they became more relaxed about ACV rather than more cautious:

> "I think it just comes with practice, yeah. […] I think you get a bit more comfortable with it, and I think it's one of those things I find I'm always saying to the girls: "This is not rocket science, these are the risks and you just have to have a go" […] Initially, I think I was nervous until I then realised that actually this isn't…you just have to use all the other skills that you've got to then go: "Okay, this is not that hard."" [SLT 8]

5.4.4 Theme 4: Worth a try or a last resort

There was a spectrum of opinions about ACV and its usefulness for patients. These opinions appeared to be formed based on the moral distress experienced by participants, the underlying subjectivity and uncertainty surrounding ACV, the purpose for which they use ACV, and their knowledge and experiences of ACV. Opinions ranged from people who think it is life-saving for patients to those who believe it should only be used as a last resort when all else has failed. Those participants that considered it life-saving described the marked impact of ACV on the comfort and well-being of some of their patients:

> "…when they feel they get, they've got a lot of sputum and that the airflow pokes it to their mouth, which we know it's going to do that! Some will find that unpleasant. Some will find that life-saving cos it's just something that had sitting there, that they can't clear…" [SLT 6]

Centrally, and more commonly, on the spectrum of opinion, were those participants who thought ACV was worth a try. These individuals believe that even in patients where there is a suspicion that they will not succeed with ACV, it should be tried anyway, just in case. There seems to be an underlying philosophy that the only way to know if something works is to give it a try and that if there is even a chance it could work, then you should try. Participants described positive experiences using ACV reinforcing this willingness to give it a go and encourage others to try it also:

> "And like I say, if I had tried it and it hadn't worked, I wouldn't be pushing, you know you wouldn't push it! But I think if you know it works…and there's a chance it could work for your patient, you know you're going to try!" [PT 7]

Participants expressed the feeling that, for these patients, there are so few options available that anything is worth a try, though again, the need for caution is present:

> "I think when you've got the lower awareness patients or the patients that cognitively are not able to do a full swallow programme, it's a bit like, well what else are you going to do? […] So, I think the benefits of it almost always

> outweigh the risk. But it does come with a caveat of there's no point in blasting air into someone's larynx if it's not going to make any difference." [SLT 10]

Participants considered ACV to be better than nothing, and certainly better than non-verbal communication options. Participants described how the need to fix patients underpins this willingness to try different interventions and ensure that patients have options for communication:

> "…I mean communication I think is the most important thing for our patients. So, however we can get them communicating I think is the way." [SLT 5]

For most participants, cuff deflation and OWV was always the first option for patients, and ACV was only considered a second-line option after this. In contrast, two participants routinely considered ACV with all patients, but this opinion appeared to be an outlier and mainly focused on swallowing:

> "Well, it's a standard procedure for me. It's something I always give to my patients when I have a session with the patient where we are working with the swallowing. Not always, of course there are patients where I don't...where if we don't see it's fitting well enough." [OT 1]

At the other end of the spectrum, many considered ACV a last resort when all else had failed:

> "…and it was just kind of a very useful way…to be honest, it was when all else had failed!" [SLT 10]

For most participants, this was because they were so successful in the use of early cuff deflation that they had little need for ACV:

> "…I guess that's one reason why we don't use ACV is because we usually go for cuff down and Passy Muir first. And I'd say on the whole … that goes well. So, we don't feel like we need to use ACV." [PT 5]

For some individuals, ACV being a last resort was also linked to the fact that there are equipment issues, such as difficulties accessing a thumb port, meaning that ACV is not an easily accessible option. For others, ACV is a last resort because HCPs want to stick to what they know and are more comfortable with, i.e., cuff deflation:

> "So, I think that because we had much more experience with the traditional way, we used it…and we use it now." [SLT 3]

Participants reported that ACV is not even an option for some patients who do not have a subglottic tube in situ, as most individuals said that changing the tracheostomy for a subglottic tube purely for the purpose of communication is generally not considered. This suggests that HCPs think that it is not worth the cost or effort of changing a tracheostomy tube purely for ACV:

> "We would need a fairly good reason, you know, to think about changing trache tubes and we do think about that for, you know, other reasons such as trying to get a Passy Muir valve on? […] But we would not necessarily think about just changing a tube to get a subglottic suction port for the sake of ACV." [PT 8]

One participant had concerns that overuse of ACV may prevent or reduce the use of early cuff deflation and one-way valve (OWV) use:

> "I guess what I would like to see continue happen is that it's very much… promoted…as not an instead of cuff down and PMV. It's very much always…promoted in those really, really…very niche patient groups. I think it'd be a terrible step backwards if it was used and the cuff down PMV early message got lost." [SLT 12]

Within the 'Worth a try or a last resort' theme, three sub-themes were developed: 'Sub-theme A: Part of the toolbox', 'Sub-theme B: Useful but limited tool', and 'Sub-theme C: Following the patient's lead'. These sub-themes were developed to capture some of the nuances of the varying opinions of ACV and how these opinions were formed.

5.4.4.1 Sub-theme A: Part of the toolbox

ACV was considered to be part of the toolbox by most participants:

> "Absolutely. As another tool in the toolbox. […] the more tools you have, the better you can individualise." [PT 2]

Some consider the role of ACV in the toolbox to be a bridge or stepping-stone towards cuff deflation:

> "…when we're using it, although we're using it to get advantage of voice, we're using it very much as a tool to try and rehabilitate swallow and desensitise their airway really. As a step towards being able to cope with cuff down. So, in hospital, I very much see it as a way, a stepping-stone to start cuff down." [PT 4]

Participants were generally excited and eager to have another option in their toolbox for these patients, as most people felt that their toolboxes had very few options available. One participant expressed the opinion that PTs select interventions for their toolkit based on their positive experiences with it rather than any evidence-base around effectiveness and safety:

> "But I mean to be honest that's like a lot of physiotherapy really! It's not…we talk about evidence-based practice [Laughs] and it's like, you know, kind of what's worked? Or worked for your patient? Did it do any harm? No. Okay. That's another tool in the toolkit." [PT 7]

Participants reported that many individuals and services added ACV to their toolkits after observing the benefits of ACV for patients. Similarly, the benefits to staff, and the improved patient-staff relationships, also seem to play a part in the consideration of ACV as part of the toolbox:

> "I think there's definitely decreased frustration among the nurses because they could understand what the patient wanted. It also helped build trust with the family members because now the family members know that the clinicians are actually listening to what the patients want and not just doing whatever they want! So, I think it was not just benefit for the bedside nurses or the physician who's providing care but it was all around. Anyone who came in contact with them, the patient had more control…from being able to communicate…" [Nurse 1]

Most participants reported feeling comfortable and confident in using ACV, and most people thought that the procedure itself was simple and straightforward:

> "Yes, it's fairly straight forward. As I said there's certainly no really adverse effects I've ever found. So, I feel really comfortable using it. There isn't an awful lot of kit to do it with either. So, it is quite an easy thing to do." [PT 6]

Some consider ACV to be as good as cuff deflation and OWV use, although many stated that it does need time and perseverance to achieve good results. ACV is considered to be a safe intervention by some, and this leads to HCPs recommending it to other clinicians for them to consider using it as part of their toolbox of interventions:

> "This is actually something you can do safely, and quickly, and you can facilitate communication which is really, you know, the crux of why we all probably started being speech therapists." [SLT 8]

Some even considered ACV safer than cuff deflation because the cuff remains inflated, and they believed the risk of aspiration would be lower.

Those participants who tend to use cuff deflation later in the patient pathway reported using ACV more frequently as part of their toolbox. However, even those who use ACV very rarely continue to consider this intervention as having a place in their toolbox, even if it is right at the bottom:

> "…I'm very open-minded and very positive about it. I just haven't…you know seen the same…patient candidacy and you know benefit in our group that has been reported elsewhere. So, a little bit curious about that. And yes, just interested to learn more and […] I continue to have it, as I say, in my toolbox." [SLT 13]

For those participants with ACV at the bottom of their toolbox, who use it infrequently,

there is usually a need to re-learn and re-orientate each time they use ACV:

> "…it's always something that I need to re-orient every time I want to use it because we don't use it very often" [SLT 7]

5.4.4.2 Sub-theme B: Useful but limited tool

Most participants thought ACV has its uses but is not a magic fix-all for all patients: it is a useful but limited tool. One of the limitations reported by participants is that it is variable in its success and effectiveness:

> "And I think I always remind people it's not always successful, so I don't ever go in hoping that it's just going to be this magic thing that works." [SLT 8]

Some participants reported that the variability of ACV could be problematic as it can limit its use and functionality, and it can also make it difficult to handover to other staff members:

> "I think the other big thing with ACV is, you know, in some patients they can tolerate it on one assessment and then maybe you go back the next assessment and it, you know, they're not tolerating it. […] So, in terms of that…repeatability of it, you know, it does sometimes…require that, you know, trained eye. And if you haven't got that experience in it." [PT 3]

Many participants stated that limiting the duration of ACV to reduce the risk of laryngeal drying could be frustrating for patients and family members and limit its utility for communication or swallowing. Another factor that led to restrictions on the use of ACV was that some participants deemed the assessment and implementation of ACV to require advanced skills; this led to a limited number of staff that were able to implement ACV and limited its use:

> "…it was only from a band 6 and above we would do those training and it was those staff that were more static in that particular area, who probably have those complex weaning kind of…skills that we taught, who could do it. […] so maybe that's…looking back, reflection maybe why we didn't use it as much as well, cos not many people could instigate it?" [PT 6]

Participants reported that ACV had limited utility for communication. In particular, they stated that it does not consistently produce immediate results for communication. Most participants said that ACV takes time and effort before positive outcomes are achieved, and sometimes those outcomes or improvements are subtle. Some participants found that ACV was only useful for patients when the SLTs were present, making it non-functional as a communication method, as they cannot be present continually. There was an element of disappointment with some participants that ACV did not meet their

expectations for communication. For some, this limited utility was described in stark terms:

> "…well given that we don't use it very often, that probably says enough! [Laughs] in that I just don't think it's that useful for our patients. I don't think they get the communication success initially, or even with some training, for it to be warranted to embed into our approach with patients." [SLT 11]

Many participants felt that the benefits from ACV were greater for swallowing than for communication:

> "I'm sure that is helping with the swallow. I'm not sure about voice though. It's just my opinion. And my colleague's opinion. It's much more important for the swallow and not so much for the voice." [SLT 3]

Participants described ACV as very fatiguing for patients and holding a risk of vocal issues because of the potential for it to be a very unnatural way of speaking without appropriate patient training and support. Several participants stated that ACV is also only suitable for a niche group of patients and usually only useful for a limited window of opportunity:

> "It's not going to completely revolutionise care, but in its little role in a small select cohort of patients, and in a wider cohort of patients for a short amount of time, it's got a real role to impact and improve patient care." [ACCP 1]

Participants stated that identifying this niche group of patients can be problematic and that, combined with its limited success, can restrict its use:

> "…you know in terms of then finding suitable patient candidates, you know, haven't found that it's…you know, it's definitely not my go to! It's not something that I've found to be something that produces loud functional voice. […] But I've found that when I have used it…voice has been you know quite whispery. Or just patients that haven't found it particularly comfortable. Haven't really enjoyed using it." [SLT 13]

Participants suggested that it is difficult for staff to build up skills and experience using ACV because of its limitations and restricted use in select patients:

> "I think that we use it as much as it should be used. I don't think we're missing anyone. I think it's a good thing for a very few people…but that's part of the problem. Like, no one will…a lot of people won't become really good at doing it because we have so few." [PT 2]

5.4.4.3 Sub-theme C: Following the patient's lead

Part of the underlying reasons for participant's views and opinions of ACV and whether it is 'life-saving', 'worth a try' or a 'last resort' appeared to be related to the patient experience of ACV, and the focus of HCPs in following the patient's lead when choosing and using interventions. Unfortunately, many participants reported that some patients tend to find ACV uncomfortable, dislike ACV or find it unacceptable:

> "…so you know, you promise these big things: "Yeah, we're going to be able to get your voice back!" And then they're like: "I don't like it, take it away, I'd rather have no voice than this feeling." [SLT 7]

Many participants reported that their patients disliked ACV and experienced discomfort. This seemed more common when ACV was used for communication, which requires higher flows than are used for sensation and swallowing. Participants reported that certain patient groups seem to be more emphatic in what they are willing and unwilling to accept when it comes to interventions for communication. In particular, some participants stated that spinal patients found ACV unacceptable, though others reported that spinal patients received the most benefit from ACV of all patient groups:

> "When we have done ACV with the spinal population for communication […] they tend to be very…prescriptive in what they do want and what they don't want. And what they do find comfortable, and what they don't find comfortable. And ACV quite often is just "no, too uncomfortable. Not doing that!" [SLT 10]

Participants described some patients asking to stop using ACV because of the discomfort that they experienced:

> "…I think they like it for that period but often it's something that's asked to discontinue it because of discomfort. And, you know, we've not had anyone that's tolerated using it as their main means of communication. Just cos they've actually not liked the sensation." [PT 4]

However, where patients can be encouraged to persevere with ACV, some participants reported that patient comfort level could improve:

> "It can be a bit dry and irritating for the patient, but that usually is I guess in the first couple of trials. And once, it's like anything, once the patient sort of gets the hang of it, they…you know it doesn't seem to be a problem after that." [PT 8]

One participant reported that their patients found the lower flow rates more uncomfortable and frustrating than the higher rates. They were led by the patient in terms of the flow rates used, even though these greatly exceeded the general upper limits suggested in some of the more recent literature:

> "So, ironically, they both found that the low flow rates quite uncomfortable. So, almost like kind of…it just didn't feel it was enough. And they just couldn't…it's frustrating, I think." [PT 7]

Other patients were reported to find ACV frustrating because of the effort to coordinate speech with the airflow. Participants stated that the lack of success with ACV could deter some patients from wanting to try it again:

> "…in our ICU, and from a patient perspective, it's not something they've found comfortable or…useful. And for some people that's enough and they don't want to try anymore." [SLT 11]

Part of following the patient's lead appears to be about providing support; participants explained that it was essential to provide patients with appropriate levels of support and education to assist patients in achieving successful voicing:

> "It may well be that what's changed also and improved is my ability to…work with the patient to help them produce voice? So, I think when we first tried it, we'd pop it on. Put the flow, the thing, and then I'd be like "okay, off you go!" Whereas…and then nothing would happen. And I'd be like "oh it doesn't, it's not working!" And … I think more latterly, I've realised that…the patients need a bit more support potentially to use that flow with their voice." [SLT 12]

Positive patient-family experience also appears to contribute to participant opinions of ACV. Participants described instances of ACV improving patient-staff and family-staff relationships because of the humanising effect, along with improvements to patient identity and autonomy:

> "…when they heard their sounds, even saying "aah" or "ee", when they heard their sound, you could see the smile on their face. They feel like a human being." [Nurse 1]

Participants described the importance of choosing and tailoring interventions according to the individual, ensuring that goals are meaningful to the patient, and focusing on patient outcomes. Some participants also advocated for careful timing of the initial ACV assessment to maximise the likelihood of them having a positive and successful first experience:

> "…patients can then see that as a bit of a failure if they're really struggled with it the first time. So, it's about kind of trying to find…obviously the right time for the patient to get that positive experience as opposed to them struggling with it the first time. Just to keep them on board." [PT 1]

Some participants reported a disparity between patient readiness and staff readiness, with patients not wanting ACV at times because of other factors, including how unwell

they feel in the moment:

> "…you know I think there's too many factors in there and I just think they're just like "Oh seriously lady, go away, like get your chipper face out of my grill!" […] Because I think in the end I find if I feel like it's torturing them…you know what I mean? It's not, but you know what I mean, if there is no real gain to actually doing it then […] let's just leave it for the day." [SLT 8]

Patient choice and the different perspectives that patients have for communication methods versus swallowing rehabilitation were discussed by several participants. One participant felt that patient choice is key regarding methods to support communication. In contrast, for swallowing rehabilitation, patients are happier to accept an intervention – even if it means experiencing discomfort – if ultimately it will help to improve their swallowing function:

> "No, I think it's more because I guess for communication it's more about their quality of life and them, so they can sort of opt to say: "No, I don't really like it. I don't want to use it, I'd rather just mouth." […] whereas, when it comes to swallow, I'm directing it […] I feel like people are much more tolerant of things when they're therapeutic and a rehab goal […] whereas, when they're like: "I don't have to use this and it's not of any benefit therapeutically to me it's just more about my quality of life." Then they're like: "No, I don't like it." [SLT 7]

5.4.5 Theme 5: Limited consideration of COVID-19 or starting from scratch

For many participants, ACV in the context of COVID-19 has been given limited consideration throughout the pandemic, and ACV use was unaltered. One participant even started implementing ACV for the first time in their hospital during COVID-19. For some, the reasons for this limited consideration were based on the fact that ACV was being conducted in an area where top levels of personal protective equipment (PPE) were being worn at all times. Thus, ACV could continue to be used regardless of whether ACV was considered to be an aerosol generating procedure (AGP) or not:

> "So, it wasn't like we were in an area that was going to put other people at risk because everyone was in PPE and all the other patients were COVID." [PT 5]

Participants reported considerable uncertainty and variability regarding the question of whether ACV is an AGP:

> "But I mean we had a back and forward discussions, as I'm sure you did too…about "What is an AGP? And how much, and why?" And that would just go round and round in circles…" [SLT 7]

For others, ACV was used so infrequently that the question of whether ACV should be

used, from an AGP or transmission risk perspective, was not raised:

> "…I don't think we probably thought about it a huge amount because it's not come up. And there haven't been other patients that we've thought "oh it would be good to try ACV with so and so"" [SLT 2]

Yet others gave limited consideration due to the limited number of patients with COVID-19 in their setting. In some cases, the limited numbers of COVID-19 patients were due to the setting (e.g., rehabilitation), and in others it was due to low community transmission levels (e.g., Australia):

> "No. Because we don't really have it!" [SLT 11]

For others, even though they had few COVID-19 patients, the concern over the potential risk of transmission meant that it still significantly impacted ACV use. Participants reported that changes to tracheostomy practices during the pandemic – such as the reduction in the numbers of tracheostomies inserted in some hospitals and the increase in the use of adjustable flange tracheostomy tubes, that usually do not have a subglottic port – also prevented some services from using ACV as much as they would have liked. There were also published papers that stated that ACV should be avoided due to the transmission risk, which held some participants back from considering using ACV:

> "…I certainly read somewhere that in the first surge that ACV shouldn't be done." [SLT 12]

For many participants, the impact of COVID-19 on ACV use was profound at times and for others throughout the pandemic. Some described needing to survive and that new or innovative techniques, like ACV, were not prioritised. This de-prioritisation of ACV as 'innovative' was reported to occur even in settings where the participant had been using ACV infrequently for more than five years:

> "…it was just such a stressful and uncertain time, that…you know other things came to be prioritised like trying to minimise staff foot traffic in with the patients, you know the COVID patients. And not wanting to implement new techniques and innovative things. And just wanting to…it's all about survival, I suppose! And trying to understand the pandemic. Trying to understand transmission risk and viral load and…you know access to PPE etcetera." [SLT 13]

Similarly, some participants stated that ACV was simply forgotten in the stress of dealing with the pandemic and staff struggling to find time to care for patients. Issues with training staff were also a contributing factor to reduced or absent ACV use:

> "...I don't know if that's the same everywhere. Basically, any kind of CPD [Continuing Professional Development] and extra training…anything exciting

> that adds to our job, has just been stopped if I'm honest. It's kind of just been you know your caseload. So, just had no time. [PT 1]

Some settings considered ACV to be an unnecessary risk:

> "I don't believe…that ICU would have asked speech to come in to a COVID patient to do ACV…and make that extra risk for possibly something that isn't […] as recognised or isn't possibly going to be, maybe as successful promptly as like a speaking valve. […] we can do without it. Because it's not as absolutely nec-, I know it's going to sound terrible. […] Not as necessary to get the trache out and get them out of the hospital and free up a bed…as cuff deflation is to get them to decannulation." [SLT 6]

For some, the impact of AGPs in the use of ACV significantly impacted its use, but participants expressed hope that practice would return to normal eventually. Some participants reported that patients were only able to receive ACV if they happened to be in an appropriate and controlled environment, which meant an inequitable service for patients:

> "Well, I'd definitely say that's probably one of the contributing factors of why we have tailed off a little bit, using it as frequently. […] So, on ICU we've got side rooms. There wasn't really as much of an issue in the side rooms. […] But when we were in the bay, and particularly when it was COVID bay…yes, it did. It did have a negative impact on using it as frequently and with cuff down Passy Muir as well." [PT 3]

Most participants described the changing nature of the pandemic, with altered processes and access to PPE, with ACV practice also changing accordingly. There was a general feeling amongst participants that patients had received sub-optimal care because of the restrictions on procedures introduced to reduce transmission risk:

> "I think it gets a bit more tricky on ITU [Intensive Treatment Unit] because the level of PPE that they're wearing varies. And I think whenever you've got a system where people are in surgical masks, but then have to gown up for certain procedures, they become more reluctant to do those procedures, don't they? And things just stop happening. […] They did stop doing things and I think that was probably quite…detrimental…to some patients' wean." [PT 4]

Many participants stated that as the use of ACV resumes after a prolonged period of disuse due to the pandemic, they feel as though they are starting from scratch with ACV because of the high staff turnover:

> "The issue we've got is it's like starting from scratch because you look round the unit, I don't recognise many faces from five years ago! They're all new, and many of them have only known COVID!" [ACCP 1]

One impact of COVID-19 reported by participants is that the risk assessment process for ACV is now more thorough, with HCPs having to think about the environment and potential risk to other staff and patients. Despite the considerable impact of COVID-19 on ACV use, general opinions of the intervention seem to be unchanged:

> "So, [sighs] will it change it? Yes, I suppose we have to give consideration to extra precautions. But I think some of those will become precautions that we will keep, going forward anyway, beyond this pandemic. Because I think it has made us think…in different ways. So, yes it will colour it. Yes, it will impact on it. But I hope it wouldn't hold it back now at this stage." [SLT 9]

5.5 Discussion

Five connected key themes were developed using a reflexive thematic analysis of interviews with 24 HCPs. These themes included: 1) moral distress amplifying the need to fix patients; 2) subjectivity and uncertainty leading to variations in practice and purpose; 3) knowledge and experience leading to control and caution; 4) worth a try or a last resort; 5) limited consideration of COVID-19 or starting from scratch.

This study demonstrates that moral distress amplifies HCPs' need to fix patients. This 'need to fix' influences opinions and uptake of ACV, with a general willingness to try anything that might help patients. Despite the growing evidence base for ACV, there remains substantial subjectivity and uncertainty regarding many aspects of ACV, and this leads to considerable variation in both the purpose for which ACV is used and how ACV is applied in practice. The limited evidence and guidance available mean that most people experiment with ACV initially and describe ACV implementation as a learning process. As their knowledge of and experience with ACV developed, most participants felt an increasing need for caution with how ACV was used to keep staff and patients safe. There was a broad spectrum of opinions about ACV, with most participants believing either that ACV was worth a try or that it is a last resort, only to be used when all else has failed. Within that spectrum of opinion, many labelled ACV as part of their toolbox for consideration with patients, dependent on their circumstances. However, some labelled ACV as a useful but limited tool that was only useful for certain purposes or with a niche group of patients and generally only for a small window of opportunity. Most participants discussed the need to follow the patient's lead and, in observation and discussion, supported them to choose or refuse ACV. The COVID-19 pandemic considerably impacted the use of ACV, particularly in severely affected regions. This has led to many participants feeling as if they are starting from scratch with ACV. Conversely, those participants from regions or settings less affected by COVID-19 gave limited consideration to its impact on ACV, and use remained essentially unchanged.

5.5.1 Theme 1: Moral distress amplifying the need to fix patients

Several participants expressed an underlying desire to make a difference for individuals as a 'need to fix' patients. Patients with a tracheostomy in the ICU are known to have a significantly reduced QoL due to a combination of factors, including the inability to vocalise, eat, and drink (Engoren et al., 2004; Freeman-Sanderson et al., 2018). Many HCPs commence their career because of a deep-seated desire to care for and make a difference in the health and QoL of their patients (Norton, 2018). Indeed, the concept that HCPs want to perform miracles has been expressed previously (Becker, 2008). The underlying need to fix patients, which could be described as a moral sensitivity, can leave HCPs vulnerable to moral distress (Lützén et al., 2010; Burston and Tuckett, 2013).

In recent years, the concepts of moral distress and moral injury have become more prevalent (Čartolovni et al., 2021). Moral distress has been described as 'knowing what is good for the patient but being unable to provide it because of constraints that are beyond our control' (Čartolovni et al., 2021). The ICU environment, and the emotional aspects of caring for critically unwell patients who are desperate for their situation to improve, can take a toll on HCPs and contribute to moral distress (Colville et al., 2019; Vincent et al., 2020). Moral distress is an increasing problem for HCPs as staffing issues worsen and the pressure and burden on staff increase. The COVID-19 pandemic appears to have further exacerbated the growing issue of moral distress in healthcare settings (Kok et al., 2020).

Moral distress can result in harmful effects for individuals and the development of 'negative feeling states', including potential feelings of blame, guilt, anguish, powerlessness, and betrayal of personally held values; this has been described as a kind of pain (Tigard, 2019; Čartolovni et al., 2021). Persistent experience of moral distress can ultimately lead to moral injury – where a deep emotional wound develops – and burnout and compassion fatigue can occur (Čartolovni et al., 2021). However, positive aspects of moral distress have also been reported. Potential positive aspects of moral distress include revealing the depths of care that HCPs have for patients, increased appreciation for positive experiences and emotions, improved understanding of oneself, and improved skills in compassionate care (Corley, 2002; Tigard, 2019). It could also be argued that an extension of these positive aspects of moral distress might be to reinforce an HCP's determination to make a difference for their patients, despite the constraints they face. One study has indicated that there may be differences between professional groups in how they respond to moral distress; Bruce *et al.* found that doctors became more withdrawn and detached in response to moral distress, whilst nurses became more emotionally invested in their patients' well-being (Bruce et al., 2015).

This study highlighted various examples of the moral distress experienced by HCPs because of the multiple constraints placed on them. Participants reported various factors contributing to moral distress, including limited available interventions, staffing issues, processes that denied patients continued access to ACV, pressure from managers, and patient distress. These experiences led to feelings of guilt, powerlessness and frustration. However, for the most part, rather than leading to burnout and compassion fatigue, these experiences and negative feeling states appear to have reinforced and amplified their 'need to fix' and do all in their power to make a difference for their patients. The 'need to fix' means that most participants were willing to try anything that might help their patients: doing anything was better than doing nothing.

In this context, opinions about ACV are formed, and implementation decisions are made. The moral distress of knowing that patients are extremely frustrated and 'dying to speak', combined with a strong underlying 'need to fix', may impact the uptake of interventions such as ACV and influence application.

5.5.2 Theme 2: Subjectivity and uncertainty leading to variations in practice and purpose

The systematic review of ACV, outlined in Chapter 3, highlighted the limited and low-level evidence available for ACV (Mills, Michou, King, et al., 2022). The impact of this is borne out in the participants' responses in this study, with most stating that there is substantial subjectivity and uncertainty surrounding ACV, which is mainly focused on ACV application, potential risks, effectiveness, and competencies. This subjectivity and uncertainty appear to result from the limited evidence and guidance, the variable interpretation and application of the evidence, and patient heterogeneity.

Part of the variability in interpretation and application of the evidence may be related to the different aspects of evidence used by many HCPs in their decision-making regarding interventions. The Joanna Briggs Institute (JBI) model of evidence-based healthcare suggests that decision-making regarding interventions must incorporate the research evidence, the clinical context, patient choice, and clinical judgement (Pearson et al., 2007). The model is a cycle with four major steps: evidence generation, evidence synthesis, evidence transfer, and evidence utilisation (Pearson et al., 2005). The JBI model further breaks down the evidence generation to include research, experience, and discourse (Pearson et al., 2005). Some HCPs may rely more heavily on one of these elements when the other elements are lacking. For example, depending on discourse, such as opinions expressed by experts or experienced clinicians, or website content (Pearson et al., 2005).

The findings of this study suggest that HCPs are more focused on their own experience and discussion with other clinicians, which may be a result of the limited evidence available. This may contribute to the variation in practice reported by participants and observed in the international survey presented in Chapter 4 (Mills, Michou, Bellamy, et al., 2022). Additionally, HCPs are under increasing pressure with limited time available to keep up to date with the evidence. They are unlikely to have time to critically appraise the evidence for each potential intervention.

Uncertainty in healthcare systems is common and has been defined as the subjective perception of ignorance that patients and HCPs can experience (Han et al., 2011; Pomare et al., 2019). One of the major aspects of uncertainty is epistemic uncertainty; this is uncertainty due to incomplete knowledge, which can either result from limited evidence or from an individual's limited ability to synthesise, interpret, and apply the evidence (Simpkin and Armstrong, 2019). Han and colleagues raised the concept of uncertainty tolerance and that HCPs develop different cognitive, emotional, and behavioural responses to uncertainty (Han et al., 2019). The authors described HCPs' responses to uncertainty as being either positive – responding with confidence and faith and being action-focused in what is viewed as an opportunity – or negative – responding with doubt and worry and avoiding decision-making or being inactive (Han et al., 2019). However, these views of responses are controversial as deciding not to do something, as a result of a considered judgement of the available evidence, is an active decision, and it is unhelpful to describe this as a negative response.

In this study, a variety of responses to the uncertainty and subjectivity surrounding ACV are observed. Despite all the uncertainties, some participants held the belief that ACV must be beneficial for patients, even if they are not directly observing benefits. This leads to an attitude of perseverance in the implementation and application of ACV. In contrast, other participants lacked confidence that they were using optimal approaches for ACV, feeling unsure when to persevere with ACV and when to stop, and feeling anxious and worried about the potential risks to patients. In some cases, the uncertainty and subjectivity seemed to lead to a level of restraint being placed on the underlying need to fix patients and the willingness to try anything. More research is needed to reduce the uncertainty and subjectivity apparent in ACV, and health economic decision-analytic modelling and a value of information framework will help to determine the level of uncertainty and direct future research. Additionally, applying a framework to help manage the uncertainty and aid decision-making – such as that outlined by Helou and colleagues – might help to reduce the variability in uncertainty management in ACV (Helou et al., 2020).

One element of the subjectivity described by participants in this study was related to ACV competencies. The Health and Safety Executive in the UK defines competence as

‘the combination of training, skills, experience and knowledge that a person has and their ability to apply them to perform a task safely’ (Health and Safety Executive, 2022). Similarly, the UK Skills for Health website describes competence as ‘the skills, knowledge and understanding needed to undertake a particular task or job to a nationally recognised level of competence’ (Skills for Health, 2022). Much of the healthcare literature related to competencies makes it clear that an assessment process is required in order to deem someone competent (Epstein and Hundert, 2002; Hanley and Higgins, 2005; Epstein, 2007; Äärі et al., 2008; Okuyama et al., 2011; Skills for Health, 2022). One method of assessment used for competencies describes four levels required for demonstrating competence: knows, knows how, shows how, does (Miller, 1990). Competencies must also be maintained, as the knowledge and skills related to a particular task will probably change over time as evidence grows (Epstein, 2007). Therefore, competency frameworks must be objective, related to specific tasks, have an assessment process which includes a practical demonstration of skills with patients, and facilitate maintenance and monitoring of competencies.

Most participants described ACV competencies – where they existed – in a subjective way, using terms such as ‘feeling competent’ and ‘feeling comfortable’ to determine competency. Although people can feel confident or comfortable performing a particular task, they cannot feel competent. These subjective descriptions of competency do not align with the definitions detailed above. This raises the question of how staff should determine and maintain competencies in ACV. There are no national or international competency frameworks for ACV, and less than 20% of participants in the international survey (Chapter 4) reported using competencies for staff assessing or delivering ACV (Mills, Michou, Bellamy, et al., 2022). Without clear standards or expectations, a consistent and objective approach to competencies is problematic (Epstein, 2007).

Competencies for ACV should ideally support an individual to be assessed and deemed competent to safely and effectively perform ACV tasks. They should include understanding and knowledge about the intervention and require individuals to demonstrate their skills and ability to perform ACV safely. Any ACV competency framework should also facilitate upskilling and competency maintenance as the evidence base evolves. As discussed by one participant, simulation may be one method to support staff in gaining practical skills in ACV. However, many participants reported substantial variability in ACV both within and between patients. Therefore, practical experience with patients is necessary in addition to simulation training to support the achievement of the ‘does’ level of competency achievement (Miller, 1990). The lack of objective competencies available to staff likely contributes to the varying approaches described, even within the same teams. Nevertheless, developing objective competencies may be problematic given the uncertainties surrounding ACV and the lack of agreement for optimal application.

The uncertainty and subjectivity seen in all aspects of ACV result in a wide variation in practice; one example is the very high airflow rates reported by some participants. Many participants describe the process of ACV as one of experimentation and trial and error, which compounds this variation in practice. The subjectivity of the outcomes observed also leads to a lack of confidence in the effectiveness of ACV, which, in combination with a lack of immediate or tangible benefits, can lead to ACV being deprioritised by staff. The uncertainty and subjectivity also result in ACV being used for different purposes, for example, purely for communication, purely for sensation and swallowing, or a combination.

There was a focus on communication as the purpose of ACV by most participants. This focus may have led to missed opportunities to observe the potential sensory and swallowing benefits of ACV; it also may have resulted in fewer patient candidates and delayed use. Those that focused more on swallowing, or had limited success with communication, reported deprioritisation of ACV by certain staff groups because swallowing benefits tend to be less tangible and have less direct benefit for staff. Staff face extreme pressure. Therefore, any intervention that assists them and reduces their burden – as well as aiding the patient – is likely to be viewed more favourably and prioritised. Some participants' focus of purpose shifted toward swallowing with increased experience with ACV. Many of those who used ACV primarily for swallowing felt that there was a lack of awareness of the benefits of ACV in this area, leading to underuse. There seemed to be an assumption amongst many participants that communication is the primary purpose and the most important benefit of ACV. This may be due to the focus on communication in the nomenclature of 'above cuff *vocalisation*' and '*talking* tracheostomy'. There was a strong emphasis on the need for more research to provide robust evidence of the benefits of ACV and reduce the uncertainty and subjectivity of ACV. An improved evidence base may help to ensure the more regular and optimised provision of ACV.

5.5.3 Theme 3: Knowledge and experience leading to control and caution

As well as increased knowledge and experience of ACV resulting in a changing focus of purpose, participants reported that increased knowledge and experience also leads to an increased need for caution. The most striking examples were some of the adverse events participants experienced and the profound effect on them and their teams. For some, these experiences were upsetting – with evidence of moral distress and feelings of guilt and betrayal of their values – and for all participants, they were concerning and led to a desire to put processes in place to protect patients, staff, and their organisation. Despite the prohibition of ACV in two settings following adverse

events, all participants wanted – and were working towards – the reinstatement of ACV, still believing in the potential value of ACV for patients.

Many participants felt that lack of knowledge and over-enthusiasm in the MDT were critical factors contributing to the unsafe use of ACV and the potential for harm. There was a lack of trust that certain team members would use ACV appropriately and anxieties about the potential patient risk. There was also self-doubt, with some participants feeling that they did not have adequate knowledge or skills to provide ACV optimally or safely. This lack of trust in self and others is probably due to the limited evidence and the uncertainties and subjectivity surrounding ACV. Newell and Swan describe different types of trust in teams; 'competence trust' is trust in another person's competence to carry out tasks (Newell and Swan, 2000). Lack of trust, both intra- and inter-professionally, has been highlighted by other researchers as a contributing factor to compromised patient care and decision-making (Vivian et al., 2009; Jones and Jones, 2011). The lack of competence trust evident in this study may be partly because many services are not using competencies, or they are using subjective competencies, perhaps leading to a lack of confidence in the competence of others. One study found that multi-disciplinary simulation training in critical care can help to improve trust between professional groups (Weller et al., 2012). Adopting such an approach for ACV training might help to improve multi-disciplinary working and implementation of ACV.

One of the critical elements of anxiety for participants was concern over the potential for laryngeal drying. This concern was apparent from the findings of the systematic review and the international survey; thus, a question was added to the topic guide regarding laryngeal mucosal drying. The systematic review (Chapter 3) demonstrated that many researchers had concerns about laryngeal drying, despite the lack of subjective or objective observations (Mills, Michou, King, et al., 2022). In the international survey, 25% of respondents reported observation of drying of the laryngeal mucosa (outlined in Section 4.4.5) (Mills, Michou, Bellamy, et al., 2022). In response to the question about laryngeal drying, none of the participants in this study reported that they had observed symptoms of laryngeal mucosal drying. However, most expressed concerns about this phenomenon occurring with the extended application of non-humidified oxygen or medical air. It is unclear whether those individuals in the survey who reported observation of laryngeal mucosal drying assumed that it was occurring – because of their concerns – or whether they have a routine method to assess for this. Further exploration is needed into laryngeal drying, as most participants reported limiting the ACV duration to prevent it.

The complexity of ACV was another reason contributing to the need for caution. There seemed to be a dichotomy between some participants who described ACV as a simple intervention and others who described it as a complex intervention requiring advanced

skills. Some individuals even described ACV as simple, whilst also recommending the need for strict processes to maintain safety. One explanation for this dichotomy is that the process of setting up ACV is simple and relatively straightforward, but the management of ACV is complex due to the variability and potential adverse outcomes. Indeed, interventions are usually deemed to be complex if they have several interacting components; are non-standardised with the need for adaptation in different contexts; have several behaviours required by those delivering or receiving the intervention; are applied to several different groups; have several and variable outcomes; and have non-linear causal pathways (Hawe et al., 2004; Craig et al., 2013). By this definition, ACV should logically be classed as a complex intervention. However, it may not be so easy to define interventions as either simple or complex, as one researcher stated: 'there are simple and complex explanations of those interventions', and an individual's perspective on complexity is dependent on the aspect of the intervention being considered (Petticrew, 2011). This aligns with the dichotomy observed amongst and within participants. Despite this dichotomy, most participants advocated for staff training, safety processes, standardisation, governance structures, clear responsibilities, good communication with the MDT, and careful patient selection.

5.5.4 Theme 4: Worth a try or a last resort

HCPs' opinions of ACV are often formed on the limited evidence available, combined with the subjective observations made during ACV use. The subjective opinions of the different participants seemed to vary widely, even when ACV was used with the same patient group. It is unclear whether these varying opinions result from this subjectivity or are related to differences in application (e.g., continuous flow versus intermittent flow, non-humidified oxygen versus humidified medical air, and different brands of tracheostomy tubes).

The spectrum of opinion on ACV ranged from believing ACV was life-saving for some patients to thinking it was worth a try, and at the other end, thinking ACV was a last resort. Observing patients' positive experiences with ACV had a marked positive impact on HCPs' opinions and application of ACV. These participants routinely considered the use of ACV with all patients, but these individuals tended to have a primary focus targeting sensation and swallowing rather than communication, where limited numbers of patients meet the requirement to be alert and cognitively intact. It is striking that despite the uncertainties about effects and risks – and in the face of the profound impact of negative experiences – ACV seems to be considered worth trying by many. The rationale for ACV being 'worth a try' was the limited number of intervention options available and the underlying burden of needing to fix patients. The lack of viable alternative treatment options seems to outweigh the concerns over the

lack of evidence for efficacy and safety, and there is a willingness to try anything that might improve patient outcomes.

Most participants considered cuff deflation the best option for patients, with ACV a second-line option at best. Those who were largely successful in using early cuff deflation tended to have very little need for ACV and rarely used it. Many participants considered ACV a last resort for their patients when all else had failed. For some, equipment issues played into these opinions, as using ACV became too much effort. For others, they preferred to stick to interventions that they knew and felt comfortable with. The limited staffing resource and pressures staff face may also precipitate the belief that it is not worth using their limited resources on ACV, given the underlying uncertainties. In particular, the complexities and inefficiencies with training large numbers of nursing staff were reported to be difficult to justify with small numbers of appropriate patients.

There seems to be a discrepancy between the participants who contemplate using ACV infrequently or believe it is a last resort, those who consider it worth trying, and those who think it is life-saving and consider it routinely for all patients. What is unclear is how these latter participants have arrived at this mindset. It could result from research experience, patient group, staffing levels, clinical experience with ACV, the approach used, or the purpose for which it is used.

5.5.4.1 Sub-Theme A: Part of the toolbox

Most participants considered ACV part of their toolbox, often as a bridge to cuff deflation. The decision for ACV to be added to their toolbox seemed to primarily rely on their personal experiences with ACV, or the experiences reported by others, rather than the evidence base itself. Pearson *et al.* state that it is common for clinicians to adopt interventions despite limited research available due to having to respond to patient needs pragmatically (Pearson et al., 2005). Furthermore, HCPs have been shown to make decisions contrary to compelling evidence and guidance (Eskes et al., 2012; Cuthbertson, 2018). The consideration that ACV is deemed simple and safe also contributed to the inclusion of ACV in their toolbox. Nevertheless, there was considerable variation as to its position. Those who usually used cuff deflation later in the patient journey tended to place ACV near the top of their toolbox and use it frequently. Conversely, those favouring early cuff deflation and OWV use or leak speech tended to have ACV at the bottom of their toolbox as a last resort. However, there is a catch-22 for those participants who use ACV rarely: infrequent use leads to a lack of familiarity and a need to re-orient to the process each time it is used.

5.5.4.2 Sub-theme B: Useful but limited tool

Although ACV was in most participants' toolboxes, many considered it a useful but limited tool. Participants described ACV as a tool with both inter- and intra-patient variability. This variability is problematic in terms of handover to nursing staff and ensuring regular provision. Most participants thought that there was a lack of consistency and functionality of ACV for communication. This often led to participants not persevering with ACV for communication. Many believed ACV was only suitable for a niche group of patients and only for a small window of opportunity. This contributes to the catch-22 of infrequent use, as limited use leads to issues in staff training and maintaining skills and knowledge. It may be that different staff have varying thresholds for perseverance, with those staff that believe ACV works being willing to persevere, even when there is no obvious benefit. In contrast, the more sceptical staff will stop ACV quickly.

5.5.4.3 Sub-theme C: Following the patient's lead

Participants highlighted the importance of following the patient's lead, supporting them to participate in decision-making about ACV wherever possible, and ensuring that goals are patient-centred and meaningful. Shared decision-making with patients is even more critical in the context of the uncertainties surrounding ACV, and it is important to discuss those uncertainties openly with patients to facilitate informed decision-making (Simpkin and Armstrong, 2019; Gheihman et al., 2020). Active partnership between staff, patients, and family is key to ensuring they can fully participate in care and decision-making (Brown et al., 2015; Burns et al., 2018).

Following the patient's lead with ACV means many participants stop trials due to patient discomfort and choice. Discomfort and dislike of ACV seem to be a particular problem for those receiving ACV for communication, with the higher airflow rates than are typically used for swallowing and sensation purposes. However, there seems to be considerable variability in the experiences of patients, even those from the same patient group, and it is unclear as to what is causing these differences. Possible factors contributing to the variability in experience are individual sensitivity differences, variable application of airflows, differences in the brand of the tracheostomy tube, and differences in the level of support and training provided. Some participants stated that perseverance was vital for patients to become accustomed to the initial discomfort. Despite the patient discomfort reported by most participants, it is clear that for some patients, even minor, non-functional benefits can be enough to provide patients with a positive, humanising experience that helps return some of their sense of identity.

Some participants reported a discrepancy between staff readiness and staff goals versus patient readiness and patient goals. Similar findings have been found in early

physical rehabilitation in the ICU, with key barriers to early rehabilitation including differing goals, cooperation, engagement, and motivation (Parry et al., 2017). One striking point raised was the difference between interventions focused on QoL – such as communication – versus interventions focused on rehabilitation – such as swallowing. One participant thought patients were much more willing to experience discomfort for something that would make them better but less willing to experience discomfort for something purely about improving their QoL. In those circumstances where there was discomfort, the patient often opted for a different communication method or preferred to wait for cuff deflation.

5.5.5 Theme 5: Limited consideration of COVID-19 or starting from scratch

The impact of COVID-19 on ACV use appears to depend on international location and the clinical setting. Limited consideration of COVID-19 was given in post-ICU settings, where COVID-19 was less of an issue because patients were unlikely to be infectious. Likewise, it was given limited consideration in countries where the prevalence of COVID-19 was lower. There was also limited consideration in COVID-19 ICUs, where higher levels of PPE were worn continually, and there were no added concerns about the risk of transmission from using ACV. There were various practice changes reported by some participants, such as a reduction in the number of tracheostomies inserted and increased use of adjustable flange tubes – that do not have a subglottic port – which resulted in a reduction in the use of ACV. However, the decrease in the number of tracheostomies reported by some participants, predominantly from countries with lower levels of COVID-19, is not borne out in the literature, which generally reported higher levels of tracheostomy insertion (McGrath, Ashby, et al., 2020; Williams and McGrath, 2021).

For many participants in regions severely affected by COVID-19, it profoundly impacted ACV use. ACV was either forgotten, with all the added stresses and pressures, or deprioritised as unnecessary. Concerns about the risk of transmission also resulted in a reduction, or complete discontinuance, of ACV. Participants who experienced this extreme impact of COVID-19 described feeling like they were starting from scratch with ACV. Despite the halting or discontinuation of ACV, there does not appear to have been a long-lasting impact or altered opinions of its use. Many participants felt that some of the processes and risk assessments introduced due to COVID-19 would remain post-pandemic.

5.5.6 Reflexivity

Reflexivity, and the critical reflection on the personal position of the researcher and how this influences the knowledge produced, is an essential component of reflexive

thematic analysis (Clarke and Braun, 2021). No interviewer or researcher is 'naïve'; everybody comes with underlying knowledge and experience, which influences their outlook and interpretation of what others say (Finlay, 2002; Le Gallais, 2008). Regarding personal reflexivity, the candidate is a Clinical Specialist Speech and Language Therapist with 15 years of clinical experience, 12 of which have included working with patients with tracheostomies. Due to the candidate having worked in various hospitals and participated in multiple committees, she knew four SLTs and two PTs professionally. This could have influenced the conduct of the interviews and may have led to these participants being more relaxed in their answers. The candidate was both an insider, as a HCP using ACV, and an outsider when speaking to non-SLTs. Speech and language therapy participants may have been more open in discussing other professional groups. Conversely, non-speech and language therapy participants may have been more circumspect with any comments regarding SLTs or how ACV should be used.

The position of the candidate and her assumptions about ACV as a result of her knowledge and experience will have influenced the analysis and interpretation of the data. The candidate first used ACV in 2012 in an acute ward setting and has used it more regularly since 2016 in intensive care. The candidate's experience with ACV has been mixed, with only two patients having real success from a communication perspective and those for a very short period of one or two days. However, from a swallowing perspective, the candidate believes that most, if not all, participants benefit from the restoration of airflow, with the observation that most patients start to swallow spontaneously where they had not been swallowing previously. The candidate has indirectly experienced two adverse events related to ACV; these experiences led to the candidate increasing the safety processes to try to reduce the risk of further events. To counteract some of the candidate's negative perceptions regarding the use of ACV for communication as the interviews progressed, she actively searched each transcript for positive comments about ACV.

Many of the participants' responses mirrored those of the candidate, particularly concerning the occurrence of adverse events. The candidate and other staff members felt there was an increased need for control and caution in ACV use, and there seemed to be an underlying fear that ACV would be prohibited if there were any further incidents. Similarly, as the candidate's knowledge of ACV increased, especially following the critical appraisal of the ACV research for the systematic review, this feeling of a 'need for caution' was further augmented.

The candidate has also developed a theory concerning the different brands of tracheostomy tubes. The varying designs of tracheostomy tubes (subglottic port diameters and exits) will presumably lead to different airflow velocities and pressures

applied to the laryngo-tracheal mucosa, with variable outcomes and comfort. They may also require altered application approaches to adjust for these differences. However, five participants were using two different brands of tracheostomy tubes to deliver ACV and did not report any differences in outcome or application.

5.5.7 Study strengths and limitations

The sample size of 24 participants is slightly larger than average for qualitative interviews in the ICU specialty, with one systematic review reporting a median of 19 HCPs interviewed (Anderson et al., 2019). Semi-structured interviews allowed the adaptation of questions and flexibility to respond to the participant's direction. The topic guide was adapted before and during the data generation phase. This enabled the addition of questions as new key issues arose, such as a question on the impact of ACV on LoS. Purposeful sampling improved the spread of respondents from different professional groups, countries, and with varying experience levels. However, the purposeful sampling criteria were not completely achieved, possibly partly due to the impact of the pandemic and partly due to the limited uptake of ACV and the limited involvement of certain professional groups. It was not possible to recruit any doctors or respiratory therapists to the study, and only one ACCP (nursing background) and one nurse (a tracheostomy specialist nurse) were recruited. The international survey (Chapter 4) found that 25% of respondents stated that doctors were involved in ACV assessments in their settings. For this reason, it would have been useful to have some representation of doctors in the sample. In contrast, just 8% of respondents stated that nurses were involved in ACV delivery, which might explain some of the challenges in recruiting nursing staff. There was a predominance of SLTs recruited, which is probably partly because the candidate is an SLT with a good speech and language therapy network and partly because SLTs are generally more involved in ACV, as it is an intervention focusing on communication and swallowing. There was also a higher proportion of staff from the UK, and secondarily, from Australia. Again, this may be due to the disproportionate use of ACV in these two countries, which the interviewing of participants from other countries confirmed. Recruitment was problematic due to the staffing issues and pressures faced by ICU staff during the COVID-19 pandemic. Employing incentives may have helped to improve recruitment but would have required a further amendment submission to the ethical review board. Due to an unforeseen interruption to the study, interviews were conducted over 13 months, with a gap of seven months. This may have affected the responses obtained, but it also may have helped to provide a broader spectrum of responses from different stages of the pandemic.

Individual interviews allowed participants to talk freely and openly about their experiences without the risk of judgement from other individuals. It is unlikely that some

of the discussions around the lack of trust in some other members of staff and other professional groups would have occurred if focus groups with mixed professional groups had been used. Focus groups may also not have facilitated such open discussion around some of the negative experiences. On the other hand, focus groups may have allowed participants to refine their views through dialogue with others with contrasting experiences and opinions.

5.5.8 Implications for clinicians and researchers

This study has highlighted the variability of implementation and uptake of ACV. Some of this could be part of the phenomenon described by Dixon-Woods and colleagues where innovations with limited evidence are sometimes implemented rapidly (Dixon-Woods et al., 2011). The authors describe rapid adoption occurring because of excitement about a new intervention combined with 'magical thinking, where doing something is seen as better than doing nothing' (Dixon-Woods et al., 2011). These ideas of newness and 'doing something' were frequently discussed by the participants in this study. Conversely, the authors state that interventions with a strong evidence base that are unexciting or not advertised well or widely are sometimes implemented in a very limited way (Dixon-Woods et al., 2011). They emphasise the importance of applying a formal approach to the adoption of new interventions or innovations to improve the implementation process (Dixon-Woods et al., 2011).

There are various frameworks and approaches to implementation science that can be used to improve and capture data on the process (Wensing, 2015), one of which is the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009). This framework incorporates five major domains: (i) the characteristics of the intervention; (ii) the inner setting (i.e., the context where implementation will occur, such as a hospital); (iii) the outer setting (i.e., the setting where the inner setting or organisation sits, such as the NHS); (iv) the individuals involved in implementation; and (v) the process of implementation (Damschroder et al., 2009). In particular, the use of CFIR before implementing an intervention has been shown to support the adaption and redesign of the strategy to optimise successful implementation (Kirk et al., 2016). Using a framework, such as the CFIR, might help standardise and optimise the implementation of ACV more widely.

Some of the subjectivity and uncertainties surrounding ACV might be improved with robust, standardised protocols, guidance, and competencies. In particular, developing objective competencies that can be implemented robustly would help to ensure consistent and safe practice. However, whether there would be a sufficient consensus regarding safe practices to develop and agree on international competencies is unclear. Using simulation may help provide opportunities for staff to practise the practical skills required for ACV. A wider focus of purpose for ACV could maximise the

potential benefits for ACV, rather than focusing purely on communication or purely on swallowing. In particular, expanding the use to swallowing in addition to communication could contribute to earlier use and a greater number of potential candidates, as the target population would be much wider than purely those that are cognitively intact, awake and attempting to communicate. Ensuring more regular use would also help to support the maintenance of competencies and avoid the need for re-orientation each time ACV is used.

Serious adverse events can lead to the prohibition of ACV in some circumstances. A careful and measured introduction of ACV may help to prevent adverse events and the potential for use to be discontinued. Implementing standardised procedures, safety processes, and competencies – alongside thorough training of all staff involved – might help to reduce the frequency of incidents, protecting patients, staff, and hospitals. The profound impact and moral distress experienced by one participant may have been exacerbated by perceived abandonment by the rest of the team and feeling solely responsible. This underscores the importance of an MDT approach which ensures shared responsibilities for successes and failures. There should also be an MDT focus on following the patient's lead with respect to ACV and ensuring that meaningful, patient-focused goals are developed jointly with patients where possible.

Many respondents provided examples of troubleshooting techniques and approaches that they recommended to maximise safety; these have been compiled in Table 21.

Table 21 Potential issues and troubleshooting suggestions

Potential issue	Trouble-shooting suggestion	Source
Tracheal dilation from misapplication of the airflow to the pilot balloon	Provide pictorial guidelines for staff	SLT 1
	Label the pilot balloon and the subglottic port	SLT 5 Nurse 1
	Place signage on the door	SLT 5
Drying or irritation of the laryngeal mucosa	Using a thumb port to allow intermittent flow	SLT 1
	Connect to a humidifier bubbler	SLT 5
Concerns about adverse events	Ensure two staff are present for the initial assessment	SLT 13
Air trapping/Subcutaneous emphysema	Use a thumb port to provide a breaking mechanism	SLT 1
	Apply air to the subglottic port using a 10 mL syringe – resistance may	SLT 2

	indicate upper airway obstruction or poor positioning of the tracheostomy	
Abdominal distension	Disconnect airflow when not in use	Nurse 1
	Do not leave the thumb port permanently in situ with airflow running with patients with cognitive deficits	SLT 5
	Position the tubing so that nothing can fall on it	Nurse 1
	Place signage to alert staff	Nurse 1
Difficulty accessing thumb ports	Cut a hole in the green bubble tubing to act as a thumb port	ACCP 1
Lack of synchronisation of vocal fold adduction with airflow	Only apply airflow on exhalation by following the breathing rhythm	OT 1
	Training with an SLT to synchronise vocalisation with exhalation and minimise vocal strain	PT 2
Lack of vocalisation	Persevere	SLT 4; SLT 8; ACCP 1
	Sit upright or out in a chair	SLT 8
	Change head position, e.g., head turn	SLT 5
	Providing support and training	SLT 12
Difficulties with independent use	Modify the tubing to place the thumb port further from the tracheostomy	SLT 6
	Use material around the thumb port hole (e.g. brad flex) to reduce movement/dexterity needed for a patient to achieve occlusion	SLT 6
Lack of use	Work with family to support and encourage ACV use	SLT 8; SLT 11
Incorrect use	Good signage, handover and staff education	PT 8
Discomfort	Pause airflow during swallowing	OT 1
	Prepare patients first by letting them feel the airflow against their cheek	SLT 11

The uncertainty surrounding ACV is impacting its use and causing limited uptake by some individuals. One participant suggested where future research should focus:

> "Well, that's the important stuff to hear too, like: what are the reasons we're not using it? Because that's probably where the research and everything needs to go for now, isn't it? Well, what are the limitations and how can we overcome that, can it be more beneficial?" [SLT 7]

5.6 Summary

This study explored the experiences and opinions of HCPs of ACV. Underlying HCPs' motivations and opinions about ACV seems to be the moral distress they experience which amplifies their essential 'need to fix' patients and may influence their opinions and decisions regarding ACV. Furthermore, the underlying subjectivities and uncertainties surrounding ACV mean opinions appear to be formed primarily based on experience. These experiences will probably be impacted by the purpose for which they use ACV and their application approach. Additionally, they probably explain the various opinions observed, with many considering ACV worth a try or a last resort. As knowledge and experience of ACV increase, the belief that there is a need for caution to protect patients and staff also increases. More research is needed to reduce the subjectivities and uncertainties surrounding ACV, provide more guidance for application, and support the development of objective competencies.

One of the issues raised in this study was that there seemed to be a generally widely held belief amongst the MDT that ACV was not worth the effort or cost of changing the tracheostomy tube purely to enable ACV use. Establishing the cost-effectiveness of ACV is essential to support decision-making regarding the use of ACV. Chapter 6 evaluates the cost-effectiveness of ACV using an early-stage decision-analytic health economic model. An application of Value of Information (VOI) analysis principles identifies information gaps to inform current adoption decisions and determine the direction and value of future research.

Chapter 6 An Early-Stage Decision-Analytic Health Economic Model of ACV

This chapter describes the development of an early-stage decision-analytic health economic model for ACV and an application of Value of Information (VOI) framework principles. Section 6.1 introduces decision-analytic modelling, reimbursement decision-making in healthcare, VOI analysis, and early-stage modelling. Section 6.2 describes the study's aims and objectives, and Section 6.3 discusses the rationale for the study. Section 6.4 outlines the model structure, parametrisation and analysis. Section 6.5 reports the results of the model and the sensitivity analyses. Section 6.6 discusses the findings, and Section 6.7 summarises this chapter.

6.1 Introduction

6.1.1 Health economic evaluation

A health economic evaluation allows different interventions (i.e., medical devices, surgery, pharmaceutical treatments, behavioural interventions) to be compared in terms of their costs and effects (Husereau et al., 2022). The aim of a health economic evaluation is not to demonstrate cost savings; the objective is to maximise the quality-adjusted life-years (QALYs) for patients given a fixed budget (Rudmik and Drummond, 2013). As discussed in Chapter 2, QALYs are the preferred outcome measure for Health-Related Quality of Life (HRQoL) in the UK (NICE, 2013). This outcome measures an individual's health state incorporating both duration and QoL, with perfect health equal to one and death equal to zero (Whitehead and Ali, 2010). A QALY of one is the equivalent of one year of perfect health (Whitehead and Ali, 2010). It is also possible for an individual to have a negative QALY, where their health state is worse than death (e.g., ICU patients). The willingness-to-pay (WTP) threshold is the maximum amount that the decision-maker is willing to pay per additional QALY. In the UK, this is usually set at £20,000 to £30,000 per incremental QALY (McCabe et al., 2008).

Health economic evaluation broadly involves calculating expected outcomes and expected costs for each treatment option. These values are then used to calculate the incremental cost (i.e., the extra cost of the new treatment compared to usual care (UC)) and the incremental effect (i.e., the extra positive effect of the new treatment compared to UC). These are used to calculate the treatment's incremental cost-effectiveness ratio (ICER) (Bambha and Kim, 2004). An ICER is the additional cost per addition of one unit of health utility, e.g., 1 QALY. If a new intervention 'dominates', then this means that the new intervention is more effective and less costly than the comparison intervention. If a new intervention is 'dominated', then the new intervention is more

expensive and less effective than the comparison intervention (Cohen and Reynolds, 2008). These figures can then be used, in conjunction with the WTP threshold, to decide whether to adopt the new treatment.

Other equivalent calculations also provide important information about the results of the health economic evaluation. The incremental net monetary benefit (INMB) is calculated by multiplying the incremental benefit by the WTP threshold and subtracting the incremental cost (Craig and Black, 2001). This statistic provides information about whether an intervention is cost-effective compared with an alternative intervention with respect to a specific WTP threshold. A positive INMB value indicates cost-effectiveness. The incremental net health benefit (INHB) is calculated by dividing the incremental cost by the WTP threshold and subtracting this from the incremental benefit (Paulden, 2020). This statistic provides information about the impact of the intervention on health, with a positive result indicating that patient health increases because of the new intervention. In contrast, a negative INHB suggests that any health benefits from the new intervention are outweighed by other health losses (Craig and Black, 2001).

6.1.2 Decision-Analytic Modelling

As discussed in Chapter 2, a Decision-Analytic Model (DAM) is a mathematical framework used in health economics to estimate the consequences of a healthcare decision in terms of costs and effects (Caro et al., 2012). Models are particularly useful to support decision-making for interventions where data is limited and there is uncertainty associated with outcomes (Buxton, 2006). A DAM provides information to support decision-makers in the selection of the most cost-effective healthcare interventions by providing a simple representation of complex healthcare decisions (Caro et al., 2012). Decision-analytic modelling enables decision-makers to make informed and rational choices about which clinical approaches should be adopted regardless of the quantity or quality of the evidence (Dowie, 1996; Sculpher et al., 2000; Elwyn et al., 2001). It also allows us to incorporate patients' attitudes and views into the decision-making process (Elwyn et al., 2001).

When used in healthcare, a DAM imposes structure on the decision problem by mapping a clinical pathway using evidence-based probabilities and utilities to estimate outcomes and cost-effectiveness for a hypothetical patient cohort (Schwartz, 1979; Sculpher et al., 2000; Siebert et al., 2012). Probabilities reflect the chance that a certain outcome will occur and they are usually estimated from the relevant evidence base. Where evidence is lacking, models may need to rely on expert opinion (Paisley, 2016). Utilities represent the strength of preference or value for different health states; as with probabilities, these are usually taken from research data or expert opinion (Briggs et al., 2012). Utilities that are accumulated over time are used to estimate

QALYs (Whitehead and Ali, 2010). Discounting is also often applied to a DAM; this ensures that costs and utilities are adjusted to account for the fact that the value of money and the value that individuals place on their health is unstable and typically depreciates over time (Attema et al., 2018). Sensitivity analysis evaluates the impact of uncertainty in the model parameters (e.g., probabilities, utilities, or costs). This analysis enables a level of confidence to be ascribed to the results, as well as the identification of parameters that have a particular impact on the results (Briggs et al., 1994).

There are three common types of DAMs in ascending order of complexity: decision trees, Markov models, and patient-level simulation. This early-stage DAM incorporates a decision tree and two Markov models.

Firstly, decision trees are the most widely used DAM and present a simple pathway for a hypothetical group of patients to pass through until they reach an endpoint, with utilities and costs assigned to each endpoint (Brennan et al., 2006). They are then combined with the probability of reaching a particular endpoint to calculate cost-effectiveness for different pathways of the tree (Rudmik and Drummond, 2013). Within decision trees, there is a one-way direction of travel, with no option for patients to return to previous states; therefore, if this needs to be incorporated into the model, additional nodes and branches must be added. This can increase the complexity of a decision tree. It is also not possible to explicitly capture the passage of time within this type of model, and evaluating the impact of patients staying in one state for a prolonged period is complex (Siebert et al., 2012). This ability of capturing time can be particularly important, especially in critical care models where the impact of patients staying in one state for a prolonged period could significantly impact costs by increasing ICU LoS. This impact on ICU LoS would be difficult to capture in a decision tree.

Second in order of complexity, Markov models comprise mutually exclusive health states, with patients only being able to exist in one state during each model cycle (Briggs and Sculpher, 1998). At each cycle, patients can move to another state or remain in their current state based on transition probabilities. Within each cycle, cost and utility estimates are assigned to each state. The cycle length can be any time period set by the modeller depending on the disease or intervention being evaluated (e.g., one hour, one day, or three months). Within Markov models, a time horizon entails the total duration of the model which should be long enough to capture all the effects and costs the intervention might impact; often this requires simulation of a lifetime time horizon (Sculpher et al., 2000).

A Markov model is run through cycles with a cohort of hypothetical patients, once for the intervention of interest and once for UC or the comparator intervention. Costs and utilities from all cycles are summed up – while taking into account the probabilities and

the time spent in each state – to calculate the QALYs and the cost-effectiveness for different scenarios (Briggs and Sculpher, 1998). Markov models can capture more complexity than decision trees and attempt to display this complexity in a simplified format (Siebert et al., 2012). As data for utilities and costs are accumulated for each cycle, this modelling approach can capture the impact of time spent in each health state for an arbitrary cycle length, unlike decision trees.

One limitation of Markov models is that they are 'memoryless'; once a patient has passed from one state to another, no information is retained about where that patient has been or for what duration (Briggs and Sculpher, 1998). This means that costs, utilities, and transition probabilities remain fixed for all patients regardless of their previous history (Barton et al., 2004). This information may be of interest in some evaluations where a previous event is likely to affect a future outcome. An example of this in the critical care specialty is that patients requiring re-intubation have a 15% higher mortality rate than those not requiring re-intubation (Menon et al., 2012). Markov models can be adapted to facilitate the capture of this data, but this might require several health states thereby making the model structure more complex.

Lastly, patient-level simulation or micro-simulation is another type of model that can more easily incorporate information about previous events and tends to be the model of choice to include this feature (Karnon et al., 2012).

6.1.3 Value of Information

There is often considerable structural and parameter uncertainty in health economic DAMs. The results of a DAM can be used to conduct a VOI analysis to estimate the cost of conducting further research to obtain additional information that would facilitate the reduction of uncertainty in the model (Wilson, 2015). VOI provides a structured, methodological approach to prioritise future research and establish optimal research design (Jackson et al., 2022). Specifically, this involves calculating a range of different outcomes including the expected net health benefit (ENHB), the expected value of perfect information (EVPI), the expected value of perfect parameter information (EVPPI), and the expected value of sample information (EVSI) (Eckermann and Willan, 2007). The ENHB estimates the health benefits to the population from the new intervention. The EVPI estimates the total cost of uncertainty by calculating the difference between the expected net benefit with perfect information – where all uncertainty and the possibility of making the wrong decision is eliminated – and the expected net benefit with the currently available information (Rothery et al., 2020). This value is the maximum amount a healthcare system should spend on research to obtain additional information for the entire applicable population for the lifetime of the technology or intervention. This supports decision-makers in making conclusions

regarding the adoption or rejection of a particular intervention and whether further research is needed before this decision can be made (Tuffaha, 2021).

The EVPPI calculates the expected value of perfect information for single or a combination of model parameters. This enables research prioritisation and the focus of research on those parameters likely to have a particular impact on the cost-effectiveness of the intervention (Fenwick et al., 2020). The EVSI allows the evaluation of specific potential research study designs, with a given sample size, to calculate the estimated VOI. The combination of the EVPI, the EVPPI, and the EVSI supports informed decision-making regarding the adoption of interventions and guides the direction of research to focus on areas that will provide the most value for money (Wilson, 2015; Fenwick et al., 2020).

To conduct a formal VOI analysis, the uncertainty within the model must be presented with parametric distributions (Fenwick et al., 2020). In early-stage modelling, parametric distributions for the data may not be available when the evidence base is limited, as with ACV. Artificially imposing parametric distributions on this poor-quality data can lead to overconfidence in the findings of a VOI analysis. Alternatively, the principles of VOI analysis can be applied using sensitivity analysis by considering the results with the VOI perspective. The VOI perspective is that it is possible to make the wrong decision about adopting an intervention, which would have consequences for QALYs and costs (Tuffaha et al., 2014). Therefore, it is essential to identify the critical areas of uncertainty that impact these consequences most. Given the limited and low-quality evidence underpinning the model being presented in the thesis, this early-stage DAM will employ VOI principles rather than conduct a formal VOI analysis.

6.1.4 Reimbursement decision-making in healthcare

To adopt a novel technology or intervention, reimbursement decisions must be made. Edlin *et al.* described the potential reimbursement decision options as a pyramid, where full reimbursement for an intervention with no recommendations for research is placed at the base of the pyramid, and no funding for the intervention with no recommendations for research is found at the top (Edlin et al., 2014). Decision-analytic modelling, and specifically VOI, can help to provide information to inform decision-making and the choice of reimbursement options on the pyramid (Jackson et al., 2022). If results from a DAM cost-effectiveness analysis indicate that a new intervention is dominant, costing less and providing more benefits than the comparator, then the new intervention is cost-effective. However, if a new intervention is not dominant, it may still be cost-effective according to the WTP threshold. In this situation, the ICER is compared to the WTP threshold; if the ICER is less than this threshold, then the intervention is determined to be cost-effective; if it is above this threshold, then the intervention is deemed not to be cost-effective (Rudmik and Drummond, 2013). The

ICER can also be compared to the ICERs of other interventions that might be removed or used less to fund this new intervention (Paulden, 2020). When funders select conditional reimbursement decisions, where further research is needed, risk sharing or intervention access with evidence development schemes can be implemented. These schemes, often part-funded by the manufacturer in the case of pharmaceuticals or medical devices, help to reduce the risk of making wrong decisions because of uncertainty (Edlin et al., 2014). VOI is a crucial component of reimbursement decision-making (Fenwick et al., 2020).

6.1.5 Early-stage modelling

Early-stage DAMs are important for various reasons. Firstly, they can help to reduce the risks associated with early adoption of an intervention in the context of limited and uncertain evidence (Love-Koh, 2020). These early-stage models are most useful for researchers, manufacturers, and early adopters of an intervention as they inform go/no-go decisions regarding new interventions (Annemans et al., 2000). Secondly, these early-stage models should be iterative and adaptable over time which, in turn, can help to facilitate more efficient future research (Sculpher et al., 1997; Abel et al., 2019).

Arguably, the most important reason for early-stage DAMs is to identify critical evidence gaps, using VOI principles, to direct future research (Love-Koh, 2020). Early-stage models can provide a foundation and direction for future robust modelling once more evidence is generated (Annemans et al., 2000). Early-stage economic evaluation of new interventions can help to ensure that research funding is directed appropriately and used efficiently (IJzerman and Steuten, 2011).

There are limitations with early-stage modelling associated with the limited evidence available to input into the model and, consequently, a heavy reliance on expert opinion. There is usually high uncertainty in an early-stage DAM and, consequently, the output is generally described as ‘potential cost-effectiveness’ (Love-Koh, 2020). Results from an early-stage DAM must be interpreted cautiously because there is likely to be considerable uncertainty in many model parameters (Abel et al., 2019). To overcome uncertainty surrounding model parameters, it is vital to conduct adaptive reviews of the literature alongside the elicitation of expert opinion (Abel et al., 2019). A thorough consultation with clinical experts is needed to ensure that the clinical pathway mapped in the model reflects actual clinical practice and that parameters are as accurate as possible (Roberts et al., 2012).

Uncertainty is inherent in any DAM, but particularly in the context of an early-stage DAM because of the limited and potentially low-quality evidence available. Structural uncertainty (i.e., the uncertainty of the model structure), is of particular concern in

early-stage models (IJzerman and Steuten, 2011). Sensitivity analysis must be conducted to ensure that the impact of parameter and structural uncertainty on model results is captured (Annemans et al., 2000). Probabilistic sensitivity analysis is the most commonly used form of sensitivity analysis, and involves quantifying the levels of confidence associated with each parameter in the form of distributions around the parameter estimate (Briggs et al., 1994). However, probabilistic sensitivity analysis can lead to over-confidence in the findings of an evaluation and the development of pseudo-certainty that an intervention is, or is not, cost-effective (Grutters et al., 2015). Deterministic sensitivity analysis is believed to be one of the most valuable forms of sensitivity analyses for early-stage models (Grutters et al., 2019). This analysis involves manually changing the parameter values to evaluate the impact of changing these values on the cost-effectiveness analysis.

6.2 Study objective

This study explored the following thesis objective:

- Objective 6: To evaluate current expected cost-effectiveness using an early-stage decision-analytic health economic model and an application of VOI framework principles to identify information gaps to inform current adoption decisions and identify the value of future research.

6.3 Rationale for the study

An economic evaluation of ACV was initially planned as a component of a feasibility RCT. Following changes to this programme of research as a result of the COVID-19 pandemic, rather than excluding the health economic evaluation entirely, the decision was made to develop an early-stage DAM for ACV to allow the synthesis of the available evidence and facilitate the estimation of the clinical and cost-effectiveness of ACV. The previous studies (Chapters 3, 4, and 5) highlighted the limited evidence available and the variation in clinical practice. Modelling is particularly important for ACV because none of the available studies contains all the evidence needed to judge cost-effectiveness. Specifically, they included minimal information on HRQoL and survival, and appropriate comparators have not been examined. Additionally, each of the studies had a short follow-up and may not have captured the costs and benefits of ACV beyond the study duration. The previous work in the thesis (Chapters 4 and 5), has also revealed the uncertainties clinicians face over whether to adopt ACV as an intervention. Additionally, it is unclear under which circumstances they should stop using ACV with individuals or de-adopt ACV. An early-stage DAM for ACV will provide decision-makers with more information to support their reimbursement choices concerning ACV and will also help to direct future research.

6.4 Methods

Ethical approval was not required, as parameters for the model were obtained from the research literature and clinical and patient experts from the research advisory group and PCPI group. This cost-effectiveness analysis followed the approach recommended by the National Institute for Health and Clinical Excellence (NICE) for undertaking cost-effectiveness analyses for technology appraisals (NICE, 2013) and is reported according to the Consolidated Health Economic Evaluating Reporting Standards (CHEERS) statement (Husereau et al., 2022).

6.4.1 Model design

The first step in developing the new health economic DAM for ACV involved a rapid literature review to ascertain if a published model could be used or adapted. Searches were conducted in Medline, Embase, CINAHL, EconLit, Web of science, and NHS Economic Evaluation Database Centre for Reviews and Dissemination (NHS EED CRD). The search strategy aimed to identify papers related to health economic modelling in tracheostomy, decannulation, and extubation (Appendix E outlines the search strategy for Medline and the breakdown of search results). The literature review identified 12 models (described in Section 6.5.1). None of these models, however, were suitable for use or adaptation, because they were not evaluating the clinical pathway of interest or they did not use appropriate states, cycle lengths or time horizons. Therefore, it was decided to develop a de novo model. This model was refined through multiple iterations from feedback and input from experts from the research advisory group (two SLTs, one critical care nurse, two intensivists, a patient representative, a family representative, a methodologist, an SLT manager, and a health economist).

6.4.2 Model structure

The structure of the model was developed iteratively and constructed using Microsoft® Excel® for Microsoft 365 MSO (Version 2301). Figure 15 illustrates the structure of the model, which entails the following components:

1. **An initial Markov model** – which maps the pathway of tracheostomy from 72 hours after insertion to ‘decannulated’ or ‘not decannulated’ in the ICU.
2. **A decision tree** – which maps four end states in the ICU, the ward, and in the first two years after discharge from hospital.
3. **A final Markov model** – which tracks the potential outcomes for these end states until death.

The model structure is relatively complex, with a 3-part hybrid model being particularly unusual. This structure was required to incorporate the complexity of the tracheostomy

weaning pathway from the ICU to death. It also is a product of the limited but focused data available. For example, more evidence was available for the first two years after discharge, but there was little evidence beyond this.

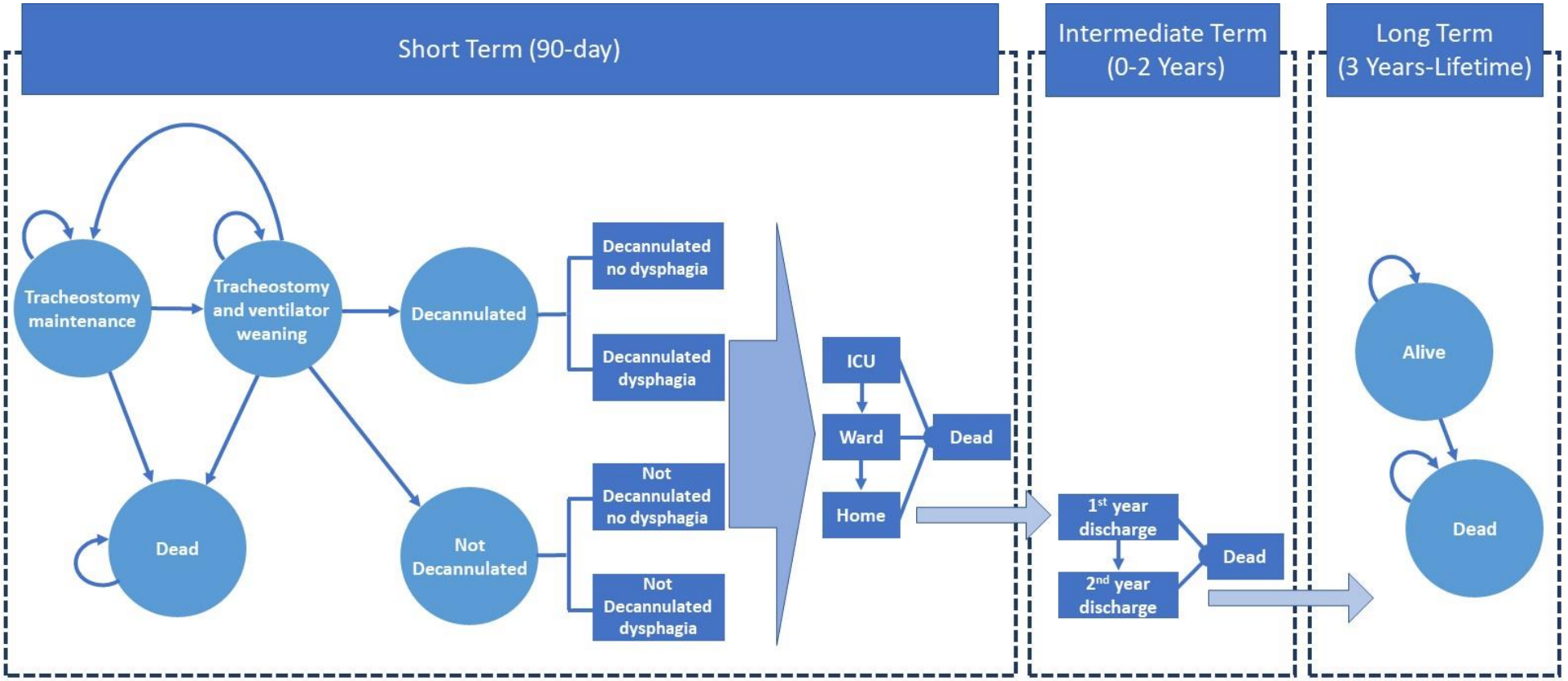

Figure 15 Decision-analytic model for ACV illustrating the three stages of the model. The Markov portions of the model have circular states, and the decision tree portion of the model has rectangular states.

The initial Markov model includes four health states to capture the tracheostomy weaning process in the ICU. States include: 'tracheostomy maintenance', 'tracheostomy and ventilator weaning', 'decannulated', 'not decannulated', and 'dead'. Tracheostomy weaning was defined as the process of weaning from the tracheostomy tube itself (i.e. cuff deflation). Ventilator weaning was defined as the process of weaning from the ventilator. Therefore, 'tracheostomy and ventilator weaning' is a state where either or both types of weaning occur. Hypothetical patients in the model can transition from 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning' and vice versa, illustrating that progression and deterioration in weaning is possible. Patients can transition from 'tracheostomy maintenance' to 'dead' and 'tracheostomy and ventilator weaning' to 'dead'. ACV can be delivered in the 'tracheostomy maintenance' and the 'tracheostomy and ventilator weaning' states. Patients reaching the 'decannulated' or 'not decannulated' states were required to spend one day in that state before moving to the end states in the decision tree.

The cycle length for the initial Markov model is one day, which is appropriate for the progress that patients with a tracheostomy typically make in the ICU, as per discussion with clinical experts (Sculpher et al., 2000). A lifetime time horizon was used, as this is important to ensure that the model captures all the consequences of the intervention in terms of costs and effects through to death (O'Mahony et al., 2015). A half-cycle correction – where adjustments are made to allow for the fact that in real life, a patient may transition part-way through a cycle – was not applied to the model. Instead, all patients moved through the Markov transitions at the end of each one-day cycle. This decision reflects the current UK NHS system of charging full days in the ICU no matter the time of discharge from the ICU.

The decision tree includes four end states: 'decannulated-no dysphagia', 'decannulated-dysphagia', 'not decannulated-no dysphagia', and 'not decannulated-dysphagia'. This decision tree captures the long-term outcomes for decannulated patients and patients not decannulated during their ICU stay. Each end state has the following states: 'ICU', 'ward', 'home', '1st year discharge', and '2nd year discharge'.

The final Markov model has an identical structure for each of the four end states with states of: 'alive' and 'dead'. The model is divided into different periods: short term (90 days), intermediate term (0–2 years), and long term (3 years–lifetime). The cycle length for the final Markov model is one year, which is typical for modelling lifetime outcomes.

Various factors were considered during the development of this model, including (i) the complexities of the tracheostomy pathway in the ICU; (ii) the complexities of ACV use; (iii) the limited evidence available for ACV; and (iv) the limited decision-analytic modelling research available in the critical care specialty. These factors, in combination

with this being an early-stage model, led to the model being simplified as much as possible. For example, the model did not allow patients to regress to need tracheostomy re-insertion after decannulation.

6.4.3 Model assumptions

Various assumptions were made in the model:

- Tracheostomy re-insertion after decannulation was impossible to minimise the complexity of the model structure.
- The 'tracheostomy maintenance' state begins 72 hours after tracheostomy insertion. This is based on the findings of the systematic review (Chapter 3) and the survey (Chapter 4), which highlighted that most clinicians and researchers are waiting 72 hours before commencing ACV.
- Percutaneous insertion of tracheostomy was *a priori* assumed.
- As per manufacturer guidelines, routine costs for changing the tracheostomy tube for a new one were incorporated into the model every 28 days for patients in the 'tracheostomy maintenance' or 'tracheostomy weaning' state.
- Hypothetical patients spend only one day in the 'decannulated' or 'not decannulated' states before moving to the end state in the decision tree.
- At the end of the 90-day period, hypothetical patients in 'tracheostomy weaning' or 'tracheostomy and ventilator weaning' were moved to the worst end state: 'not decannulated-dysphagia'.
- At the end of the 90-day period, any hypothetical patients in the 1-day 'decannulated' state moved to the worst decannulated state: 'decannulated-dysphagia'.
- At the end of the 90-day period, any hypothetical patients in the 1-day 'not decannulated' state moved to the worst not decannulated state: 'not decannulated-dysphagia'.
- Due to the nature of a Markov model, the probability that patients transition between states is based on the current state and not on any previous history, such as deterioration, adverse events, or pneumonia.

6.4.4 Patient cohort

Patients included in the model were those with a tracheostomy in general ICU, commencing 72 hours after tracheostomy insertion. Patients entering the model were 63 years old, with a 64% probability of being male. These figures were derived from the median of some of the key papers included in the model (Engoren et al., 2004; van der Lely et al., 2006; Freeman-Sanderson et al., 2011; Daly et al., 2016; Depuydt et al., 2016; Vargas et al., 2018). The model was designed for patients from the UK being

cared for in the NHS. However, as is typical for a DAM, research from any country were considered as potential model parameters (Karnon et al., 2012).

6.4.5 Comparators

The model was designed to compare a hypothetical cohort of patients receiving usual care (UC) with a hypothetical cohort of patients receiving ACV. UC consists of patients receiving speech and language therapy support to facilitate non-verbal communication in the 'tracheostomy maintenance' state (e.g., communication boards) and being nil-by-mouth. In the 'tracheostomy and ventilator weaning' state, patients in UC may receive periods of cuff deflation and one-way valve (OWV) use and may commence some oral intake. In contrast, patients in the ACV cohort would receive a defined ACV intervention in both the 'tracheostomy maintenance' and the 'tracheostomy and ventilator weaning' states in addition to UC. The hypothetical ACV intervention was developed from evidence from the systematic review (Chapter 3) and the international survey (Chapter 4) and consisted of the following:

- introduction at 72 hours after tracheostomy insertion
- non-humidified oxygen delivered intermittently using a thumb port
- airflows of ≤ 6 L/min
- total daily duration of 60 minutes
- four 15-minute sessions
- delivered by a combination of speech and language therapy, physiotherapy, and nursing staff
- provision until 'decannulated' or 'not decannulated'

6.4.6 Parameter acquisition

Another rapid literature review was conducted to acquire the required parameters for the model. Parameters were also taken from the systematic review of the ACV literature (Chapter 3). Searches for this rapid review were conducted in Medline, Embase, Web of science, and the International Network of Agencies for Health Technology Assessment (INAHTA) database. The search strategy aimed to identify papers that were related to tracheostomy weaning, costs, QoL, cardiac surgery, and dysphagia (Appendix F outlines the search strategy for Medline and the search results).

Some parameters for the model were obtained from the literature. Where there was a lack of evidence or conflicting evidence for parameters, expert opinion was elicited through structured, individual, online, facilitated surveys following the National Institute for Health Research (NIHR) Health Technology Assessment reference protocol for structured expert elicitation in healthcare decision-making (Bojke et al., 2021). The expert group was composed from members of the research advisory group and the

PCPI group, two additional SLTs, and the research candidate. In total this included five SLTs, one critical care nurse, two intensivists, and one patient representative. The expert group was diverse, with considerable expertise in the area. All experts, except the candidate, had not been involved in developing the expert elicitation survey.

Experts were individually asked their opinion about each area where there was a lack of published evidence. Experts were presented with definitions and a description of the model. They were then asked to complete sections of the online survey while taking into consideration data from the studies that had been selected for inclusion in the model. Experts were asked to incorporate the evidence and their experience as they responded to the survey questions. Questions were as simple and consistent as possible, asking for observable quantities rather than complex numbers or ratios. Structured expert elicitation aims to avoid seeking an artificial consensus, but rather the variation in responses are actively sought to allow the uncertainty to be captured and evaluated in sensitivity analyses (Soares et al., 2020).

To reduce the burden on experts, the questions were targeted towards expertise (Appendix G details the survey questions for SLTs, Appendix H the questions for doctors and nurses, and Appendix I the questions for the patient representative). Doctors and nurses were asked questions about UC, SLTs were asked about UC and ACV, and the patient representative was asked about QoL and utility values for UC and ACV. As per best practice, some responses were further clarified and revised by email with four experts (Bojke et al., 2021).

The variable interval method (VIM) was employed, which elicits plausible probabilities or quantities (Haakma et al., 2014; Soares et al., 2018). Experts were asked to provide the following estimates for each question:

- The lowest plausible value
- The highest plausible value
- Their best guess for the value (or mode)
- Their confidence that the interval, from lowest to highest, captured the true value (from 50% to 100%)

The final question in each question series ascertained the experts' level of confidence in their answers. Additionally, at the end of the session, experts were asked to describe their experience of completing the survey. These questions supported validation of the results as per the expert elicitation guidance (Bojke et al., 2021).

The parameters used in the model are described in Section 6.5.3.

6.4.7 Transition probabilities

The probabilities for transition between ‘tracheostomy maintenance’, ‘tracheostomy and ventilator weaning’, ‘decannulated’, ‘not decannulated’, ‘dead’, ‘decannulated-dysphagia’, ‘decannulated-no dysphagia’, ‘not-decannulated-dysphagia’, and ‘not decannulated-no dysphagia’ were identified from the literature and expert opinion. Most studies did not provide information that could be directly used for transition probabilities, so calculations were performed to convert the available data into usable daily transition probabilities. For example, there were no daily transition probabilities from ‘tracheostomy maintenance’ to ‘dead’. Nonetheless, some papers reported the percentage of ICU mortality and ICU LoS. This data was transformed using the survival function formula assuming an exponential distribution to produce daily transition probabilities (Chhatwal et al., 2016).

A variety of transition probabilities were produced for each transition route in the model based on the different evidence available in combination with expert opinion. For example, the transition probability for ‘maintenance’ to ‘dead’ had four options for UC and 21 for ACV. For UC, three of the probabilities were produced from three different studies (van der Lely et al., 2006; Choate et al., 2009; Vargas et al., 2018), and one probability was produced from a median value of these papers. For ACV, the 21 options were derived from each of the three studies, and the median of these data was combined with the five experts’ responses and their mean which was derived from a meta-analysis.

Experts were asked to provide their opinions about the absolute difference they thought ACV could make to specific values. For example, they were asked about the absolute difference in the percentage of patients who would experience dysphagia after decannulation in those who had received ACV compared to those who had received UC. When combined with the published data, it occasionally resulted in implausible negative transition probabilities. When this occurred, probabilities were anchored and censored at zero.

6.4.8 Utilities

Each health state and end state was assigned a utility value. Utilities, where available, were used directly from the studies. These were primarily the European Quality of Life 5-Dimensions (EQ-5D) questionnaire values. Where EQ-5D utilities were unavailable in published studies, the data presented were either converted into a utility or calculated by inputting the available values into the European Quality of Life 5-Dimensions 5-Levels (EQ-5D-5L) Index Value Calculator (Van Hout et al., 2012). For example, one study only reported the EQ-5D visual analogue scale (VAS) with a result of 40 (from a total score of 100) (Freeman-Sanderson et al., 2018). The primary author was

contacted to request the utility score, but they could not provide this information, reporting that an ethics amendment would be required. Therefore, this VAS score was directly converted to a utility value of 0.4. Another example was a study that reported the means of the EQ-5D-5L data but had not reported the utility value, which might be a result of the lack of an Italian value set (Vargas et al., 2018). In this instance, the means of the EQ-5D-5L data were input to the EQ-5D-5L calculator using the UK value set to calculate a utility value. EQ-5D utility values were also obtained from a patient representative for each state for UC and ACV.

For the end states, the initial QALYs were calculated as part of the Markov model that was part of the initial 90 days after tracheostomy insertion. The QALYs for the intermediate stage, from 90 days to 2 years after discharge, were calculated as part of the decision tree. Final composite QALYs were calculated for three years to lifetime as part of the final Markov model. These QALYs were calculated from the available data accounting for the average age and sex of the patients, potential discharge destinations, the mortality risk over the subsequent years after ICU discharge, and the life expectancy of patients. QALYs were estimated for the patients according to age and sex based on the 2020-based interim national population projections life tables (Hernández Alava et al., 2022; Office for National Statistics, 2022). Discounting was applied to costs and QALYs occurring after one year using a value of 3.5% per annum per the NICE reference case methodology (NICE, 2013).

6.4.9 Resources

The perspective of UK NHS healthcare was adopted, and healthcare costs until death were included. Only direct patient care costs were included and indirect or wider societal costs were not incorporated, such as days lost from work, in line with the reference case framework adopted by NICE (NICE, 2013). Resource use was obtained from: the National Cost Collection from the National Schedule of NHS Costs Year 2020-21 (NHS England, 2020); the National tariff workbook from NHS England's National Tariff Payment System (NHS England, 2022); the Units of Costs of Health and Social Care 2022 Manual (Jones et al., 2022); and the eCommerce Deployment NHS Supply Chain, 2023 (NHS Supply Chain, 2023). Age-related health costs were obtained from a study estimating the future healthcare costs of an ageing UK population (Caley and Sidhu, 2011). Unit costs were applied to each resource item and inflated to the year 2021 using the Hospital and Community Health Services Index for years 2005 to 2014 and the NHS Cost Inflation Index for years 2015 to 2021 (Curtis, 2009; Jones et al., 2022). Where there was uncertainty regarding costs, this was accounted for by using univariate sensitivity analysis. Discounting was applied to the end states using a value of 3.5%.

Adverse events, such as subcutaneous emphysema or tracheal dilation, were incorporated into the costs via transitions and LoS. For example, patients experiencing an adverse event would regress to 'tracheostomy maintenance', increasing costs via the state's higher cost and the increased ICU LoS.

6.4.10 Sensitivity analyses

The ICER for this model is dependent on the following factors:

- the utilities for the different states
- the cost per day in the general ICU
- the cost per day on the general ward
- the cost per day of ACV
- the number of days in the general ICU
- the number of days on the general ward
- the long-term utilities and costs for survivors in the different end states

Given the level of structural and parameter uncertainty in the model, one-way sensitivity analysis was used rather than probabilistic sensitivity analysis. Although probabilistic sensitivity analysis should be run based on best practice for modelling (Claxton, 2008), it can provide the decision-maker with an overconfidence in the analysis findings if uncertainties are not accurately captured by the probabilistic distributions. Given the current evidence base, this was considered the case here. One-way sensitivity analyses can underestimate the level of uncertainty in the model, but it is more often interpreted more cautiously as a result (Claxton, 2008).

One-way sensitivity analyses were conducted to evaluate the critical determinants for cost-effectiveness for ACV. Sensitivity analyses are essential to assess the uncertainty surrounding costs and effects. Understanding the level of uncertainty in the model is vital to validate the model's expected cost-effectiveness, explore the potential consequences of uncertain decision-making, and identify where further research is needed (Claxton, 2008). Several scenario analyses were run to evaluate the key structural uncertainties in the model. These included:

1. *Sensitivity analysis of the effectiveness of ACV*: In the base-case analysis, the most plausible effectiveness was assumed from the data available. In the sensitivity analyses, this parameter was varied to estimate the level of effectiveness needed to achieve cost-effectiveness for ACV to identify which element(s) of effectiveness are critical in determining cost-effectiveness.
2. *Sensitivity analysis of ICU costs*: In the base-case analysis, ICU costs of £2672.47 per day for 'tracheostomy maintenance', £2327.26 per day for 'tracheostomy and ventilator weaning', £1893.94 for 'decannulated', and £2211.79 for 'not decannulated' was assumed. In the sensitivity analysis, these

costs were varied to estimate the impact of varying the ICU bed costs per day on the cost-effectiveness of ACV.

3. *Sensitivity analysis of long-term outcomes after ACV*: In the base-case analysis, ACV effects occurred purely during the states where it was used: 'tracheostomy maintenance' and 'tracheostomy and ventilator weaning'. Sensitivity analyses used utility inflators to explore the impact of longer-term positive outcomes from ACV.

6.4.11 Data analysis and reporting

All analyses were conducted in Microsoft® Excel®, Microsoft 365, Microsoft Office (Version 2301). A deterministic model was employed, using defined probabilities, utilities, and costs to estimate cost-effectiveness. Face validity was ascertained through the univariate sensitivity analysis and from an experienced health economist checking the model.

For UC and ACV, the following outcomes will be reported: the QALYs, the cost, the INMB, and the INHB. The incremental cost for ACV will also be reported along with the difference in QALYs between ACV and UC. The ICER will be calculated to evaluate the cost-effectiveness of ACV (Craig and Black, 2001). Given the levels and type of uncertainty in the model, cost-effectiveness acceptability curves (CEACs) to illustrate the probability of ACV being cost-effective at a WTP per QALY threshold will not be constructed as it is not possible to quantify all the uncertainty probabilistically. The focus of the analysis is the univariate sensitivity analysis, which allows the determination of the critical drivers of uncertainty and the identification of areas for future research.

All these elements will be reported for the base-case scenario and for the sensitivity analyses described in Section 6.4.10.

6.5 Results

6.5.1 Decision analytic modelling of patients in critical care

The rapid review of the literature for decision-analytic modelling found a limited application of DAMs in the context of the critical care specialty, especially in relation to models focused on ETT and tracheostomy in adult ICUs.

Table 22 presents the decision-analytic modelling literature relevant for this model. This summary focuses on the methodology, as this informed the model structure. Three studies built a decision tree (Ost et al., 2003; Liu and Rudmik, 2016; Tsai et al., 2019); one study developed a decision tree-Markov hybrid (Cox, Carson, Govert, et al., 2007); six constructed Markov models (Aikawa et al., 2005; Macario et al., 2006; Bhatnagar et

al., 2012; Saunders and Geogopoulos, 2018; Hudson and Singh, 2019; Saunders et al., 2022); and one developed a patient-level simulation model (Al et al., 2010). There was an additional study (Ridley and Morris, 2007) that did not report the type of model and provided limited methodological information but informative costing data. Macario and colleagues suggested that Markov models are the most appropriate of the DAMs to use in critical care due to the rapid changes in the medical condition experienced by most patients and because events can occur multiple times, i.e., re-intubation (Macario et al., 2006).

Most of the studies described in Table 22 included health states for intubated or tracheostomised patients but did not focus specifically on the extubation or decannulation pathways. Only two studies evaluated extubation (Saunders and Geogopoulos, 2018) and decannulation (Liu and Rudmik, 2016). Many studies were lacking in methodological details; for example, some studies did not report cycle length (Aikawa et al., 2005; Bhatnagar et al., 2012; Saunders and Geogopoulos, 2018), and others did not provide the time horizon (Bhatnagar et al., 2012; Hudson and Singh, 2019). When provided, the time horizon varied from 28 days (Al et al., 2010) to lifetime (Cox, Carson, Govert, et al., 2007). Likewise, the cycle length varied from one hour (Al et al., 2010) to one week (Cox, Carson, Govert, et al., 2007).

Most studies estimated utilities and probabilities from the research literature. In contrast, some explicitly stated that expert opinion was also used (Aikawa et al., 2005), and others used databanks or retrospective hospital data (Bhatnagar et al., 2012; Hudson and Singh, 2019). Utilities were often not clearly described, and few studies used QALYs. Where described, utilities were often a proxy, such as ‘avoidance of tracheostomy’ (Liu and Rudmik, 2016), ‘survival’ (Ost et al., 2003), ‘successful extubation’ (Tsai et al., 2019), or ‘improvement factor’ (Bhatnagar et al., 2012). This variability in the utilities used in critical care modelling indicates a paucity of data for HRQoL utility weights in this clinical area. A mix of univariate, multi-variate, and probabilistic sensitivity analysis was employed, with only one study conducting a VOI analysis (Tsai et al., 2019).

A systematic review of HRQoL and cost-utility analysis in critical care, which included 80 studies, highlighted various issues with the evidence available in this area (Lau et al., 2021). One of the major issues discussed was the difficulty in obtaining patient-reported QoL measures from critically unwell patients who may be sedated. The poor methodological quality of critical care health economic evaluations and inconsistent reporting of conflict of interest was also mentioned, which is particularly concerning in industry-sponsored studies. The authors state there is a lack of validation of HRQoL measures in the critical care population (Lau et al., 2021).

None of the DAMs available in the literature were suitable to address the aims of this study. A de novo model was therefore developed.

Table 22 Modelling in critical care

Reference	Type of model	Topic	Nodes and branches or States	Cycle length	Time horizon	Sources	Primary utility	Patient group	Sensitivity analysis
Liu and Rudmik, 2016	Decision tree	Evaluation of cost-effectiveness of early tracheostomy compared to late tracheostomy	**Decision node branches:** early tracheostomy; late tracheostomy. **Chance nodes' branches:** early tracheostomy; no tracheostomy; short-term complications; survive; no complications; pneumonia; no pneumonia. **Terminal nodes:** decannulation; discharge with tracheostomy; short-term mortality; pneumonia; no pneumonia.	Not reported	90 days	Literature; healthcare cost and utilisation project database (USD, 2016 value)	Avoidance of tracheostomy (state lack of research to inform QALYs)	Hypothetical mixed group of critical care patients.	Probabilistic with 15,000 simulations
Ost *et al.*, 2003	Decision tree	Evaluation of the cost-effectiveness of different diagnostic and treatment approaches for rapid treatment of VAP	**Decision node 1 branch:** no diagnostic test; ETT aspirate; mini-BAL; bronchoscopy. **Decision node 2 branches:** no initial antibiotics; one antibiotic; two antibiotics; three antibiotics. **Chance nodes' branches:** adequate initial antibiotic; inadequate initial antibiotics; test positive-adjust antibiotics; test negative; survive VAP; clinically unstable-continue antibiotics; clinically stable-stop antibiotics. **Terminal nodes:** survive ICU; die ICU; die VAP.	Not reported	Not reported	Literature; Medicare reimbursement costs; institutional hospital cost data (USD, 2002 value)	Multiple analyses of each outcome of interest: survival; financial cost; financial cost per survivor; antibiotic use; antibiotic use per survivor; combined financial cost-antibiotic use cost per survivor.	Hypothetical cohort of immunocompet-ent ICU patients, intubated for seven days, with late-onset VAP.	Univariate, multi-variate, and probabilistic for all variables

Tsai *et al.*, 2019	Decision tree and VOI analysis (+ other data science techniques)	Identification of key factors to support decision-making for extubation in the ICU	**Decision node 1 branch:** use prediction mode; by experience. **Decision node 2 branches:** extubate; not extubate. **Chance nodes:** predict failure; predict success. **Terminal nodes:** success; fail; not extubate.	Not reported	Not reported	Retrospective patient data from National Cheng Kung University Hospital. Costs were time in the ICU, not monetary value.	Successful extubation.	Surgical intubated ICU patients.	VOI analysis estimated EVPI and EVPPI. Univariate sensitivity analysis.
Cox, Carson, Govert, *et al.*, 2007	Decision tree and Markov model	An economic evaluation of prolonged mechanical ventilation	**Decision node 1 branches:** prolonged mechanical ventilation; withdrawal of care. **Chance nodes' branches:** survive hospitalisation; die during hospitalisation. **Terminal nodes:** dead. Survive hospitalisation forms the start of the Markov model. **States:** hospital; home/well; dead; facility; rehab facility; home; skilled nursing facility; hospital; dead; Long-term acute care facility; home; rehab facility; skilled nursing facility; hospital; dead; skilled nursing facility; home; rehab facility; nursing home-vent; nursing home; hospital; dead; nursing home; hospital; dead; home; hospital; dead.	One week	Lifetime	Literature, and primarily based on data from an observational cohort study.	Used QoL data from the observational cohort study (unspecified and unable to access paper).	Medical or surgical critically ill patients assumed to have been ventilated for ≥ 21 days and have a tracheostomy. Comparator patients who did not have a tracheostomy and had ventilation withdrawn between 7 and 21 days.	One-way and multi-way probabilistic sensitivity analyses over 1000 simulations.

Aikawa *et al.*, 2005	Markov model	Exploring the cost-effectiveness of using Sivelestat to treat acute lung injury in patients in the ICU	**States:** ICU plus intubated; ICU plus weaned from mechanical ventilation; admission to general ward; death.	Not explicitly stated, but it appears to be one day.	30 days after admissi-on to the ICU	Data from RCT of Sivelestat; expert opinion; Japanese National Health Insurance drug prices and medical fees (Japanese Yen, 2001 value).	Discharge rate; weaning rate; mortality. No QALYs incorporated.	Patients with acute lung injury associated with SIRS caused by infection who began treatment under mechanical ventilation in the ICU.	Univariate sensitivity analyses for: mortality, mechanical ventilator weaning rate, duration of time to step-down to ward after weaning completed, and ICU drug costs.
Bhatnagar, Mayberry and Nirula, 2012	Markov model	Evaluating whether ORIF of flail chest is cost-effective	**States:** trauma with flail chest; ORIF; standard of care; no intubation; intubation <96 hours; intubation >96 hours; VAP; no VAP; tracheostomy; no tracheostomy; complications; death; survival.	Not reported	Not reported	Literature; national trauma data bank; National Medicare Reimbursement figures (US dollars, 2010 values).	Arbitrary QoL improvement factor used to estimate a 0 to 15% improvement for ORIF. Series of reduced QoL probabilities were assigned to possible complications. Unclear whether these were derived from literature, expert opinion, or researchers.	Patients with flail chest following trauma (not all requiring intubation).	Sensitivity analyses for: VAP probabilities and QoL improvement factor probabilities.

Macario, Chow and Dexter, 2006	Markov model	Evaluating the cost-effectiveness of a neuro-muscular blocking agent for the management of acute respiratory distress syndrome in the ICU	**States:** ICU intubated; ICU extubated; hospital ward; off-site long-term care; home; death.	3.5 days	6 months; sub-analysis with 1month time horizon.	Literature (USD, 2004 value).	Unclear estimation, report 'wide range of quality of life for each health state'. Discuss EQ-5D and Rosser index, but unclear if they were used.	55 year old man with ARDS secondary to pneumonia	Probabilistic sensitivity analysis, 10,000 simulations including all probabilities, utilities, and costs. Validity check against published data.
Saunders and Geogopoul-os, 2018	Markov model	Evaluating the cost-effectiveness of proportional-assist ventilation compared to pressure support ventilation in the US and UK	**States:** ventilator asynchrony < 10%; ventilator asynchrony > 10%; spontaneous breathing; hospital; home; dead.	Not reported	40 years	Literature	QALY	Cohort of ventilated patients in the ICU (presumed intubated rather than tracheostomised, but not explicitly stated). Lack of detail regarding patient characteristics.	Probabilistic sensitivity analysis, 2000 simulations. WTP thresholds of $50,000 and £30,000 per QALY. Validity checked with published data.
Saunders, Davis and Bosma, 2022	Markov model (adapted from above)	Evaluating the cost-utility of proportional-assist ventilation compared to pressure support ventilation	**States:** asynchrony; synchrony; VAP; spontaneous breathing trial; ICU (no mechanical ventilation); dead; general ward; home.	One day	One year	Literature; pragmatic analysis performed by the research team; Canadian authorities and databases (Canadian dollar, 2017 value)	EQ-5D estimated by author due to limited QALY data available. Adverse events incorporated: tracheostomy insertion, VAP, nosocomial infection, reintubation	ICU patients receiving invasive mechanical ventilation who have completed the acute phase of ventilatory support and have entered the recovery phase.	Probabilistic sensitivity analysis, 2000 simulations. Willingness-to-pay threshold of $50,000 per QALY gained.

Hudson and Singh, 2019	Markov model	Evaluation for whether increasing discharge led to a reduction in cardiovascular surgery	**States:** awaiting admission; rejected admission due to lack of available bed; admitted to ICU; admitted to ICU-ready to transfer; and transferred. (N.B. rather than having a state for death, the probability of death was included based on mortality data)	24 hours	No specific time horizon; instead, the model was run until 10^8 patients had been in a state.	Patient data from cardiac ICU in Alberta, Canada.	Surgical cancellation rate	Patients in cardiovascular ICU	Univariate sensitivity analysis: transfer probability (model run 231 times)
Al *et al.*, 2010	Patient-level simulation Markov model	Evaluating the incremental cost-consequence of remifentanil-based sedation compared to conventional sedation in patients on mechanical ventilation in the ICU	**States:** mechanical ventilation-maintenance; mechanical ventilation-eligible to start weaning; mechanical ventilation-weaning started; mechanical ventilation-eligible to extubate; post-extubation; post-extubation-eligible for discharge; discharged from ICU; death. N.B. certain states – the 'eligible' states – were not always used by patients passing through the pathway if what they were eligible for was performed immediately. Allowed transition from the treatment group to the conventional sedation group when patients stopped treatment early.	One hour	28 (to match trial)	Dutch clinical trial; Dutch micro-costing study (Euros, 2006 value).	Length of stay on the ICU and duration of mechanical ventilation. Constant mortality rate for both groups. VAP and infections are not included. Side effects and complications of sedatives are not included. Staffing resources for drug administration are not included.	Patients in a Dutch ICU with expected mechanical ventilation time of two to three days.	Sub-group analysis with patients where weaning began within 72 hours. Probabilistic sensitivity analysis.

Ridley and Morris, 2007	Unreported	Cost-effectiveness of adult intensive care in the UK	**States:** not stated explicitly but appears to be: 'ICU', 'No ICU', 'Died', 'Survived'.	Not reported	Lifetime	Systematic review and meta-analysis; literature; a cohort of patients at the Western Infirmary, Glasgow; the intensive care national audit and research centre data; NHS reference costs	QALY from EQ-5D, SF-36, and Patrick's Perceived Quality of Life	General adult ICU patients	Yes, but not described

EQ-5D – European Quality of Life 5 dimensions questionnaire; ETT – endotracheal tube; EVPI – expected value of perfect information; EVPPI – expected value of perfect parameter information; ICU – intensive care unit; mini-BAL – mini-bronchoalveolar lavage; ORIF – open reduction with internal fixation; QALY – quality-adjusted life-year; QOL – quality of life; RCT – randomised controlled trial; SIRS – systemic inflammatory response syndrome; USD – United States Dollars; VAP – ventilator-associated pneumonia; VOI – value of information; WTP – willingness-to-pay

6.5.2 Expert contributor characteristics

Five SLTs, one nurse, two doctors, and one patient participated in the expert elicitation survey. The characteristics of the expert contributors are outlined in Table 23.

Table 23 Characteristics of expert contributors

Professional group	SLT (5), Nurse (1), Doctors (2)
Country	UK (5), New Zealand (1), Greece (1), Ireland (1)
Gender	Female (6) Male (2)
Number of years practising clinically in critical care	1-5 years (2) 10-15 years (1) 15-20 years (3) >20 years (2)
Types of critical care units with experience	Burns (2) Cardiac (5) General (8) Neurology/Neurosurgery (4) Paediatrics (1) Spinal (2)

6.5.3 Study parameters

The study parameters were gathered from a range of critical care studies. The quality and reporting of the relevant data were highly variable. Many of the studies included mixed populations, either of patients who had and had not received a tracheostomy or in terms of their primary diagnosis or reason for admission. Given the limited and low-quality data specific to tracheostomy in the general ICU population, some data not specific to the target patient cohort were included. The various parameters used in the model are outlined below and include transition probabilities, utilities, and resource use.

6.5.3.1 Transition probabilities

The base-case transition probabilities and the ranges used for sensitivity analysis in the model are reported in Table 24 for UC and in Table 25 for ACV. The base-case survival

probabilities used for the end states are reported in Table 26. These survival probabilities are common for both UC and ACV. For all tables, the transition probabilities not specifically mentioned were calculated from other values included in the table, as all probabilities should add up to one.

6.5.3.2 Utilities

The model's base-case utilities and the ranges used for sensitivity analysis are outlined in Table 27 for UC and Table 28 for ACV.

6.5.3.3 Resources

The resource unit costs applied to the model are described in Table 29.

Table 24 Base-Case transition probabilities for UC

Variable	Base-Case estimate	Range	Data Source	Details and assumptions
'Tracheostomy maintenance' to 'tracheostomy and ventilator weaning'	0.154	No range	Freeman-Sanderson *et al.*, 2011	Only one study identified the time with a tracheostomy before active ventilator weaning.
'Tracheostomy and ventilator weaning' to 'tracheostomy maintenance'	0.032	0.007-0.79	Colomo *et al.*, 2015; Daly *et al.*, 2016; 8 experts	The assumption is that patients can regress to 'tracheostomy maintenance' if they deteriorate. The experts were asked to consider any reason for regression, whereas the studies only provided data on regression related to chest infections or pneumonia. For this reason, a meta-analysis of the expert data was used for the base-case estimate.
'Tracheostomy and ventilator weaning' to 'decannulated'	0.061	0.020-0.249	Engoren, Arslanian-Engoren and Fenn-Buderer, 2004; Lely *et al.*, 2006; Choate, Barbetti and Currey, 2009; Romero *et al.*, 2010; Freeman-Sanderson *et al.*, 2011; Colomo *et al.*, 2015; Daly *et al.*, 2016	The meta-analysis of the study values was used for the base-case estimate.
'Tracheostomy and ventilator weaning' to 'not decannulated'	0.003	0.003-0.015	Engoren, Arslanian-Engoren and Fenn-Buderer, 2004; Choate, Barbetti and Currey, 2009; Freeman-Sanderson *et al.*, 2011	The focus of this transition probability was 'not decannulated' in the ICU. However, none of the studies specifically looked at the location of decannulation. The assumption made is that these values for decannulation occurred in ICU. The meta-analysis of the study values was used for the base-case estimate.

‘Decannulated’ to ‘decannulated-dysphagia’	0.133	0.089-0.174	Freeman-Sanderson *et al.*, 2011; Daly *et al.*, 2016	It is assumed that these values underestimate the percentage of patients with dysphagia after decannulation as they report on aspiration and not taking oral intake, rather than the percentage of patients diagnosed with dysphagia. The meta-analysis of these study values was used for the base-case estimate.
‘Not decannulated’ to ‘not decannulated-dysphagia’	0.820	0.025-0.820	Choate, Barbetti and Currey, 2009; Freeman-Sanderson *et al.*, 2011	The Freeman-Sanderson (2011) value was used as it was specifically reporting on dysphagia in non-decannulated patients. In contrast, the other paper provided percentages of patients failing decannulation for dysphagia-related reasons and probably underestimated the proportion of non-decannulated patients with dysphagia.
‘Tracheostomy maintenance’ to ‘dead’ And ‘Tracheostomy and ventilator weaning’ to ‘dead’	0.008	0.008-0.020	van der Lely et al., 2006; Choate et al., 2009; Vargas et al., 2018	These transition probabilities were calculated from ICU mortality, with the assumption that the probability of mortality is the same within the ‘tracheostomy maintenance’ and ‘tracheostomy and ventilator weaning’ states as the average for the whole ICU stay.

Table 25 Base-Case transition probabilities for ACV for the Markov portion of the model

Variable	Base-Case estimate	Range	Data Source	Details and assumptions
'Tracheostomy maintenance' to 'tracheostomy and ventilator weaning'	0.221	0.154-0.283	Freeman-Sanderson *et al.*, 2011; 5 expert SLTs	Experts were asked to estimate the absolute change in the number of days spent in 'tracheostomy maintenance' that might occur due to ACV. The difference between the median of this figure and the Freeman-Sanderson *et al.,* (2011) value was used for the base-case estimate.
'Tracheostomy and ventilator weaning' to 'tracheostomy maintenance'	0.019	0-0.079	Colomo *et al.*, 2015; Daly *et al.*, 2016; 8 expert values for UC; 5 SLT experts for ACV	Experts were asked to estimate the absolute change to the percentage of patients regressing to 'tracheostomy maintenance' that might occur as a result of ACV. The base-case estimate is taken from a meta-analysis of the experts' values for UC compared to a meta-analysis of the experts' values for ACV. As with UC, the expert data was used for the base-case estimate as it incorporated all reasons for regression to 'tracheostomy maintenance'. When expert values were combined with study values, this resulted in some implausible, negative probabilities, which were censored at zero.
'Tracheostomy and ventilator weaning' to 'decannulated'	0.074	0.021-0.865	Engoren et al., 2004; van der Lely et al., 2006; Choate et al., 2009; Romero et al., 2010; Freeman-Sanderson et al., 2011; Colomo et al., 2015; Daly et al., 2016; 5 SLT experts	Experts were asked to estimate the absolute change in the percentage of patients decannulated and the absolute change in the number of days spent in 'tracheostomy and ventilator weaning' that might occur due to ACV. The base-case estimate is calculated from the meta-analysis of the expert estimate on the percentage of patients decannulated and the median of the study values. The upper range is assumed to have such a high value due to a study reporting the percentage of decannulated non-dysphagic patients (Daly et al., 2016).

‘Tracheostomy and ventilator weaning’ to ‘not decannulated’	0.003	0.003-0.015	Engoren, Arslanian-Engoren and Fenn-Buderer, 2004; Choate, Barbetti and Currey, 2009; Freeman-Sanderson *et al.*, 2011	The assumption was that ACV does not directly impact the transition probability to ‘not decannulated’. Therefore, the same transition probability was used as for UC.
‘Decannulated’ to ‘decannulated-dysphagia’	0.013	0-0.124	Freeman-Sanderson *et al.*, 2011; Daly *et al.*, 2016; 5 SLT experts	Experts were asked to estimate the absolute change in the percentage of decannulated patients who might have dysphagia due to ACV. The base-case estimate is taken from the difference between the meta-analysis of the experts’ values and the meta-analysis of the study values. When expert values were combined with study values this resulted in some implausible negative probabilities which were censored at zero.
‘Not decannulated’ to ‘not decannulated-dysphagia’	0.731	0-0.820	Choate, Barbetti and Currey, 2009; Freeman-Sanderson *et al.*, 2011; 5 SLT experts	Experts were asked to estimate the absolute change to the percentage of ‘not decannulated’ patients with dysphagia as a result of ACV. The base-case estimate is taken from the difference between the meta-analysis of the experts’ values and the Freeman-Sanderson value, as this was believed to be the most accurate estimate (as discussed for UC). When expert values were combined with study values this resulted in some implausible negative probabilities which were censored at zero.
‘Tracheostomy maintenance’ to ‘dead’ And ‘Tracheostomy and ventilator weaning’ to ‘dead’	0.008	0.005-0.020	van der Lely et al., 2006; Choate et al., 2009; Vargas et al., 2018; 5 expert SLTs.	Experts were asked to estimate the absolute change to the percentage mortality that might occur due to ACV. The difference between the meta-analysis of these values and the meta-analysis of the values in the literature was calculated. The assumption was made that the probability of mortality is the same in both ‘tracheostomy weaning’ and ‘tracheostomy and ventilator weaning’ compared to ICU mortality and that ACV impacts mortality to the same level in both ‘tracheostomy maintenance’ and ‘tracheostomy and ventilator weaning’.

Table 26 Base-Case mortality and survival probabilities for UC and ACV for the decision tree portion of the short term (90 days), the intermediate term (0-2 years), and the long term (3 years to lifetime)

Variable	Base-Case estimate	Range	Data Source	Details and assumptions
Daily probability of mortality in the ICU for those in: 'decannulated-no dysphagia' AND 'decannulated-dysphagia' AND 'not decannulated-no dysphagia' AND 'not decannulated-no dysphagia'	0.008	0.008-0.020	van der Lely et al., 2006; Choate et al., 2009; Vargas et al., 2018	These transition probabilities are the same as for the Markov portion of the model for UC. The assumption was made that there was no difference in the probability of mortality in any state during the ICU stay for UC and that once ACV was no longer in use, it would have no impact on mortality.
Daily probability of mortality on the ward for those in 'decannulated-no dysphagia'	0.010	0.004-0.015	Cuthbertson *et al.*, 2010; Depuydt *et al.*, 2016; Vargas *et al.*, 2018	The median of the ward mortality rates was taken from these studies and converted into a daily mortality rate. The assumption was made that the patients in these studies were not dysphagic, but this was not explicitly reported.

Daily probability of mortality on the ward for those in 'decannulated-dysphagia'	0.018	0.007-0.029	Cuthbertson *et al.*, 2010; Depuydt *et al.*, 2016; Patel *et al.*, 2018; Vargas *et al.*, 2018	The same studies were used as for the ward mortality for those in 'decannulated-no dysphagia' but in combination with the Patel *et al.* (2018) study that reported that patients with dysphagia are 1.7 times more likely to die in hospital. The base-case value was taken from the median of the studies in combination with the 1.7 times increase in mortality.
Daily probability of mortality on the ward for those in 'not decannulated-no dysphagia'	0.007	No range	Depuydt *et al.*, 2016	Limited data regarding the mortality of patients with a tracheostomy on the ward is available. The assumption is that the patients in this study were not dysphagic, but this was not explicitly reported.
Daily probability of mortality on the ward for those in 'not decannulated-dysphagia'	0.012	No range	Depuydt *et al.*, 2016; Patel *et al.*, 2018	The same study as for the ward mortality for those in 'not decannulated-no dysphagia' was used in combination with the Patel *et al.* (2018) study and adjusting for the 1.7 times increase in mortality.
Daily probability of mortality during the first year after discharge for those in 'decannulated-no dysphagia'	0.0006	0.0003-0.0007	Cuthbertson *et al.*, 2010; Freeman-Sanderson *et al.*, 2011; Vargas *et al.*, 2018	The median 1-year mortality was converted into a daily probability of mortality. The assumption is that the patients in these studies were not dysphagic, but this was not explicitly reported.
Daily probability of mortality during the first year after discharge for those in 'decannulated-dysphagia'	0.0011	0.0005-0.0014	Cuthbertson *et al.*, 2010; Freeman-Sanderson *et al.*, 2011; Patel *et al.*, 2018; Vargas *et al.*, 2018	The median 1-year mortality was converted into a daily probability of mortality and used in combination with the Patel *et al.* (2018) study and adjusting for the 1.7 times increase in mortality. As there is no data for the mortality risk in dysphagic, decannulated patients after discharge from the ICU, the assumption is made that the reported 1.7 times increase in mortality in the hospital also holds for the first year after discharge.

Daily probability of mortality during the first year after discharge for those in 'not decannulated-no dysphagia'	0.0009	0.0009-0.0010	Depuydt *et al.*, 2016	The median 1-year mortality was calculated from the mortality of both ventilated and non-ventilated patients with a tracheostomy from this study. This was converted into a daily probability of mortality. The assumption is that the patients in this study were not dysphagic, but this was not explicitly reported.
Daily probability of mortality during the first year after discharge for those in 'not decannulated-dysphagia'	0.0019	0.0017-0.0020	Depuydt *et al.*, 2016; Patel *et al.*, 2018	The median 1-year mortality was calculated from the mortality of both ventilated and non-ventilated patients with a tracheostomy from the Depuydt *et al.* (2016) study in combination with the Patel *et al.* (2018) study, with adjustment for the 1.7 times increase in mortality. This was converted into a daily probability. As there is no data for the mortality risk in dysphagic patients with a tracheostomy after discharge from the ICU, the assumption is made that the reported 1.7 times increase in mortality in hospital also holds true for the first year after discharge.
Probability of survival of the first year after discharge for those in 'decannulated-no dysphagia'	0.734	0.320-0.770	Cuthbertson *et al.*, 2010; Vargas *et al.*, 2018	The meta-analysis of the 1-year survival probability of the studies was used. The assumption is that the patients in these studies were not dysphagic, but this was not explicitly reported.
Probability of survival of the first year after discharge for those in 'decannulated-dysphagia'	0.547	0.0-0.609	Cuthbertson *et al.*, 2010; Patel *et al.*, 2018; Vargas *et al.*, 2018	The meta-analysis of the 1-year survival probability of the studies was used in combination with the Patel *et al.* (2018) study and adjusting for the 1.7 times increase in mortality. As there is no data for the mortality risk in dysphagic, decannulated patients after discharge from the ICU, the assumption is made that the reported 1.7 times increase in mortality in hospital also holds true for the first year after discharge.

Probability of survival of the first year after discharge for those in 'not decannulated-no dysphagia'	0.522	0.490-0.551	Depuydt *et al.*, 2016	The meta-analysis of the 1-year survival probability for both ventilated and non-ventilated patients with a tracheostomy from this study was used. The assumption is that the patients in this study were not dysphagic, but this was not reported.
Probability of survival of the first year after discharge for those in 'not decannulated-dysphagia'	0.187	0.133-0.237	Depuydt *et al.*, 2016; Patel *et al.*, 2018	The meta-analysis of the 1-year survival probability for both ventilated and non-ventilated patients with a tracheostomy from the Depuydt *et al.* (2016) study was used in combination with the Patel *et al.* (2018) study with adjustment for the 1.7 times increase in mortality. As there is no data for the mortality risk in dysphagic patients with a tracheostomy after discharge from the ICU, the assumption is made that the reported 1.7 times increase in mortality in hospital also holds true for the first year after discharge.
Probability of survival of the second year after discharge for those in 'decannulated-no dysphagia', 'decannulated-dysphagia', 'not-decannulated-no dysphagia', and 'not decannulated-dysphagia'	0.720	No range	Cuthbertson *et al.*, 2010	There is limited data available for survival in the second year after discharge. It is assumed that the probability of survival is the same for all end states by this point of recovery, and that dysphagia will either have resolved or no longer impact mortality rates.

Table 27 Base-Case utilities for UC

Variable	Base-Case estimate	Range	Data Source	Details and assumptions
'Dead'	0	N/A		As per standard utility value in health economics.
'Maintenance'	-0.510	-0.510-0.400	Freeman-Sanderson *et al.*, 2018; Pandian *et al.*, 2020; expert patient opinion	Limited data is available for utilities specifically for the 'maintenance' state. Therefore, the expert opinion value was used for the base-case estimate as it was assumed to be the most accurate.
'Tracheostomy and ventilator weaning'	-0.269	-0.269-0.540	Freeman-Sanderson *et al.*, 2018; expert patient opinion	There is limited data available for utilities specifically for the 'tracheostomy and ventilator weaning' state. Therefore, the expert opinion value was used for the base-case estimate as it was assumed to be the most accurate.
'Decannulated'	0.448	0.417-0.690	Freeman-Sanderson *et al.*, 2018; Vargas *et al.*, 2018; expert patient opinion	There is limited data available for utilities specifically for the 'decannulated' state. Therefore, the expert opinion value was used for the base-case estimate as it was assumed to be the most accurate.
'Not decannulated'	0.064	No range	Expert patient opinion	No utility data are available specifically for the 'not decannulated' state in the ICU. Therefore, the expert opinion value was used for the base-case estimate as it was assumed to be the most accurate.

'Decannulated-no dysphagia'				This utility value is broken down into utility values for: the rest of the ICU stay, the ward stay, the first year after discharge, the second year after discharge, and the third year until death.
ICU	0.585	0.585-0.69	Freeman-Sanderson *et al.*, 2018; expert patient opinion	The expert value was used for the base-case estimate as the Freeman-Sanderson value was for patients able to vocalise with a tracheostomy in the ICU.
ward	0.585	0.585-0.69	Freeman-Sanderson *et al.*, 2018; expert patient opinion	The expert value was used for the base-case estimate as the Freeman-Sanderson value was for patients able to vocalise with a tracheostomy in the ICU.
1st year after discharge	0.585	0.585-0.666	Cuthbertson *et al.*, 2005, 2010; expert patient opinion	The expert value was used for the base-case estimate as the Cuthbertson studies did not specify if patients had a tracheostomy in the ICU.
2nd year after discharge	0.701	0.585-0.701	Cuthbertson *et al.*, 2010; expert patient opinion	The Cuthbertson *et al*. (2010) value was used as the expert patient had been asked to provide a utility value for the composite endpoints. However, during the discussion, it was clear that their focus was on utility during the rest of the hospital admission. Despite the Cuthbertson study not specifying whether patients had a tracheostomy, it was assumed that by two years post-discharge, the utilities for non-dysphagic decannulated patients would be similar to other ICU patients.
3rd year to death	N/A	Male: 0.590 (age 62) to 0.484 (age 117); Female: 0.570 (age 62) to 0.411 (age 114)	Cuthbertson *et al.*, 2010; Hernández Alava, Pudney and Wailoo, 2022; Office for National Statistics, 2022	This was calculated using the NICE Decision Support Unit (DSU) report, which estimates EQ-5D by age and sex (Hernández Alava et al., 2022) and the Office for National Statistics (ONS) Life Tables (Office for National Statistics, 2022). An HRQoL deflator of 0.70 was used to adjust the EQ-5D values for the prior experience of these patients.

'Decannulated-dysphagia'				This utility value is broken down into utility values for: the rest of the ICU stay, the ward stay, the first year after discharge, the second year after discharge, and the third year until death.
ICU	0.585	0.55-0.585	Bendsen *et al.*, 2022; expert patient opinion	The expert value was used for the base-case estimate as the Bendsen value was for general dysphagic patients in the community, not patients who had experienced tracheostomy in the ICU and were currently in the ICU.
ward	0.585	0.55-0.585	Bendsen *et al.*, 2022; expert patient opinion	The expert value was used for the base-case estimate as the Bendsen value was for general dysphagic patients in the community, not patients who had experienced having a tracheostomy in the ICU and were on a hospital ward.
1st year after discharge	0.55	0.55-0.585	Bendsen *et al.*, 2022; expert patient opinion	The Bendsen *et al*, (2022) utility value was used because it was elicited from dysphagic patients in the community. The expert patient had been asked to provide a utility value for the composite endpoints, but during the discussion it was clear that their focus was on utility during the rest of the hospital admission.
2nd year after discharge	0.55	0.55-0.585	Bendsen *et al.*, 2022; expert patient opinion	The Bendsen *et al*, (2022) utility value was used as this was for dysphagic patients in the community. The expert patient had been asked to provide a utility value for the composite endpoints, but during the discussion it was clear that their focus was on utility during the rest of the hospital admission.
3rd year to death	N/A	Male: 0.463 (age 62) to 0.380 (age 117); Female: 0.447 (age 62) to 0.322 (age 114)	Bendsen *et al.*, 2022; Hernández Alava, Pudney and Wailoo, 2022; Office for National Statistics, 2022	This was calculated using the NICE DSU report which estimates EQ-5D by age and sex (Hernández Alava et al., 2022) and the ONS Life Tables (Office for National Statistics, 2022). A HRQoL deflator of 0.55 was used to adjust the EQ-5D values for the prior experience of these patients.

'Not decannulated-no dysphagia'				This utility value is broken down into utility values for: the rest of the ICU stay, the ward stay, the first year after discharge, the second year after discharge, and the third year until death.
ICU	0.239	No range	Expert patient opinion	The expert value was used for the base-case estimate as no utility data is available for this patient group.
ward	0.239	No range	Expert patient opinion	The expert value was used for the base-case estimate as there is no utility data available for this patient group.
1st year after discharge	0.239	0.239-0.666	Cuthbertson *et al.*, 2005, 2010; expert patient opinion	The expert value was used for the base-case estimate as the Cuthbertson studies did not specify if patients had had a tracheostomy.
2nd year after discharge	0.239	0.239-0.701	Cuthbertson *et al.*, 2010; expert patient opinion	The expert value was used for the base-case estimate as the Cuthbertson studies did not specify if patients had had a tracheostomy.
3rd year to death	N/A	Male: 0.526 (age 62) to 0.432 (age 117); Female: 0.508 (age 62) to 0.366 (age 114)	Cuthbertson *et al.*, 2010; Bendsen *et al.*, 2022; Hernández Alava, Pudney and Wailoo, 2022; Office for National Statistics, 2022	This was calculated using the NICE DSU report which estimates EQ-5D by age and sex (Hernández Alava et al., 2022) and the ONS Life Tables (Office for National Statistics, 2022). A HRQoL deflator of 0.63 (calculated from a median of the Cuthbertson *et al.* (2010) value and the Bendsen *et al.* (2022) value) was used to adjust the EQ-5D values for the prior experience of these patients.

'Not decannulated-dysphagia'				This utility value is broken down into utility values for: the rest of the ICU stay, the ward stay, the first year after discharge, the second year after discharge, and the third year until death.
ICU	0.145	No range	Expert patient opinion	The expert value was used for the base-case estimate as there is no utility data available for this patient group.
ward	0.145	0.145-0.55	Bendsen *et al.*, 2022; expert patient opinion	The expert value was used for the base-case estimate as the Bendsen value was for general dysphagic patients in the community, not patients who have a tracheostomy and have recently stepped down from an ICU.
1st year after discharge	0.145	0.145-0.55	Bendsen *et al.*, 2022; expert patient opinion	The expert value was used for the base-case estimate as the Bendsen value was for general dysphagic patients in the community, not patients who have a tracheostomy and spent time on the ICU.
2nd year after discharge	0.145	0.145-0.55	Bendsen *et al.*, 2022; expert patient opinion	The expert value was used for the base-case estimate as the Bendsen value was for general dysphagic patients in the community, not patients who have a tracheostomy and spent time on the ICU.
3rd year to death	N/A	Male: 0.463 (age 62) to 0.380 (age 117); Female: 0.447 (age 62) to 0.322 (age 114)	Bendsen *et al.*, 2022; Hernández Alava, Pudney and Wailoo, 2022; Office for National Statistics, 2022	This was calculated using the NICE DSU report which estimates EQ-5D by age and sex (Hernández Alava et al., 2022) and the ONS Life Tables (Office for National Statistics, 2022). A HRQoL deflator of 0.55 was used to adjust the EQ-5D values for the prior experience of these patients.

Table 28 Base-Case utilities for ACV

Variable	Base-Case estimate	Range	Data Source	Details and assumptions
'Dead'	0	N/A		As per standard utility value in health economics.
'Maintenance'	-0.271	-0.271-0.540	Freeman-Sanderson *et al.*, 2018; Pandian *et al.*, 2020; expert patient opinion	There is limited data available for utilities specifically for the 'maintenance' state when receiving ACV. Therefore, the expert opinion value was used as it was assumed to be the most accurate.
'Tracheostomy and ventilator weaning'	-0.068	-0.068-0.54	Freeman-Sanderson *et al.*, 2018; Pandian *et al.*, 2020; expert patient opinion	There is limited data available for utilities specifically for the 'tracheostomy and ventilator weaning' state when receiving ACV. Therefore, the expert opinion value was used as it was assumed to be the most accurate.
'Decannulated'; 'Not decannulated'; 'Decannulated-no dysphagia'; 'Decannulated-dysphagia'; 'Not decannulated-no dysphagia'; 'Not decannulated-dysphagia'	As per UC			Each of the values for these different states is the same as for UC, as it is assumed that ACV has no impact on utilities once discontinued.

Table 29 Unit costs applied to the model

Resource item	Unit cost	Conversion	Adjustment for Inflation	Source	Details and assumptions
'Dead'	£0	N/A	N/A		As per standard cost value in health economics.
ICU bed day cost 'maintenance'	£2,672	N/A	N/A	*National Schedule of NHS Costs Year: 2020-21*, 2020	Weighted average costs calculated for non-specific, general adult critical care patients with an average of three to six organs supported.
ICU bed day cost 'tracheostomy and ventilator weaning'	£2,327	N/A	N/A	*National Schedule of NHS Costs Year: 2020-21*, 2020	Weighted average costs calculated for non-specific, general adult critical care patients with an average of one to three organs supported.
ICU bed day cost 'decannulated'	£1,893	N/A	N/A	*National Schedule of NHS Costs Year: 2020-21*, 2020	Weighted average costs calculated for non-specific, general adult critical care patients with an average of zero to one organ supported.
ICU bed day cost 'not decannulated'	£2,211	N/A	N/A	*National Schedule of NHS Costs Year: 2020-21*, 2020	Weighted average costs calculated for non-specific, general adult critical care patients with an average of one to two organs supported.
Ward bed day cost 'decannulated'	£282	N/A	N/A	*National Tariff Workbook (Annex A) 2022/23*, 2022	Median costs of the per day long stay payment were calculated for a range of general medical conditions (Note: activity data was not provided, and it was not possible to calculate the weighted average).
Ward bed day cost 'not decannulated'	£313	N/A	N/A	*National Tariff Workbook (Annex A) 2022/23*, 2022	The cost for tracheostomy per day long stay payment was used (Note: activity data was not provided, and it was not possible to calculate the weighted average).

Thumb ports for ACV	£1.08 per port	N/A	N/A	eCommerce Deployment NHS Supply Chain, 2023	The costs used in the model varied according to the replacement frequency (e.g., daily or weekly). Weekly was used for base-case.
Oxygen tubing for ACV	£5.28 per 50m roll (3m needed for ACV)	N/A	N/A	eCommerce Deployment NHS Supply Chain, 2023	The costs used in the model varied according to the replacement frequency (e.g., daily or weekly). Weekly was used for base-case.
10 mL syringes for ACV	£0.04 per syringe	N/A	N/A	eCommerce Deployment NHS Supply Chain, 2023	Costings were used to allow for a replacement syringe for each ACV session.
Portex Blueline Ultra SuctionAid Tracheostomy	£69.63	N/A	N/A	eCommerce Deployment NHS Supply Chain, 2023	The median cost of Portex Blueline Ultra SuctionAid tracheostomy sizes 6, 7, 8, and 9 was used.
Consultant staff cost per hour session	£143	N/A	N/A	Jones *et al.*, 2022	Cost per working hour for a hospital-based Consultant (medical).
Nurse staff cost per hour session	£48	N/A	N/A	Jones *et al.*, 2022	The median of band 5 and 6 costs was used.
Physiotherapy staff cost per hour session	£55.25	N/A	N/A	Jones *et al.*, 2022	Median of bands 5 to 8a costs was used.
Registrar staff cost per hour session	£73	N/A	N/A	Jones *et al.*, 2022	Cost per working hour for a hospital-based Registrar.
Speech and language therapy staff cost per hour session	£60	N/A	N/A	Jones *et al.*, 2022	Median of band 6 to band 8a costs was used.

Nursing home costs per day	£181	N/A	N/A	Jones *et al.*, 2022	Establishment cost plus personal living expenses and external services per permanent resident per day. Used a probability of 0.042 patients requiring transfer to a nursing home.
Home care worker costs one session per day	£23	N/A	N/A	Cheung *et al.*, 2006; Jones *et al.*, 2022	Home care worker cost per weekday hour. Costings of two sessions per day for year one were used.
Rehabilitation ward costs per day	£550	N/A	N/A	*National Schedule of NHS Costs Year : 2020-21*, 2020	Value from rehabilitation for 'other disorders'. A probability of 0.217 was used for patients requiring transfer to a rehabilitation ward following discharge for 36 days. A 0.332 inflator was used for requiring readmission to rehab for patients with dysphagia. Costed for a 6-week rehabilitation stay in the first year.
Readmission cost for respiratory disorders	£1235	N/A	N/A	Cheung *et al.*, 2006; Hirshberg *et al.*, 2019; *National Schedule of NHS Costs Year : 2020-21*, 2020	Calculated from the weighted average of a short stay admission for other respiratory disorders with multiple or single interventions. The assumption is that most readmissions will be respiratory-related. A probability of 0.410 was used for patients requiring re-admission in the first year after discharge. A probability of 0.39 was used for patients requiring re-admission in the second year after discharge.
Outpatient consultant visit	£235	N/A	N/A	Cheung *et al.*, 2006; Jones *et al.*, 2022	A weighted average of all outpatient attendances. A median of 3.5 visits per year was applied in years 1 and 2.
General Practitioner visit	£42	N/A	N/A	Cheung *et al.*, 2006; Jones *et al.*, 2022	Cost of consultation lasting 9.22 minutes (including direct care staff costs). A median of 3.5 visits per year was applied in years 1 and 2.

Annual healthcare costs for median 45-74 year-old 'decannulated-no dysphagia'	£950 (2006)	N/A	£1327.88 (2021)	Caley and Sidhu, 2011	Annual healthcare costs for different age groups from 2006 were converted to 2021 prices. These costs were used in combination with the Office of National Statistics (ONS) life tables to calculate annual healthcare costs from 3 years after discharge to death.
Annual healthcare costs for median 45-74 year-old 'decannulated-dysphagia'	£1,274 (2006)	N/A	£1779.35 (2021)	Caley and Sidhu, 2011	Annual healthcare costs for different age groups from 2006 were converted to 2021 prices. These costs were combined with ONS life tables to calculate annual healthcare costs from 3 years after discharge to death. They were also inflated by 1.34 to account for increased costs associated with dysphagia.
Annual healthcare costs for median 45-74 year-old 'not decannulated-no dysphagia'	£1,112 (2006)	N/A	£1553.61 (2021)	Caley and Sidhu, 2011	This value was calculated from the median of the annual healthcare costs for 'decannulated-no dysphagia' and 'decannulated-dysphagia' as no evidence was available to support the cost of a tracheostomised patient in the community. These costs were used in combination with ONS life tables to calculate annual healthcare costs from 3 years after discharge to death.
Annual healthcare costs for median 45-74 year-old 'not decannulated-dysphagia'	£1,490 (2006)	N/A	£2,081.84 (2021)	Caley and Sidhu, 2011	As for the cost of 'not decannulated-dysphagia' there was no evidence to support the cost of a tracheostomised patient in the community. The cost for 'not decannulated-dysphagia' were inflated by 1.34 to account for increased costs associated with dysphagia. These costs were converted to 2021 prices and combined with ONS life tables to calculate annual healthcare costs from 3 years after discharge to death.

6.5.3.4 Other parameters

Other key parameters include:

- Discount rate for costs and QALYs of 3.5% was used from one year onwards (NICE, 2013)
- Death inflator of 70% in dysphagic states during ward stay (Patel et al., 2018)
- Death inflator of 25% in non-dysphagic states in the long-term stage of the model (three years to lifetime) to account for the ongoing reduced life expectancy assumed after discharge from critical care. This value has been used in other cost-effectiveness analyses in the critical care population (Angus et al., 2003; Cox, Carson, Govert, et al., 2007; Cox, Carson, Lindquist, et al., 2007)
- Death inflator of 43% in dysphagia states in the long-term stage of the model (three years to lifetime) to account for the ongoing reduced life expectancy assumed after discharge from critical care combined with the increased risk of death in the dysphagic population (Angus et al., 2003; Cox, Carson, Govert, et al., 2007; Cox, Carson, Lindquist, et al., 2007; Patel et al., 2018)
- LoS in the ICU after decannulation of 11 days (van der Lely et al., 2006)
- LoS on the ward after decannulation of 19 days, which was calculated from the median of two key studies (Engoren et al., 2004; Freeman-Sanderson et al., 2011)
- LoS inflator of 43% for patients with dysphagia (Patel et al., 2018)
- 64% probability of being male calculated from the median of the primary papers used in the model (Engoren et al., 2004; van der Lely et al., 2006; Freeman-Sanderson et al., 2011; Daly et al., 2016; Depuydt et al., 2016; Vargas et al., 2018)
- Median age of 62.5 years calculated from the median of the primary papers used in the model (Engoren et al., 2004; van der Lely et al., 2006; Freeman-Sanderson et al., 2011; Daly et al., 2016; Depuydt et al., 2016; Vargas et al., 2018)

6.5.4 Summary of main results

6.5.4.1 Cost-Effectiveness

The transition of hypothetical patients through the short-term portion of the model is illustrated in Figure 16 as a Markov trace for patients in UC and ACV. Patients receiving ACV transition through the model more quickly than those receiving UC, with a greater proportion ending up in the ‘decannulated-no dysphagia’ state.

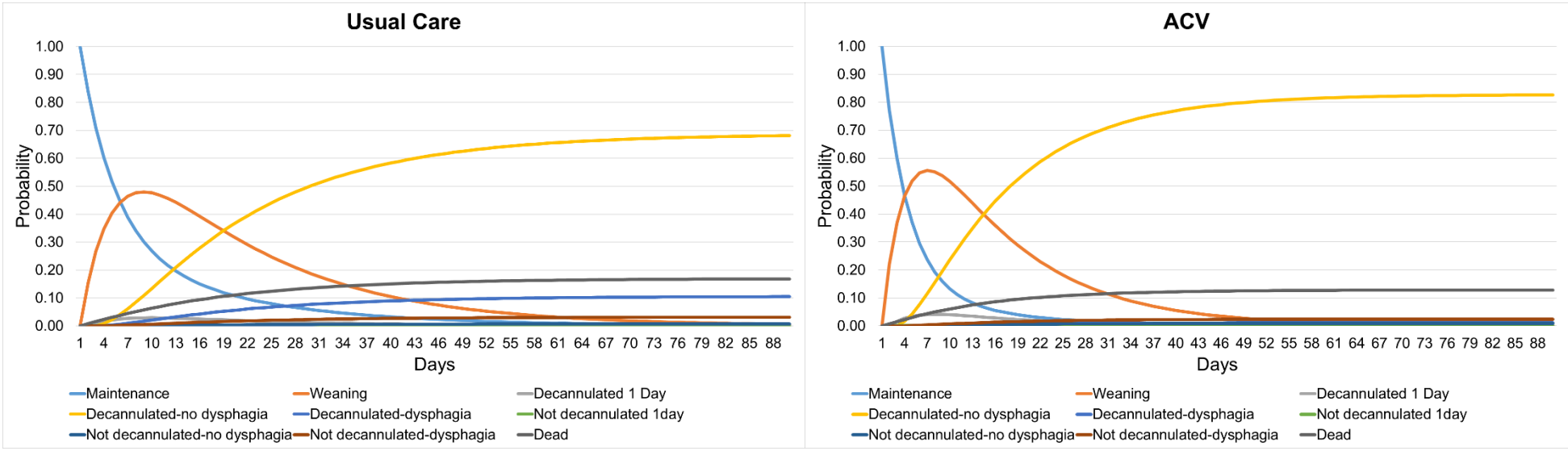

Figure 16 Markov trace for base-case scenario (*Left:* UC trace; *Right:* ACV trace)

The costs, QALYs, and cost-effectiveness for each stage of the model for UC and ACV using base-case estimates are outlined in Table 30. The analysis reveals that ACV is potentially cost-effective, dominating UC with cost savings of £9,488.16 and 0.395 QALYs gained overall.

Table 30 Base-case scenario cost-effectiveness for short term, intermediate term, long term, and total

	UC	**ACV**		**Base-case results**
Short term (90-days)				
90-day costs	£77,850.52	£66,508.55	**90-day difference in costs**	-£11,341.97
90-day QALYs	0.047	0.075	**90-day difference in QALYs**	0.028
			90-day ICER	ACV Dominates
			90-day INMB (£20,000 WTP threshold)	£11,903
			90-day INHB (£20,000 WTP threshold)	0.595
Intermediate term (1-2 years)				
Year 1-2 costs	£10,667.70	£11,753.14	**Year 1-2 difference in costs**	£1,085.44
Year 1-2 QALYs	0.535	0.599	**Year 1-2 difference in QALYs**	0.064
			Year 1-2 ICER	£16,974.14
			Year 1-2 INMB (£20,000 WTP threshold)	£193
			Year 1-2 INHB (£20,000 WTP threshold)	0.010
Long term (3 years to Lifetime)				
Year 3-Lifetime costs	£6,293.20	£7,061.57	**Year 3-Lifetime difference in costs**	£768.37
Year 3-Lifetime QALYs	2.156	2.458	**Year 3-Lifetime difference in QALYs**	0.303

			Year 3-Lifetime ICER	£2,539.22
			Year 3-Lifetime INMB (£20,000 WTP threshold)	£5,284
			Year 3-Lifetime INHB (£20,000 WTP threshold)	0.264
Total				
Total costs	£94,811.42	£85,323.26	**Total difference in costs**	-£9,488.16
Total QALYs	2.738	3.132	**Total difference in QALYs**	0.395
			Total ICER	ACV Dominates
			Total INMB (£20,000 WTP threshold)	£17,380
			Total INHB (£20,000 WTP threshold)	0.869

6.5.5 Sensitivity analysis

6.5.5.1 Sensitivity analysis of the effectiveness of ACV

Several sensitivity analyses were conducted to explore the effectiveness parameters for ACV and how they impacted overall cost-effectiveness. Sensitivity analysis 1 examined the impact of varying all parameters for UC and ACV; the altered values for both analyses are reported in Table 31. Sensitivity analysis 1 used the best parameters for UC, including utilities from the literature rather than the experts, and the worst parameters for ACV provided by the experts. For example, where one expert stated that ACV would have a 0% impact on the probability of death, the UC values were used. The findings of sensitivity analysis 1 are reported in Table 32.

Table 31 Altered parameters for sensitivity analysis 1 compared to base-case parameters

Variable	Base-Case estimate		Sensitivity Analysis 1: best outcomes for UC, worst outcomes for ACV, and highest ACV costs	
	UC	ACV	UC	ACV
'Tracheostomy maintenance' to 'tracheostomy and ventilator weaning'	0.154	0.221	0.154	0.154
'Tracheostomy and ventilator weaning' to 'tracheostomy maintenance'	0.032	0.019	0.007	0.007
'Tracheostomy and ventilator weaning' to 'decannulated'	0.061	0.074	0.249	0.487
'Tracheostomy and ventilator weaning' to 'not decannulated'	0.003	0.003	0.003	0.003
'Decannulated' to 'decannulated-dysphagia'	0.133	0.013	0.089	0.083
'Not decannulated' to 'not decannulated-dysphagia'	0.820	0.731	0.025	0.025
'Tracheostomy maintenance' to 'dead' And 'Tracheostomy and ventilator weaning' to 'dead'	0.0077321	0.0077318	0.0076765	0.0076765
Cost in 'tracheostomy maintenance'	£2,672 per day	£2,747 per day	£2,672 per day	£2,761 per day
Cost in 'tracheostomy and ventilator weaning'	£2,327 per day	£2,402 per day	£2,327 per day	£2,415 per day
Utility in 'tracheostomy maintenance'	-0.510	-0.271	0.354	-0.271
Utility in 'tracheostomy and ventilator weaning'	-0.269	-0.068	0.540	-0.068
Utility in 'decannulated'	0.448	As per UC	0.690	As per UC
Utility in 'not decannulated'	0.064	As per UC	0.064	As per UC
Utility in 'decannulated-no dysphagia' in the ICU	0.585	As per UC	0.690	As per UC

Utility in ‘decannulated-dysphagia’ in the ICU	0.585	As per UC	0.585	As per UC
Utility in ‘not decannulated-no dysphagia’ in the ICU	0.239	As per UC	0.239	As per UC
Utility in ‘not decannulated-dysphagia’ in the ICU	0.145	As per UC	0.145	As per UC
Utility in ‘decannulated-no dysphagia’ on the ward	0.585	As per UC	0.690	As per UC
Utility in ‘decannulated-dysphagia’ on the ward	0.585	As per UC	0.585	As per UC
Utility in ‘not decannulated-no dysphagia’ on the ward	0.239	As per UC	0.239	As per UC
Utility in ‘not decannulated-dysphagia’ on the ward	0.145	As per UC	0.550	As per UC
Utility in ‘decannulated-no dysphagia’ in the 1st year	0.585	As per UC	0.666	As per UC
Utility in ‘decannulated-dysphagia’ in the 1st year	0.55	As per UC	0.585	As per UC
Utility in ‘not decannulated-no dysphagia’ in the 1st year	0.239	As per UC	0.666	As per UC
Utility in ‘not decannulated-dysphagia’ in the 1st year	0.145	As per UC	0.550	As per UC
Utility in ‘decannulated-no dysphagia’ in the 2nd year	0.701	As per UC	0.701	As per UC
Utility in ‘decannulated-dysphagia’ in the 2nd year	0.55	As per UC	0.585	As per UC
Utility in ‘not decannulated-no dysphagia’ in the 2nd year	0.239	As per UC	0.701	As per UC
Utility in ‘not decannulated-dysphagia’ in the 2nd year	0.145	As per UC	0.550	As per UC

Table 32 Sensitivity cost-effectiveness analysis 1 compared with base-case results

	Base-case results	Sensitivity Analysis 1: best outcomes for UC, worst outcomes for ACV, and highest ACV costs
Short term (90-days)		
90-day difference in costs	-£11,341.97	-£3,154.37
90-day difference in QALYs	0.028	-0.008
90-day ICER	ACV Dominates	£405,896.05
90-day INMB (£20,000 WTP threshold)	£11,903	£2,999
90-day INHB (£20,000 WTP threshold)	0.595	0.150
Intermediate term (1-2 years)		
Year 1-2 difference in costs	£1,085.44	£209.87
Year 1-2 difference in QALYs	0.064	0.012
Year 1-2 ICER	£16,974.14	£17,429.11
Year 1-2 INMB (£20,000 WTP threshold)	£193	£31
Year 1-2 INHB (£20,000 WTP threshold)	0.010	0.002
Long term (3 years to Lifetime)		
Year 3-Lifetime difference in costs	£768.37	£130.44
Year 3-Lifetime difference in QALYs	0.303	0.050
Year 3-Lifetime ICER	£2,539.22	£2,601.21
Year 3-Lifetime INMB (£20,000 WTP threshold)	£5,284	£872
Year 3-Lifetime INHB (£20,000 WTP threshold)	0.264	0.044
Total		
Total difference in costs	-£9,488.16	-£2,814.07
Total difference in QALYs	0.395	0.054
Total ICER	ACV Dominates	ACV Dominates
Total INMB (£20,000 WTP threshold)	£17,380	£3,902
Total INHB (£20,000 WTP threshold)	0.869	0.195

Sensitivity analysis 2 evaluated the impact of ACV having a negative effect on the ICU and ward LoS. No experts reported that ACV would have a negative impact on ICU or ward LoS, but the RCT of ACV found that ICU LoS was 20 days more, and ward LoS was 25 days more in the ACV group (Pandian et al., 2020). For this sensitivity analysis, the base-case scenario parameters were used for both UC and ACV, but for ACV, the ICU LoS after patients reached the end states was increased by 20 days, and the ward LoS was increased by 25 days. The results of this sensitivity analysis are reported in Table 33.

Table 33 Sensitivity cost-effectiveness analysis 2 compared with base-case results

	Base-case results	**Sensitivity Analysis 2: transition probabilities the same for UC and ACV, with longer ICU LoS and ward LoS for ACV**
Short term (90-days)		
90-day difference in costs	-£11,341.97	£19,785.45
90-day difference in QALYs	0.028	0.050
90-day ICER	ACV Dominates	£395,234.80
90-day INMB (£20,000 WTP threshold)	£11,903	-£18,784
90-day INHB (£20,000 WTP threshold)	0.595	-0.939
Intermediate term (1-2 years)		
Year 1-2 difference in costs	£1,085.44	-£2,211.52
Year 1-2 difference in QALYs	0.064	-0.104
Year 1-2 ICER	£16,974.14	£21,246.87
Year 1-2 INMB (£20,000 WTP threshold)	£193	£130
Year 1-2 INHB (£20,000 WTP threshold)	0.010	0.006
Long term (3 years to Lifetime)		
Year 3-Lifetime difference in costs	£768.37	-£1,171.73
Year 3-Lifetime difference in QALYs	0.303	-0.387
Year 3-Lifetime ICER	£2,539.22	£3,026.63
Year 3-Lifetime INMB (£20,000 WTP threshold)	£5,284	-£6,571

Year 3-Lifetime INHB (£20,000 WTP threshold)	0.264	-0.329
Total		
Total difference in costs	-£9,488.16	£16,402.20
Total difference in QALYs	0.395	-0.441
Total ICER	ACV Dominates	UC Dominates
Total INMB (£20,000 WTP threshold)	£17,380	-£25,226
Total INHB (£20,000 WTP threshold)	0.869	-1.261

Sensitivity analyses 3 to 6 focused on evaluating the impact of ACV on transition probabilities and how hypothetical patients transition through the model. The altered parameter values for each sensitivity analysis are reported in Table 34. Sensitivity analysis 3 used the best outcomes for UC but applied base-case utility values for UC and ACV. This analysis explored ACV not having an impact on transition probabilities, which included no difference in the probability of transition for any of the following: 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning', 'tracheostomy and ventilator weaning' to 'tracheostomy maintenance', 'tracheostomy and ventilator weaning' to 'decannulated', 'decannulated' to 'decannulated-dysphagia', 'not decannulated' to 'not decannulated-dysphagia', or from any state to 'dead'. Sensitivity analyses 4 and 5 used base-case estimates for UC and ACV but varied one transition probability in each analysis to explore which might have the largest impact on cost-effectiveness. Sensitivity analysis 4 examined the probability of 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning'. Sensitivity analysis 5 explored the probability of 'tracheostomy and ventilator weaning' to 'decannulated'. Sensitivity analysis 6 examined the probability of 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning' and 'tracheostomy and ventilator weaning' to 'decannulated'. The results of sensitivity analyses 3 to 6 are reported in Table 35. The Markov trace for sensitivity analysis 3 is illustrated in Figure 17.

Table 34 Altered parameters for sensitivity analysis 3, 4, 5, and 6 compared to base-case parameters

Variable	Base-Case estimate		Sensitivity Analysis 3: best outcomes for UC, base-case utility values, and ACV having no impact on transition probabilities		Sensitivity Analysis 4: base-case estimates except the probability for transition from 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning' was the same for UC and ACV		Sensitivity Analysis 5: base-case estimates except the probability for transition from 'tracheostomy and ventilator weaning' to 'decannulated' was the same for UC and ACV		Sensitivity Analysis 6: base-case estimates except the probability for transition from 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning' and for 'tracheostomy and ventilator weaning' to 'decannulated' were the same for UC and ACV	
	UC	**ACV**	**UC**	**ACV**	**UC**	**ACV**	**UC**	**ACV**	**UC**	**ACV**
'Tracheostomy maintenance' to 'tracheostomy and ventilator weaning'	0.154	0.221	0.154	0.154	0.154	0.154	0.154	0.221	0.154	0.154
'Tracheostomy and ventilator weaning' to 'tracheostomy maintenance'	0.032	0.019	0.007	0.007	0.032	0.019	0.032	0.019	0.032	0.019
'Tracheostomy and ventilator weaning' to 'decannulated'	0.061	0.074	0.249	0.249	0.061	0.074	0.061	0.061	0.061	0.061

‘Tracheostomy and ventilator weaning’ to ‘not decannulated’	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
‘Decannulated’ to ‘decannulated-dysphagia’	0.133	0.013	0.089	0.089	0.133	0.013	0.133	0.013	0.133	0.013
‘Not decannulated’ to ‘not decannulated-dysphagia’	0.820	0.731	0.025	0.025	0.820	0.731	0.820	0.731	0.820	0.731
‘Tracheostomy maintenance’ to ‘dead’ And ‘Tracheostomy and ventilator weaning’ to ‘dead’	0.0077321	0.0077318	0.0076765	0.0076765	0.0077321	0.0077318	0.0077321	0.0077318	0.0077321	0.0077318
Cost in ‘tracheostomy maintenance’	£2,672 per day	£2,747 per day	£2,672 per day	£2,761 per day	£2,672 per day	£2,747 per day	£2,672 per day	£2,747 per day	£2,672 per day	£2,747 per day
Cost in ‘tracheostomy and ventilator weaning’	£2,327 per day	£2,402 per day	£2,327 per day	£2,415 per day	£2,327 per day	£2,402 per day	£2,327 per day	£2,402 per day	£2,327 per day	£2,402 per day

Table 35 Sensitivity cost-effectiveness analyses 3, 4, 5, and 6 compared with base-case results

	Base-case results	Sensitivity Analysis 3: best outcomes for UC, base-case utility values, and ACV having no impact on transition probabilities	Sensitivity Analysis 4: base-case estimates except the probability for transition from 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning' was the same for UC and ACV	Sensitivity Analysis 5: base-case estimates except the probability for transition from 'tracheostomy and ventilator weaning' to 'decannulated' was the same for UC and ACV	Sensitivity Analysis 6: base-case estimates except the probability for transition from 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning' and for 'tracheostomy and ventilator weaning' to 'decannulated' were the same for UC and ACV
Short term (90-days)					
90-day difference in costs	-£11,341.97	£883.45	-£6,335.89	-£6,399.34	-£1,380.99
90-day difference in QALYs	0.028	0.010	0.023	0.023	0.018
90-day ICER	ACV Dominates	£87,371.98	ACV Dominates	ACV Dominates	ACV Dominates
90-day INMB (£20,000 WTP threshold)	£11,903	-£681	£6,793	£6,866	£1,744
90-day INHB (£20,000 WTP threshold)	0.595	-0.034	0.340	0.343	0.087

Intermediate term (1-2 years)					
Year 1-2 difference in costs	£1,085.44	£0	£900.64	£837.23	£653.00
Year 1-2 difference in QALYs	0.064	0.000	0.054	0.050	0.041
Year 1-2 ICER	£16,974.14	£0	£16,568.48	£16,593.73	£16,020.86
Year 1-2 INMB (£20,000 WTP threshold)	£193	£0	£187	£172	£162
Year 1-2 INHB (£20,000 WTP threshold)	0.010	0.000	0.009	0.009	0.008
Long term (3 years to Lifetime)					
Year 3-Lifetime difference in costs	£768.37	£0	£644.81	£540.32	£406.07
Year 3-Lifetime difference in QALYs	0.303	0.000	0.262	0.241	0.199
Year 3-Lifetime ICER	£2,539.22	£0	£2,458.38	£2,242.56	£2,036.17
Year 3-Lifetime INMB (£20,000 WTP threshold)	£5,284	£0	£4,601	£4,278	£3582
Year 3-Lifetime INHB (£20,000 WTP threshold)	0.264	0.000	0.230	0.214	0.179

Total					
Total difference in costs	-£9,488.16	£883.45	-£4,790.44	-£5,021.78	-£321.92
Total difference in QALYs	0.395	0.010	0.340	0.315	0.258
Total ICER	ACV Dominates	£87,371.98	ACV Dominates	ACV Dominates	ACV Dominates
Total INMB (£20,000 WTP threshold)	£17,380	-£681	£11,581	£11,316	£5,488
Total INHB (£20,000 WTP threshold)	0.869	-0.034	0.579	0.566	0.274

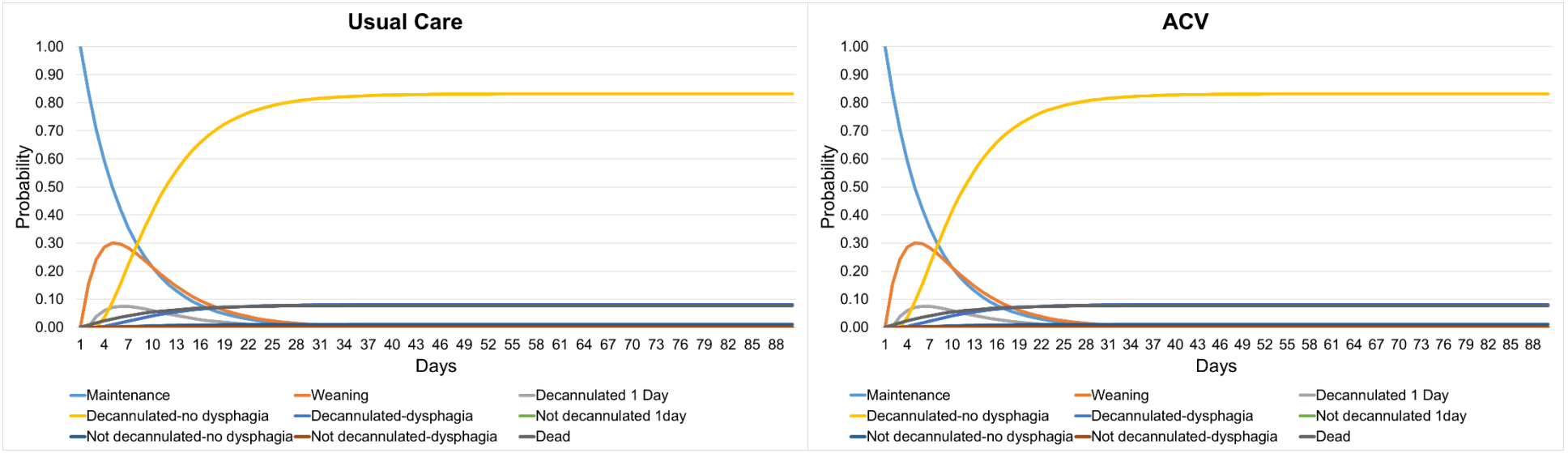

Figure 17 Markov trace for sensitivity analysis 3 (*Left:* UC trace; *Right:* ACV trace). Illustrating there is no difference in transition probabilities between UC and ACV

6.5.5.2 Sensitivity analysis of ICU costs

Sensitivity analyses 7 and 8 focused on exploring ICU costs and their impact on the cost-effectiveness of ACV. Sensitivity analysis 7 used a cost of £2672 for all ICU bed day costs regardless of the state of the model. Sensitivity analysis 8 evaluated using an ICU LoS of one day after patients reached 'decannulated' or 'not decannulated' rather than the base-case estimate of 11 days. The results of sensitivity analyses 7 and 8 are described in Table 36.

Table 36 Sensitivity cost-effectiveness analyses 7 and 8 compared with base-case results

	Base-case results	**Sensitivity Analysis 7: ICU bed costs the same for all states in the model**	**Sensitivity Analysis 8: ICU LoS after 'decannulated' or 'not decannulated' of 1 day**
Short term (90-days)			
90-day difference in costs	-£11,341.97	-£11,716.87	-£11,424.25
90-day difference in QALYs	0.028	0.028	0.029
90-day ICER	ACV Dominates	ACV Dominates	ACV Dominates
90-day INMB (£20,000 WTP threshold)	£11,903	£12,278	£11,998
90-day INHB (£20,000 WTP threshold)	0.595	0.614	0.600
Intermediate term (1-2 years)			
Year 1-2 difference in costs	£1,085.44	£1,085.44	£1,110.45
Year 1-2 difference in QALYs	0.064	0.064	0.066
Year 1-2 ICER	£16,974.14	£16,974.14	£16,705.82
Year 1-2 INMB (£20,000 WTP threshold)	£193	£193	£219
Year 1-2 INHB (£20,000 WTP threshold)	0.010	0.010	0.011

Long term (3 years to Lifetime)			
Year 3-Lifetime difference in costs	£768.37	£768.37	£790.80
Year 3-Lifetime difference in QALYs	0.303	0.303	0.319
Year 3-Lifetime ICER	£2,539.22	£2,539.22	£2,482.40
Year 3-Lifetime INMB (£20,000 WTP threshold)	£5,284	£5,284	£5,580
Year 3-Lifetime INHB (£20,000 WTP threshold)	0.264	0.264	0.279
Total			
Total difference in costs	-£9,488.16	-£9,863.07	-£9,523.01
Total difference in QALYs	0.395	0.395	0.414
Total ICER	ACV Dominates	ACV Dominates	ACV Dominates
Total INMB (£20,000 WTP threshold)	£17,380	£17,755	£17,798
Total INHB (£20,000 WTP threshold)	0.869	0.888	0.890

6.5.5.3 Sensitivity analysis of long-term outcomes after ACV

Sensitivity analyses 9 and 10 evaluate how the introduction of a positive effect from ACV that lasts beyond intervention delivery impacts the cost-effectiveness of the intervention. Sensitivity analysis 9 explores using an ACV utility inflator of 1% for all states after ‘tracheostomy and ventilator weaning’, and sensitivity analysis 10 uses an ACV utility inflator of 10%. The sensitivity analyses are reported in Table 37.

Table 37 Sensitivity cost-effectiveness analyses 9 and 10 compared with base-case results

	Base-case results	Sensitivity Analysis 9: positive effects for ACV beyond the delivery period using a utility inflator of 1%	Sensitivity Analysis 10: positive effects for ACV beyond the delivery period using a utility inflator of 10%
Short term (90-days)			
90-day difference in costs	-£11,341.97	-£11,341.97	-£11,341.97
90-day difference in QALYs	0.028	0.029	0.036
90-day ICER	ACV Dominates	ACV Dominates	ACV Dominates
90-day INMB (£20,000 WTP threshold)	£11,903	£11,919	£12,061
90-day INHB (£20,000 WTP threshold)	0.595	0.596	0.603
Intermediate term (1-2 years)			
Year 1-2 difference in costs	£1,085.44	£1,085.44	£1,085.44
Year 1-2 difference in QALYs	0.064	0.070	0.124
Year 1-2 ICER	£16,974.14	£15,520.17	£8,763.90
Year 1-2 INMB (£20,000 WTP threshold)	£193	£313	£1,392
Year 1-2 INHB (£20,000 WTP threshold)	0.010	0.016	0.070
Long term (3 years to Lifetime)			
Year 3-Lifetime difference in costs	£768.37	£768.37	£768.37
Year 3-Lifetime difference in QALYs	0.303	0.327	0.548
Year 3-Lifetime ICER	£2,539.22	£2,348.43	£1,401.02
Year 3-Lifetime INMB (£20,000 WTP threshold)	£5,284	£5,775	£10,200
Year 3-Lifetime INHB (£20,000 WTP threshold)	0.264	0.289	0.510

Total			
Total difference in costs	-£9,488.16	-£9,488.16	-£9,488.16
Total difference in QALYs	0.395	0.426	0.708
Total ICER	ACV Dominates	ACV Dominates	ACV Dominates
Total INMB (£20,000 WTP threshold)	£17,380	£18,008	£23,653
Total INHB (£20,000 WTP threshold)	0.869	0.900	1.183

6.6 Discussion

This chapter presents the structure, parametrisation, and results of the first early-stage DAM evaluating ACV against UC in the context of UK critically ill patients in the general ICU. There has been limited use of DAMs within the critical care specialty. Similarly, there has been limited application in the context of the anaesthesia specialty, and the various reasons postulated for this appear applicable to the critical care field (Yentis, 2006). Potential reasons for the limited use of DAMs in critical care include (i) the paucity of data and research efforts required to enable the estimation of probabilities and utilities; (ii) the complex treatment processes in critical care making the DAM challenging to map; and (iii) potential challenges in obtaining utilities from patients in the ICU (Yentis, 2006).

This early-stage DAM applying VOI principles identifies some of the critical areas of uncertainty which have the most significant impact on cost-effectiveness. Furthermore, it will help to direct future research to the areas that will provide the most value and reduce levels of uncertainty. This model provides a starting point for future cost-effectiveness analysis which should be built upon as new evidence regarding ACV accrues.

6.6.1 Cost-effectiveness of ACV

The base-case scenario indicates that ACV is potentially cost-effective overall, with ACV dominating in the model's short-term stage and overall. This means that ACV is more effective and less costly than UC when considered during the lifetime of the model and the first 90-day period of the model. However, during the model's intermediate and long-term stages, ACV costs more than UC but is more effective. With a WTP threshold of £20,000 (as is typically used by NICE), ACV is cost-effective during the intermediate and long-term stages of the model, with ICERs of £16,974 and

£2,539 per QALY, respectively. The total lifetime cost savings are £9,488, and the lifetime QALYs gained are 0.395, with most of the cost savings (£11,342) occurring during the 90-day period and most of the QALYs (0.303) gained during the long-term stage of the model. The findings of this analysis suggest substantial cost savings, probably due to reduced ICU LoS during the first 90 days of the model and considerable improvements to the QoL of patients over their lifetime. Overall, the cost-effectiveness of ACV is almost entirely driven by the cost savings made in the short-term stage of the model because of reduced ICU LoS. This highlights the importance of future research to reduce the uncertainty in the effect of ACV on the ICU LoS as this appears to be the primary driver for the cost-effectiveness of ACV, based on existing evidence and expert opinion.

The finding that most of the QALYs are gained during the long-term stage of the model may be surprising, given that there are no differences in QALYs between states for UC and ACV after the 'tracheostomy and ventilator weaning' state when ACV is no longer used. These results are driven by patients who have received ACV being more likely to transition to an end state with a higher utility value, for example, 'decannulated-no dysphagia'. Given that there are no direct ACV costs after the 'tracheostomy and ventilator weaning' state of the model, the increased costs during the intermediate and long-term stages of the model are potentially due to the increased survival in the ACV group, with dead patients generating no costs. The extent of the cost savings during the short-term stage combined with the increase in QALYs throughout all stages of the model, outweighs the increased costs associated with ACV during the later stages of the model.

6.6.2 Sensitivity analyses

One-way sensitivity analyses were conducted to explore where the uncertainty in the model lies and to apply VOI principles to identify key drivers of cost-effectiveness changes.

6.6.2.1 Sensitivity analysis of the effectiveness of ACV

Sensitivity analysis 1 explored the impact of increasing the costs of ACV using daily replacement of thumb ports and oxygen tubing while also increasing the effectiveness of UC and reducing the effectiveness of ACV. Increasing and reducing effectiveness for UC and ACV included adjusting the probabilities for transition through the model and the utilities for each state to be the best and worst, respectively, as determined by the literature and expert opinion. Despite these changes, the results demonstrate that ACV continues to dominate UC overall but was not cost-effective in the short term. The extent of the overall cost-effectiveness was reduced compared to the base-case scenario. The cost saving was reduced from £9,488 in the base-case scenario to

£2,814. The increase in QALYs was also reduced from 0.395 in the base-case scenario to 0.054. This indicates that even if the effectiveness of ACV is substantially less than that estimated by experts, and even when it is equivalent to UC for some parameters, it can still be cost-effective because of the substantial cost savings in the short-term portion of the model. Furthermore, it shows that even when utility values from the literature are used, rather than the much lower values provided by the patient expert, QALYs are still gained overall, though they are much reduced with a slight loss in the short term.

Sensitivity analysis 2 evaluated the impact of ACV having a negative impact on the ICU LoS and ward LoS. All clinical experts believed ACV would have either a neutral or positive effect on LoS, and the interview findings also supported this belief. In contrast, the RCT of ACV reported that patients receiving ACV had a 20-day increase in the ICU stay and a 25-day increase in ward stay (Pandian et al., 2020). RCT data is usually given priority over expert opinion in health economic evaluations, and typically this data would be used in the base-case scenario. However, personal communication with the researchers for this RCT revealed several key factors that may have caused this unexpected finding of increased LoS. Firstly, 40% of the control group proceeded to cuff deflation and OWV trials, but none of the ACV group did. One study has shown that early cuff deflation can accelerate the tracheostomy weaning process, though it did not reduce ICU or hospital LoS (Martin et al., 2021). However, this early cuff deflation study allowed the control group to have cuff deflation from 48 hours, whereas the ACV RCT actively restricted cuff deflation for five days of treatment (Pandian et al., 2020; Martin et al., 2021). Delaying cuff deflation for such a prolonged period will presumably adversely affect the ICU and ward LoS. Secondly, there was a significantly greater number of patients with medical pulmonary impairment in the ACV group compared to the control group. This patient group may take longer to recover and require a more extended ICU and hospital stay, skewing the ACV group's data. Thirdly, the local hospitals and discharge destinations reportedly did not accept patients with the Portex BLUSA tracheostomy tube, meaning that patients had to have a tracheostomy tube change or be decannulated before transfer. This could have resulted in an increase in LoS for some patients in the ACV group. These factors, in combination with the high risk of bias in the study, led to the decision to apply this increased LoS estimate in a sensitivity analysis rather than in the base-case scenario.

This sensitivity analysis evaluated the impact of the additional ICU and ward LoS reported in the RCT on the cost-effectiveness analysis while keeping all other parameters at base-case values (Pandian et al., 2020). There was a significant impact on cost-effectiveness, with UC dominating and being less costly and more effective than ACV. The total difference in cost was an additional £16,402, with a loss of -0.441 QALYs, with the additional cost occurring during the short-term stage of the model.

Sensitivity analyses 3 to 6 varied ACV's impact on the transition probabilities and how hypothetical patients moved through the model. The average expert opinion was that ACV would: 1) reduce the risk of mortality; 2) increase the rate of transition from 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning'; 3) reduce the risk of regression from 'tracheostomy and ventilator weaning' to 'tracheostomy maintenance'; 4) increase the rate of transition from 'tracheostomy and ventilator weaning' to 'decannulated' and the proportion of patients that would be decannulated; and 5) reduce the risk of patients developing dysphagia whether decannulated or not decannulated. Sensitivity analysis 3 evaluated ACV as having no impact on all these transition probabilities, with the transition probabilities being set to the same values as for UC. This analysis showed that ACV is not cost-effective, with an overall ICER of £87,372 per QALY and an overall gain of just 0.010 QALYs. In this analysis, all the costs of ACV and the QALYs gained occurred during the short-term stage of the model. This sensitivity analysis was the only other analysis in which ACV was not cost-effective, in addition to sensitivity analysis 2. Sensitivity analyses 2 and 3 suggest that the key determining factor influencing the cost-effectiveness of ACV is how patients move through the model and how ACV impacts the various transition probabilities, as this impacts costly ICU LoS.

Sensitivity analyses 4 to 6 evaluated the specific transition probabilities that appear to be the most critical drivers of cost-effectiveness by having the greatest impact on LoS. Sensitivity analysis 4 set the probability of transition from 'tracheostomy maintenance' to 'tracheostomy and ventilator weaning' for ACV to the same value as for UC, with all other parameters remaining at base-case values. ACV remained dominant to UC, both in the short-term stage and overall, but the total cost savings were £4,698 less, and the total QALYs added compared to UC were 0.055 less than in the base-case scenario. The reduction in QALYs gained occurs at each stage of the model, but the reduction in cost savings was primarily lost in the short-term stage due to the increased ICU LoS. This suggests that even if ACV has no impact on accelerating the patient transition to weaning, it could still be cost-effective. Nevertheless, the extent of this cost-effectiveness and the cost savings would be considerably reduced.

Sensitivity analysis 5 set the transition probability from 'tracheostomy and ventilator weaning' to 'decannulated' for ACV to be the same as for UC and kept all other parameters at base-case values. ACV remained dominant to UC, both in the short-term stage and overall, but the total cost savings were £4,466 less, and the total QALYs added were 0.080 less than in the base-case scenario. The reduction in QALYs gained occurs primarily in the long-term stage of the model. In contrast, the reduction in cost savings occurs mainly in the short-term stage due to an increase in ICU LoS. Similarly to sensitivity analysis 4, even if ACV has no impact on accelerating the patient

transition to decannulation, it would still be cost-effective. However, the extent of this cost-effectiveness and cost saving would be much reduced.

Sensitivity analysis 6 set the probability of transition from ‘tracheostomy maintenance’ to ‘tracheostomy and ventilator weaning’ and for ‘tracheostomy and ventilator weaning’ to ‘decannulated’ to the same values for ACV as for UC while keeping all other parameters at base-case values. ACV remained dominant to UC, both in the short-term stage and overall, but the cost savings were £9,166 less, and the QALYs added compared to UC were 0.137 less than in the base-case scenario. This reveals that even when the two transition probabilities that have the most impact on cost are set to be unaffected by ACV, ACV remains less costly and more effective than UC.

It appears that it is only when ACV has no impact on all transition probabilities and no influence on the speed with which patients move through the decannulation pathway, or when it increases ICU and ward LoS in other ways, that ACV is not cost-effective. The key transition probabilities that appear to have the most influence on cost-effectiveness appear to be the probability of transition from ‘tracheostomy maintenance’ to ‘tracheostomy and ventilator weaning’ and from ‘tracheostomy and ventilator weaning’ to ‘decannulated’. Therefore, determining whether ACV has a negative effect on LoS appears crucial to establish with certainty if ACV is cost-effective. If ACV has a negative impact on LoS, a critical question will be whether it is due to the impact on transition probabilities (i.e., the speed of weaning) or other factors. From personal discussions with the authors of the RCT (Pandian et al., 2020), other factors were implicated in the increase in LoS seen in the ACV group. For example, delayed discharge or hospital transfer due to problems with other hospitals or facilities accepting tracheostomy tubes with subglottic ports, delays before insertion of the tracheostomy tube, and the fact that the control group continued with cuff deflation and OWV trials, which may have impacted on the speed of the tracheostomy weaning process. Many of these factors are mitigable, whereas if ACV adversely affects the speed of weaning, it is unlikely to be cost-effective.

6.6.2.2 Sensitivity analysis of ICU costs

Sensitivity analyses 7 and 8 explored the impact of altering ICU cost on the cost-effectiveness of ACV. In the base-case scenario, the cost of an ICU bed per day for patients in the ‘tracheostomy maintenance’ state was more expensive than a day in the ‘tracheostomy and ventilator weaning’ state, with the assumption that patients in ‘tracheostomy maintenance’ were sicker and would require additional organ support at an additional cost. Similarly, the cost of an ICU bed for a patient in the ‘tracheostomy and ventilator weaning’’ state was more expensive than the cost of an ICU bed in the ‘not decannulated’ state, which was, in turn, more expensive than the cost of an ICU bed in the ‘decannulated’ state. Sensitivity analysis 7 used the highest ICU bed day

cost of £2,672.47 for all states. This analysis revealed that ACV still dominated in the short-term stage and overall. Indeed, ACV was more cost-effective, with an additional £375 cost saving but no additional QALYs gained compared to the base-case scenario.

Sensitivity analysis 8 evaluated a shorter ICU LoS of one day once the 'decannulated' or 'not decannulated' state was reached. The only data reporting ICU LoS after decannulation reported a median of 11 days in the ICU (van der Lely et al., 2006). However, this duration is not in keeping with the clinical experience of the candidate or other clinical experts, who tend to observe much shorter ICU LoS after decannulation. This duration also potentially distorts the overall average ICU LoS, which ranged from 17.7 days to 39 days in the included studies (van der Lely et al., 2006; Romero et al., 2010; Freeman-Sanderson et al., 2011; Depuydt et al., 2016). This analysis revealed that ACV still dominated in the short term and overall. It also improved cost-effectiveness with an additional cost saving of £35 and an additional 0.019 QALYs gained compared to the base-case scenario. ICU costs are generally uncertain and variable from patient to patient, dependent on the level of organ support. Therefore, the costs chosen for the base-case scenario hold a high level of uncertainty. The findings of these analyses suggest that this uncertainty is unlikely to affect cost-effectiveness substantially and increases confidence in the validity of the results. It appears that the primary driver of cost savings in the model is due to the difference in LoS between ACV and UC rather than differences in times spent in states of varying cost. In the base-case scenario, ACV has no effect on LoS in the ICU after the point of reaching 'decannulated' or 'not decannulated'. However, the ICU LoS at this point was inflated for patients with dysphagia, and in the ACV group fewer patients reached the 'decannulated-dysphagia' and 'not decannulated-dysphagia' states. Despite this, the duration of this period of ICU LoS after 'decannulated' or 'not decannulated' had little impact on overall cost-effectiveness.

6.6.2.3 Sensitivity analysis of long-term outcomes after ACV

The base-case scenario assumed that ACV purely provided a positive effect during delivery, with no long-term positive effects. This was based on the research available, which all focuses on the immediate positive effects of ACV. Sensitivity analyses 9 and 10 explore the potential impact of ACV eliciting a long-term positive effect after delivery is stopped. Sensitivity analysis 9 evaluated using a utility inflator of 1% applied to all ACV utilities from 'decannulated' and 'not decannulated' onwards. The analysis reveals that ACV still dominates UC for both the short-term stage and overall, with added QALYs in the intermediate and long-term stages of the model, with 0.031 QALYs gained in total. Similarly, sensitivity analysis 10 explored the application of a utility inflator of 10% to all ACV utilities from 'decannulated' and 'not decannulated' onwards. This analysis showed QALYs gained in the short-term stage and substantial QALYs

gained in the intermediate- and long-term stages. The total increase in QALYs gained compared to the base-case scenario was 0.313. These analyses suggest that if ACV provides sustained utilities beyond immediate delivery, for instance, if a better experience in the ICU reduces symptoms of post-intensive care syndrome and post-traumatic stress disorder, this could significantly impact the cost-effectiveness.

6.6.3 Impact on utilities

The elicitation of utilities from the expert patient representative revealed negative utilities for most states within the ICU. This starkly contrasted with the utilities reported in the literature, which were mostly >0.5. Despite this high uncertainty in utility values, with significant disparity between literature and expert values, using the higher utility values from the literature in sensitivity analysis 1 did not make ACV cost-ineffective, though it did reduce the QALYs gained. This is probably due to the short duration most patients spent in the short-term stage of the model. Therefore, the utility values are unlikely to play a vital role in determining the cost-effectiveness of ACV.

The utilities available in the literature were flawed in various ways. Many of them were elicited post-ICU and, therefore, unlikely to be genuinely reflective of the ICU stay. Others had not reported calculated utilities from the QoL outcome measure, instead providing visual analogue scores or the means of the raw data. This inconsistent data reporting made the conversion of these scores into utility values problematic. Other studies have not used validated QoL measures that can be easily used to calculate utility values. Although these disease-specific QoL measures are often more sensitive to QoL changes, generic utility measures, such as EQ-5D, are generally recommended (Taylor et al., 2023).

This research highlights the critical care evidence base gap for EQ-5D outcomes for critically unwell patients during their ICU stay. Some patients in the ICU may be unable to complete the EQ-5D questionnaire due to sedation or delirium. However, two studies have reported that, although proxy measures of EQ-5D completed by HCPs, family members, or carers were different from patient-reported scores, these differences were unlikely to be clinically meaningful (Hung et al., 2010; Dinglas et al., 2013). Dinglas and colleagues asked patients and proxies to rate baseline QoL before ICU admission retrospectively and found that proxies had slight to fair agreement with patient scores (Dinglas et al., 2013). Hung and colleagues asked patients to complete the EQ-5D whilst receiving mechanical ventilation in the ICU and invited family members and nurses to complete a proxy EQ-5D questionnaire (Hung et al., 2010). They reported that relatives provided the most accurate EQ-5D scores for cognitively intact patients but that for cognitively impaired patients, any proxy provided acceptable EQ-5D scores (Hung et al., 2010).

Additionally, most of the critical care research reports short-term QoL, with the most extended data collection being five years (Cuthbertson et al., 2010). Furthermore, this data did not explicitly report utility weights from patients that had received a tracheostomy in the ICU, though this patient group may have been included in the mixed population (Cuthbertson et al., 2010). As well as capturing EQ-5D of patients with a tracheostomy during each stage of their ICU stay, it is essential to collect EQ-5D through to death. The 5-year EQ-5D data suggests that following an ICU stay, the QoL of patients remains lower than an age- and sex-matched cohort. At five years, the utility values were still 0.14 lower than the matched cohort (Cuthbertson et al., 2010). These lower utilities probably persist beyond five years, but the data is currently unavailable.

When ICU researchers cannot complete EQ-5D questionnaires with patients because of ventilation or sedation, they often make assumptions about QALYs and typically assign a value of zero (Taylor et al., 2023). Many patients immediately following tracheostomy are immobile, unable to perform self-care, unable to carry out their usual activities, endure severe or extreme pain and discomfort, and experience severe anxiety and depression. Table 38 illustrates some of the potential utility values calculated from a range of EQ-5D responses taken from the EQ-5D-5L Index Value Calculator, illustrating that the EQ-5D utilities for patients with a tracheostomy are more plausibly negative, a value of worse than death, than to be 0 or higher (Van Hout et al., 2012). The expert values obtained in this study are likely to be more genuinely reflective of the utilities for patients during the ICU. An important area for future research is to collect EQ-5D data from patients with a tracheostomy, and proxies, where necessary, at all stages of the patient pathway.

The potential impact of ACV on utilities is highly uncertain. This is due to the general issues with the quality of the QoL data available for patients with a tracheostomy in the ICU, as outlined above, but also due to the lack of available data for the specific impact of ACV on QoL. More detail is needed for both elements to reduce the uncertainty in the model and allow for more definite conclusions regarding the utility benefits of ACV.

Table 38 Potential EQ-5D-5L utility calculations from a range of questionnaire responses

Mobility score	Self-care score	Usual Activities score	Pain and Discomfort Score	Anxiety and Depression score	EQ-5D-5L Index Utility Value
5 (I am unable to walk about)	5 (I am unable to wash or dress myself)	5 (I am unable to do my usual activities)	5 (I have extreme pain or discomfort)	5 (I am extremely anxious or depressed)	-0.594
5 (I am unable to walk about)	5 (I am unable to wash or dress myself)	5 (I am unable to do my usual activities)	4 (I have severe pain or discomfort)	4 (I am severely anxious or depressed)	-0.352
5 (I am unable to walk about)	5 (I am unable to wash or dress myself)	5 (I am unable to do my usual activities)	3 (I have moderate pain or discomfort)	3 (I am moderately anxious or depressed)	-0.166
5 (I am unable to walk about)	5 (I am unable to wash or dress myself)	5 (I am unable to do my usual activities)	2 (I have slight pain or discomfort)	2 (I am slightly anxious or depressed)	-0.127
5 (I am unable to walk about)	5 (I am unable to wash or dress myself)	5 (I am unable to do my usual activities)	1 (I have no pain or discomfort)	1 (I am not anxious or depressed)	0.028

6.6.4 Impact on resource use and costs

The sensitivity analyses demonstrated that even when there are only minor improvements to QoL, ACV appears to be a cost-effective intervention, likely because of its relatively low resource costs. The infection control requirements for replacing the oxygen tubing and thumb ports are unclear, and the international survey (Chapter 4) revealed that HCPs have a highly variable approach to equipment replacement. The daily cost of ACV in the ICU was calculated to be just £75 if the thumb port and oxygen tubing were replaced weekly with 'low cost' nursing staff predominantly delivering the 60 minutes of daily intervention split into four sessions of 15 minutes. This cost also included an extra 20 minutes of administration time per day, and speech and language therapy providing an average of 70 minutes per week for review and support. The daily cost of ACV in the ICU was increased to just £89 if thumb ports and oxygen tubing were replaced daily, and the ACV sessions were provided with 'high cost' physiotherapy and SLT staff delivering the 60 minutes of daily intervention. This cost also included speech and language therapy providing an average of 70 minutes per week for review and support.

There is a lack of evidence currently to support the dose, intensity and frequency of ACV that is required to facilitate a positive effect on outcomes, including QoL, as found by the systematic review (Chapter 3), the international survey (Chapter 4), and the HCP interviews (Chapter 5) (Mills, Michou, King, et al., 2022; Mills, Michou, Bellamy, et al., 2022; Mills et al., 2023). In this model, four 15-minute sessions per day were costed, and this was based on the evidence available and expert consultation. Given the low cost of the intervention, even if the frequency of delivery were increased to eight sessions per day, this would probably have minimal effect on overall costs or cost-effectiveness.

This model did not incorporate training, education, or set-up costs. However, as the substantial cost savings occur within the ICU portion of the model, where the ACV costs and resource use also occur, these set-up costs could easily be incorporated into the model, with minimal impact on the overall cost-effectiveness or the costs within the ICU. Access to resources, such as staff time to deliver ACV and time to provide training, was raised as a major barrier to ACV implementation and use, both in the international survey (Chapter 4) and the interviews with HCPs (Chapter 5) (Mills, Michou, Bellamy, et al., 2022; Mills et al., 2023). Further research to provide information to reduce the uncertainty in this model and increase confidence in the cost-effectiveness, and potential cost savings associated with ACV, might help to provide evidence supporting the probable need for increased staffing to deliver the intervention.

Sensitivity analysis reveals that the most important driver of cost within the model is ICU LoS, which is primarily impacted by the transition of patients through the weaning

pathway. If ACV positively affects the speed of the weaning process and patients transition to decannulation more quickly, it is cost-effective. If ACV does not positively impact the speed of the weaning process, then the cost-effectiveness will presumably depend on the extent of the QALYs provided in the short-, intermediate-, and long-term stages. A key priority for future research is to evaluate whether ACV positively impacts tracheostomy weaning and whether this reduces ICU LoS.

6.6.5 Value of information principles

An application of VOI principles was employed using one-way sensitivity analyses rather than formal VOI analysis because of the level of structural and parameter uncertainty within the model. There was limited and low-quality data available to input into the model, leading to higher levels of uncertainty with respect to the interpretation of the findings. The sensitivity analyses applied to the model revealed that certain aspects of the costs and effects of ACV appear to be more important in the overall cost-effectiveness calculations. These areas and questions need to be the focus of future research. As discussed earlier, the primary driver of cost within the model is whether ACV affects the speed of transition through the weaning pathway to decannulation and, consequently, whether it reduces ICU LoS.

There are two primary drivers of QALYs in the model. Firstly, whether ACV impacts which end state patients transition to. Experts suggested that ACV would lead to higher rates of decannulation and lower rates of dysphagia, and 'decannulated' and 'no dysphagia' states had higher utilities, and lower costs, associated with them. Ascertaining whether ACV does have this impact on the proportion of patients in different end states is critical to reducing the uncertainty around the effects of ACV on QALYs and costs, particularly in the long-term stage. The second driver of QALYs in the model is whether or not ACV has a sustained positive impact on QoL after treatment is completed. Negative experiences during the ICU stay can have a long-lasting impact on patients' QoL, with lower QALYs for up to 5 years after ICU discharge compared to age-matched individuals and many patients experiencing PICS and post-traumatic stress disorder (Cuthbertson et al., 2010; Needham et al., 2012). If ACV improves QoL and the ICU experience, this could help to improve QoL in the longer term through a reduction in PICS and post-traumatic stress disorder. When utilities were added beyond the delivery of ACV in the ICU, substantial QALYs were added to patients in the intermediate and long-term stages of the model.

6.6.6 Model validation

Various steps were taken to assess the model's validity and usefulness in determining the cost-effectiveness of ACV. Firstly, a range of clinicians with different experiences and backgrounds were involved in the development of the structure of the model to

reduce bias and ensure face validity (Tappenden and Chilcott, 2014). User-defined values were used to check for errors in the data entry and formulae. These 'black box' verification checks included: checking the clinical trajectory (probabilities adding up to one), the QALY estimations (utilities and discounting of utilities working appropriately), and cost estimation (costs and discounting of costs functioning correctly) (Tappenden and Chilcott, 2014). A trace analysis of the Markov portion of the model was conducted to check validity. The model was also verified and checked for computational errors by an experienced health economist. It was not possible to conduct cross-validity or external-validity due to the lack of similar models and limited evidence.

6.6.7 Study strengths and limitations

The major limitations of this study related to the limited and low-quality data available for the various model parameters. It resulted in some of the data that was selected and incorporated into the model not being specifically related to patients with a tracheostomy or general ICU patients. For example, some cardiac ICU data was used because of the limited dysphagia-related data for general ICU patients. There are probably high levels of uncertainty in several parameters due to the non-specific data used. The limited and low-quality utility data available for the model meant that some of the available data had to be manipulated to make it usable. An example is when EQ-5D utilities were not provided in the literature, and a Visual Analogue Score was directly converted into a utility value. This is not considered best practice for calculating utility values, but it was the only option available with no access to the raw data to use the EQ-5D-5L Index Value Calculator (Van Hout et al., 2012).

This model includes patient expert-elicited utilities, which, as discussed earlier, appear to be more genuinely reflective of patients' experiences in the ICU. Furthermore, the patient used the EQ-5D-5L calculator directly, choosing the level for each dimension to determine the utility value for each state for UC and ACV (Van Hout et al., 2012). Whilst time-consuming, this method probably improved the accuracy of the utility value provided, compared with choosing a number on a scale of -0.594 to 1. However, only one patient was involved in the expert elicitation, and their perceptions of the utilities at different states in the ICU will have been biased according to their ICU experience. Additionally, the patient's response may have been influenced by being more than six years post-discharge from the ICU and having had no direct experience with ACV.

One of the elements that was clear in the interviews with HCPs (Chapter 5) was that there seems to be generation of 'process utility' when ACV is used. Process utility is when the treatment process itself provides some level of utility for patients, for example, in giving the patient information, reassurance, or dignity (Donaldson and Shackley, 1997). Several participants in Chapter 5 described patients' positive response to ACV, even when it brought no functional benefits. It is hypothesised that

the process of doing something towards their recovery may have made them feel like they were making progress, even when there were no functional gains. Future research evaluating the effectiveness of ACV must gather information on any potential process utility as part of the overall utility function of patients (Brennan and Dixon, 2013). It is important to involve patients in determining what should be included in utility measures, and it may be helpful to consider WTP in addition to QALYs (Donaldson and Shackley, 1997).

Another limitation of this study was that some of the values provided during the expert elicitation were implausible and had to be censored at zero. Experts were asked to estimate the absolute change to the percentage of patients regressing to 'tracheostomy maintenance' that might occur as a result of ACV. The base-case estimate is taken from a meta-analysis of the experts' values for UC compared to a meta-analysis of the experts' values for ACV. As with UC, the expert data was used for the base-case estimate as it incorporated all reasons for regression to 'tracheostomy maintenance'. One expert gave a best value estimate of 45% for the absolute reduction. This value was greater than the average values for UC. Therefore, when expert values were combined with study values this resulted in an implausible, negative probability which was censored at zero. These implausible values given by experts might have been due to unclear instructions provided by the candidate. More thorough explanations and verification with experts would be required in future expert elicitation work.

The limited and low-quality data available for the various parameters of the model meant that various assumptions had to be made. These assumptions, for example, that the mortality for 'tracheostomy maintenance' and 'tracheostomy and ventilator weaning' are the same, may not be accurate. These assumptions may have had a considerable impact on the results. If ACV reduces the likelihood of regression to 'tracheostomy maintenance', as suggested by most experts, and mortality is higher in this state, it could considerably impact ACV's cost-effectiveness and result in more cost savings and QALYs gained. Some of these assumptions must be further explored in future research.

Another assumption in this model is that all patients are suitable for ACV and benefit similarly. However, the research to date suggests that this is not the case. The systematic review (Chapter 3), the international survey (Chapter 4), and the interviews with HCPs (Chapter 5) demonstrate that not all patients tolerate or benefit from ACV, and it is unclear which patients benefit more or less (Mills, Michou, King, et al., 2022; Mills, Michou, Bellamy, et al., 2022; Mills et al., 2023). Most research has focused on improving either communication or swallowing, and the interviews (Chapter 5) confirmed this variation in the purpose of ACV use (Mills et al., 2023). Research with a dual focus of purpose might show better patient toleration, with an adaptation of airflow

using lower rates for swallowing and additional benefits for more patients. The cost-effectiveness findings of this study may be an overestimation. Further research is needed to provide more robust evidence for the effectiveness of ACV for specific patient groups and for all potential outcomes: communication, swallowing, airway protection, time to decannulation, and LoS.

There were also limitations related to the model structure, which was refined with input from a range of experienced critical care clinicians. As such, it captures much of the complexity of the lifetime pathway of patients who receive a tracheostomy in the ICU. It can be challenging to capture the most important factors for patients in a DAM (Elwyn et al., 2001). A patient and family representative were included in the discussions around the design of the structure of the model, and the patient representative was involved in deriving some of the utilities used in the model. However, the DAM may not fully reflect the patient pathway and the heterogeneity of the patients in the ICU, even within the same patient population, which increases the uncertainty in the model. Clinical management and clinical pathways in the ICU are complex, and patients typically receive multiple treatments simultaneously. These interventions may have complex interactions that may act synergistically, antagonistically, or independently (Barr and Pandharipande, 2013; Sutt et al., 2016; Sutt et al., 2017; Haines et al., 2023). Much of ICU management is based on clinical behaviours and decisions rather than following strict protocols, particularly regarding weaning, and this makes even defining a control group highly problematic (Chiche and Angus, 2008). Evaluating ICU interventions in isolation and determining their cost-effectiveness and safety is usually complex and challenging (Chiche and Angus, 2008; Delaney et al., 2008).

Some of the restrictions on Markov models and decision trees mean that some of the complexities of the pathway could not be captured in this model. For example, mortality risk has been shown to increase following pneumonia, with an attributable mortality of between 3 and 42% (Forel et al., 2012; Melsen et al., 2013). Therefore, patients regressing to ‘tracheostomy maintenance’ after developing VAP should have a higher mortality risk. Furthermore, multiple VAPs with multiple regressions might raise the mortality risk even further. However, a Markov is memoryless and does not allow these nuances to be built into this model.

A second example of a limitation of the structure of the model is that once reaching the end states, within the 90-day period of the model, hypothetical patients enter a post-Markov decision tree. During this stage of the model, any final ICU stay is captured, along with ward stay, and home stay. At the end of this 90-day period, all patients are then ‘at home’ for the intermediate portion of the model. Therefore, to ensure that patients had an appropriate amount of ICU stay after ‘decannulated’ or ‘not decannulated’, this was added for some patients who reached these states towards the

end of the 90-day period whilst patients were also receiving ‘at home’ costs and utilities in the intermediate stage. This ‘double-counting’ of costs and utilities with a small portion of patients for a short period was unavoidable due to the limitations of decision trees.

Another limitation of the model structure is that once patients reach the end states (e.g., ‘not decannulated-dysphagia’), the patients remain in those states until death. It is highly doubtful that all patients who are not decannulated and dysphagic at 90-days would persist in this state to death; many patients would be later decannulated and recover swallowing function. A Markov or decision tree which allowed the capture of these potential changes would be too complex to build. Therefore, hypothetical patients remained in these end states, but QALYs and costs improved over the intermediate stage of the model. In future revisions of this model, the pathway may better lend itself to a patient simulation model, which would support a memory feature and more individualised pathways.

One of the model’s strengths is the lifetime horizon, which most critical care models do not employ, as described in Section 6.5.1. A lifetime horizon is best practice in health economic modelling, as it means that all the potential long-term consequences of ACV can be captured in the model (O’Mahony et al., 2015). However, all the ACV research looks at the immediate effects of use, making it challenging to incorporate the potential long-term costs and consequences of ACV. Additionally, the data quality for mortality, costs, and utilities deteriorates after an ICU stay because most critical care studies focus on the ICU and ward period. A recent review of HRQoL and cost utility analyses in critical care highlighted some of the issues surrounding time horizons, such as, the need for standardisation, using either six or twelve month time horizons for future evaluations (Lau et al., 2021). This suggestion was reiterated in Lau’s more recent overview of HRQoL in the critical care population (Lau et al., 2022). However, this approach may lead to biased results, and it is essential to start collecting longitudinal data in critical care studies so that lifetime horizons with accurate and reliable data can be used. A recent publication making practical recommendations for ICU researchers conducting economic evaluations alongside RCTs supports this stance (Taylor et al., 2023). They recommend that there should be a longer-term follow-up to account for the ongoing chronic health issues that many ICU patients experience after discharge (Taylor et al., 2023).

6.6.8 Implications for clinicians and researchers

Given the level of structural and parameter uncertainty in this model, the findings of this study cannot provide a definitive answer to the question of the cost-effectiveness of ACV. However, the results suggest that ACV may only have to provide marginal improvements to QALYs during the ICU stay to be dominant, costing less and being

more effective than UC, in this short-term period. The costs of ACV during the ICU compared to UC are relatively low at a maximum of £89 per day if delivered in four 15-minute sessions using 'high cost' staff with daily equipment replacement. Most of this cost comprises the staff costs associated with ACV delivery, review, and monitoring.

The VOI principles applied through one-way sensitivity analysis revealed that the key drivers of uncertainty for cost in the model are related to the effect of ACV on the transition of patients through the weaning process and the impact on LoS. The key drivers of uncertainty for QALYs in the model are whether ACV impacts which end states patients transition to and whether ACV has a sustained effect on QoL after the intervention is complete by improving the ICU experience and consequently reducing PICS and post-traumatic stress disorder after discharge home. Future research should focus on reducing the uncertainty in these areas to provide a more comprehensive and robust cost-effectiveness analysis.

Another key area for future research is to improve the quality of some of the other critical care parameters needed for health economic modelling. Specifically, more detailed data is necessary for the mortality of patients with a tracheostomy, including mortality rates at each stage of the weaning process. The cost of an ICU bed at different stages of the tracheostomy weaning process is also unclear. Ascertaining the average level of organ support required at various stages of the weaning process would enable more accurate NHS costing of ICU bed costs per day. Additionally, EQ-5D data is needed for patients with a tracheostomy, from insertion to death, to ensure accurate cost-effectiveness analysis. Until all of this missing or uncertain data is collected and reported transparently and completely, cost-effectiveness analysis of ACV, or other ICU interventions, will be heavily biased and uncertain.

Where there is uncertainty about an intervention's cost-effectiveness, various options are available to decision-makers (Eckermann and Willan, 2008). The first option is to delay adoption and conduct further research. This is the most suitable option where decisions are irreversible or a significant cost is associated with reversing the decision. The second option is to adopt the intervention without further research. The third option is to adopt the intervention whilst continuing research. Options two and three are generally chosen when adoption decisions are reversible, and there are opportunity costs (i.e., a loss of potential benefit to patients by not adopting early) associated with delaying and not treating patients with the intervention now (Eckermann and Willan, 2008). For those clinical services that have already adopted ACV into clinical practice in the ICU, the findings of this study are unlikely to result in the decision to de-adopt ACV. However, those clinical services that are not using ACV may find the results of this study useful as they consider the reimbursement pyramid and their decision about whether to adopt ACV in practice (Eckermann and Willan, 2008; Edlin et al., 2014). The

findings of this study seem to suggest that the position of ACV is somewhere in the middle of the pyramid, where ACV can be provided to 'all patients with selected indications, so long as research to establish its effectiveness occurs' (Edlin et al., 2014). The costs of ACV are relatively low, particularly compared to the daily cost of ICU care. Therefore, adopting the intervention whilst continuing research to provide further information about the effectiveness and costs associated with ACV appears to be a reasonable option given the potential for loss of opportunity costs if the decision to adopt is delayed. Additionally, ACV is an intervention that could be easily and quickly reversed should the evidence base change. This study has highlighted the specific areas for further research, which will help to reduce the uncertainty in the model and enable future more robust cost-effectiveness analysis.

6.7 Summary

This chapter provides an overview of the main concepts underpinning decision-analytic modelling and reimbursement decisions, and it describes the available literature within the critical care specialty, focusing on tracheostomy weaning. This literature summary highlights the lack of modelling in this area and some issues with access to data to estimate parameters needed for a model. There is a lack of data on QoL and QALYs for patients with a tracheostomy in the ICU, both during their ICU stay and in the longer term. Furthermore, the complex critical care pathways are typically challenging to map using a DAM.

The development of the first DAM and the first evaluation of ACV cost-effectiveness is described in this chapter. There are considerable structural and parameter uncertainties in the model because of the limited and low-quality data available, and analysis results should be treated with caution. However, the base-case scenario reveals that ACV is dominant to UC, being less costly and more effective in the short-term stage of the model and overall. The only scenarios in which ACV was not cost-effective were when ACV had no impact on any transition probability, with no influence on the speed of tracheostomy weaning or regression to tracheostomy maintenance, or when ICU and ward LoS were increased. The findings of this study suggest that there is no reason for decision-makers to de-adopt the use of ACV. Furthermore, it appears that new decision-makers may wish to consider adopting ACV whilst research continues, as there may be a loss of opportunity costs from delaying the decision, particularly as ACV is an easily reversible intervention.

Chapter 7 of the thesis will summarise and conclude the research conducted in Chapters 3 to 6 and discuss the clinical and research implications of this body of work.

Chapter 7 Conclusions and Future Directions

This chapter summarises and discusses the research completed in the thesis and explains the impact of the COVID-19 pandemic on the research. Section 7.1 provides an overview of the chapter. Section 7.2 describes the impact of the COVID-19 pandemic on the research. Section 7.3 discusses the contribution of the thesis to the field, and Section 7.4 proposes a range of new theoretical insights into ACV. Section 7.5 discusses the strengths and limitations of the research, and Section 7.6 considers the clinical implications of the research. Section 7.7 describes areas for future research, and Section 7.8 concludes the thesis.

Some of the discussion presented in this chapter has been published in an invited paper in *Intensive Care Medicine*:

Mills, C.S., Cuthbertson, B.H. and Michou, E., 2023. What's new in reducing the impact of tracheostomy on communication and swallowing in the ICU. *Intensive Care Medicine*, pp.1-4.

7.1 Overview

Patients with a tracheostomy typically spend days, weeks, and even months unable to eat, drink, or communicate using their voice. These experiences have a profound impact on their QoL and well-being. ACV offers a potential route to restore laryngo-pharyngeal airflow with possible benefits for sensation, swallowing, airway protection, communication, QoL, and cost savings. However, there has been limited research in this area and a lack of guidance for best clinical practice. The primary aims of the thesis were to explore the potential for ACV to improve outcomes for patients with a tracheostomy, to investigate the prevalence of complications and safety issues, and to ascertain the cost-effectiveness of the intervention. The over-arching hypothesis of the thesis is that regular use of ACV may result in improved swallowing function, improved ability to communicate, reduced length of time to decannulation, reduced LoS, improved HRQoL, and cost savings, indicating the need for a full definitive RCT.

7.2 Impact of COVID-19

COVID-19 impacted the thesis in various ways; specifically, it affected the research plan, the research conduct, and the aims and hypotheses of the thesis. Each will be discussed in turn.

7.2.1 Impact of COVID-19 on the research plan

Two significant changes were made to the research plan due to COVID-19.

7.2.1.1 Workstream 3: qualitative interview study

For the interview study (Chapter 5), the original research proposal aimed to evaluate the current opinions of ACV including the patients, relatives, and HCPs. The objectives were:

- To evaluate the opinions of patients, relatives, and staff regarding the use of ACV
- To identify the optimal application of ACV to maximise compliance of patients and staff
- To identify the barriers to recruitment to the feasibility study
- To recruit patients to the research advisory group to provide ongoing support and advice for the research project

The plan was to achieve these aims and objectives through interviews of focus groups of patients, carers, and HCPs using framework analysis. Given that specific information might be needed for the feasibility RCT, this qualitative workstream took a more structured and quantitative approach. The findings of this study would have enabled the development of an ACV intervention protocol for the planned feasibility study. The plan was to recruit these patients and family members primarily via ICU follow-up clinics, which typically occur three to six months after hospital discharge. Upon completing the data analysis, the intention was to conduct a consensus group meeting to finalise an ACV intervention protocol. As discussed in Chapter 5, after discussion with the advisory group and PCPI group, the decision was made to replace focus groups with individual interviews, and ethical approval was received to conduct these interviews in the ICU. When the COVID-19 pandemic was declared, the interview study (Chapter 5) was due to imminently commence in ICUs in Manchester, Leeds, and London.

At the same time, the findings of the systematic review and the survey indicated that achieving any agreement or consensus on optimal approaches to ACV would be unlikely. A review of the planned approach to design the ACV intervention protocol was underway when the COVID-19 pandemic arrived in March 2020. It became apparent that interviews with patients and relatives in the ICU would be impossible. Many sites across the UK had stopped using ACV due to concerns about the increased risk of COVID-19 transmission, as many viewed ACV as an aerosol generating procedure (AGP) (McGrath, Ashby, et al., 2020; Zaga, Pandian, et al., 2020). Furthermore, with restrictions on visiting, relatives were absent at the bedside and unable to develop experience with ACV as a communication partner. With the uncertainty around the duration of the pandemic and when ACV use might resume in hospitals, the decision was made to exclude the patient and relative interviews from this study.

The adaptable and iterative qualitative research approach allowed the continual review and revision of research aims, objectives, and questions. At this stage, the aims and objectives of this workstream were revised to capture information about how COVID-19 impacted ACV use. Following additional training in qualitative research, the objectives were also amended to be more appropriate for qualitative research methodology rather than quantitative. Aims and objectives were updated to those outlined in Chapter 5, and research questions were explicitly stated. The planned number of interviews with HCPs was expanded, aiming for approximately 30 interviews with a range of HCPs from different countries.

7.2.1.2 Workstream 4: randomised controlled feasibility study

For the fourth study of the thesis, the research plan was to conduct a 60-patient, single-centre, prospective, open, parallel-group, randomised controlled feasibility study to determine the feasibility of conducting a full definitive RCT to investigate whether ACV results in improvements in swallowing, communication, tracheostomy weaning, and cost savings. As part of this feasibility RCT, the plan included conducting an exploratory micro-costing and time-in-motion study to determine the cost-effectiveness of ACV. Similar to the reasons for the changes to the third study, it was clear that conducting this feasibility RCT would not be possible because of the limitations on using ACV.

It would have been plausible to exclude the planned health economic Decision-Analytic Model (DAM) which would have been built on trial data. However, in collaboration with supervisors, the decision was made to develop an early-stage health economic DAM to evaluate the cost-effectiveness of ACV based on the evidence available. This study focused on identifying the most significant areas of uncertainty in ACV and the critical drivers of cost-effectiveness. Conducting this analysis now ensures that any future feasibility RCT or definitive RCT is more appropriately targeted to answer the critical research questions that provide the most value.

7.2.2 Impact of COVID-19 on the research conduct

The COVID-19 pandemic severely impacted the conduct of the interview study (Chapter 5). HCPs in ICUs were working under significant pressure, particularly during COVID-19 waves, affecting recruitment, especially of doctors and nurses. Some interviews were also slightly rushed, as participants were interviewing at work and had to return to their ICUs due to clinical pressures.

7.2.3 Impact of COVID-19 on the aims and hypothesis of the thesis

Despite the impact of COVID-19 on various aspects of the research plan and conduct, the primary aims of the thesis were still accomplished by the adapted research plan.

The potential for ACV to improve outcomes for patients with a tracheostomy was explored via the systematic review (Chapter 3), the survey (Chapter 4), the interview study (Chapter 5), and the health economic DAM (Chapter 6). The prevalence of complications and safety issues was determined in the systematic review, the survey, and the interview study. Finally, the cost-effectiveness of ACV was evaluated in the health economic DAM.

Similarly, the over-arching hypothesis of the thesis was partially addressed by the research conducted. The systematic review, the survey, and the interview study found that ACV can result in improvements to swallowing, communication, and QoL. Additionally, the health economic DAM (Chapter 6) also found that ACV can lead to improve HRQoL and cost savings and identified key areas that need to be evaluated in a full definitive RCT. The interview study and the discussions with expert clinicians in the development of the DAM also revealed that some clinicians believe that ACV may accelerate the tracheostomy weaning process and reduce the length of time to decannulation and reduce the ICU LoS. Although the various aspects of the hypothesis are addressed in this body of research, they are addressed predominantly using qualitative methodology and with subjective outcomes. The planned feasibility RCT would have provided quantitative data to evaluate these important hypotheses about the potential effects of ACV.

7.3 Contribution of the thesis to the field

Chapter 3: Evidence for Above Cuff Vocalisation in patients with a tracheostomy: a systematic review

The thesis provides the first systematic review of the ACV literature, highlighting the scarce and low-level evidence available. All studies had a high risk of bias, and most had small sample sizes. It reveals that there are a variety of potential benefits for patients receiving ACV, but that there are also minor and more serious safety issues and complications. However, there was a lack of evidence for the extent or importance of these issues, and not all pertinent outcome measures were evaluated, including the incidence of pneumonia, the time to decannulation, mortality, or cost-effectiveness. It draws attention to the variability of ACV application in research, and the lack of clear evidence to support any particular approach or any rigorous guidance for clinical practice. The thesis – and the publication of the systematic review – provides HCPs with a robust critical appraisal of the literature which can be used to support decision-making regarding ACV implementation and application in clinical practice.

Chapter 4: Determining the prevalence, implementation approaches, and opinions of ACV: a survey of healthcare professionals

The international survey of HCPs provides the first data on prevalence of ACV use and clinical application of ACV. There is limited uptake of ACV, and this study confirms that the variability of ACV application evident in the literature extends into clinical practice. Variations in tracheostomy management and weaning and limited access to speech and language therapy may also be compounding the inconsistent approach to ACV. There was a lack of agreement of the optimal application of ACV, and it is unclear whether it would be possible to achieve a consensus on a standardised or optimal approach to ACV. This study confirmed the findings of the systematic review, with reports of both minor and more infrequent serious complications. These included the first reports of the complication of bleeding at the stomal site and/or the subglottic region, thought to be associated with ACV application. Similar to the systematic review, most respondents reported benefits for patients receiving ACV. However, there was considerable variety of opinions about the extent of these benefits and which patient groups benefited most. This variability may be a consequence of the different approaches taken by participants. This study also highlighted, for the first time, what barriers exist to the successful implementation and use of ACV. Staff proficiency and training were the most commonly reported barriers, and this is probably a result of the lack of availability of training resources and the underlying lack of evidence.

Chapter 5: Worth a try or a last resort: Healthcare professionals' experiences and opinions of ACV

The qualitative interview study is the first to explore opinions and experiences of HCPs using ACV. The five major themes developed were: 1) moral distress amplifying the need to fix patients; 2) subjectivity and uncertainty leading to variations in practice and purpose; 3) knowledge and experience leading to control and caution; 4) worth a try or a last resort; 5) limited consideration of COVID-19 or starting from scratch. HCPs' perspectives on ACV seemed to be underpinned by experiences of moral distress and an underlying 'need to fix' their patients. This may also influence their opinions and decisions regarding ACV. Furthermore, the underlying subjectivities and uncertainties surrounding ACV, because of the limited evidence base, means opinions of ACV appear to be formed primarily on the basis of their experiences. These experiences are likely to be impacted by the purpose for which they use ACV and their application approach, and probably explains the variety of opinions observed. HCPs had a variety of opinions about ACV; these varied from thinking that ACV was worth a try, to considering ACV to be a last resort when other options had failed. Most participants considered ACV a part of their toolbox, but the relative position or importance of ACV in their toolbox varied. As knowledge and experience of ACV increase, HCPs developed a more cautious approach to ACV use to maximise safety for patients and staff. The impact of COVID-19 on ACV use appears to be dependent on international location and clinical setting. Limited consideration of COVID-19 was given when there were

minimal concerns about transmission risk. Where there were serious concerns about transmission risk, and pressures of COVID-19 were high, ACV use was often discontinued or deprioritised. In these settings, as ACV use was reimplemented, participants described feeling they were starting from scratch with ACV.

These themes support the findings of the systematic review and the survey: that there are varied opinions of ACV and approaches to application. This study also led to the development of a theory that different brands of tracheostomy tube may result in differing velocities and pressure of the airflow which might be leading to the varying effectiveness reported. This theory will be discussed in more detail in Section 7.4.2.1. If true, this theory provides another reason for the diverse opinions of ACV. For the first time, the impact of negative experiences of ACV can be seen and that these experiences seem to lead to a more cautious and controlled approach to ACV use. The various barriers to successful ACV use amplifies the findings of the survey and highlights the desire of HCPs to overcome these barriers and to optimise ACV use. ACV troubleshooting approaches from the systematic review, the international survey, and the qualitative interviews have been collated. These trouble-shooting tips will be a practical, evidence-based resource for HCPs to support their clinical application of ACV.

Chapter 6: An early-stage decision-analytic health economic model of ACV

The early-stage DAM and application of VOI principles provide the first cost-effectiveness analysis of ACV. This early-stage de novo DAM for ACV was comprised of a hybrid Markov–Decision Tree–Markov model to best represent the decannulation pathway for patients receiving usual care (UC) or ACV. The DAM was split into the short term (90 days), the intermediate term (0-2 years), and the long term (3 years–lifetime).

Cost-effectiveness analysis using this model revealed that ACV is dominant to UC in the base-case scenario; this means that it is less costly than UC and more effective. In the base-case scenario, using the most likely parameters for UC and ACV, ACV was dominant in the short-term stage and overall and was cost-effective (more costly but more effective than UC with a willingness-to-pay (WTP) threshold of £20,000) in the intermediate- and long-term stages.

These findings must be interpreted with caution because of the considerable structural and parameter uncertainties in the model due to the low-quality data available for both UC and ACV. One crucial data dilemma involved whether to use questionable data from the RCT for ACV (Pandian et al., 2020), which found greater ICU and ward LoS in the ACV group, or expert data, which suggested that ACV reduced LoS. The one-way sensitivity analysis and applications of VOI principles revealed the critical drivers for cost and QALYs in the model. The key drivers for cost are related to the potential

impact that ACV has on the rate of transition through the states and the speed of weaning. If ACV accelerates the tracheostomy weaning process, the associated reduction in ICU LoS leads to substantial cost savings. The key drivers for QALYs were whether ACV influences which end states patients transition to; if ACV increases the likelihood of decannulation or no dysphagia, then there are improved QALYs and costs in the long-term stage. Secondly, if ACV has a sustained impact on utilities after discontinuing the intervention, this also substantially increases QALYs in the long-term stage.

The application of VOI principles identified particular areas for future research that would help to reduce the uncertainty within the model and increase the confidence in the findings of the model. Various critical areas for future research were identified, including the need for improved data on the mortality and QoL of patients with a tracheostomy at different stages of the weaning process, with the need for lifetime follow-up. Additionally, it is vital to understand whether ACV has an adverse impact on ICU and ward LoS, and if it does, whether the cause is mitigable. Determining the impact of ACV on patients' transition through the weaning pathway appears critical to understanding the impact on LoS and determining the cost-effectiveness of ACV.

7.4 New theoretical insights

This research has led to some important theoretical insights that can help to develop the practice and evaluation of ACV. Firstly, that ACV is a complex intervention and should be evaluated as such. Secondly, a range of theoretical insights have been developed to explain the uncertainty, subjectivity, and variation that is seen in ACV's implementation and application. These theoretical insights will be discussed in the subsequent sections.

7.4.1 A complex intervention

This research has revealed a variation in opinion between those who described ACV as simple and those who described it as complex. Some interview participants even described it as complex and simple in different contexts. This dichotomy between these opinions could confuse issues surrounding ACV. It appears to contribute to some of the variation in approach seen, for example, which staff are involved in ACV assessment and delivery.

The conclusion of the findings of these studies is that ACV is a complex intervention. Many of the descriptions of ACV as a simple intervention relate to the application process and the fact that it generally does not require special equipment or extensive training to set up at the bedside. Many HCPs believe that connecting the subglottic port to medical air or oxygen via oxygen tubing is a simple and straightforward process. In

contrast, participants who described ACV as complex were particularly focused on the variability and uncertainty surrounding ACV. They believed there was a need for thorough staff training and for the assessment and delivery of ACV to be restricted to experienced staff with advanced skills. This experience and skill were perceived to be essential as a result of various concerns: lack of consistency of response in patients with variation from session to session; uncertainty about optimal delivery; uncertainty about which patients will benefit; uncertainty about when to stop; and the risk of adverse events that might lead to prohibition of ACV. It appears that the process of setting up ACV is a simple one, but the management of ACV is a complex one.

The research on complex interventions also supports the conclusion that ACV is a complex intervention. A complex intervention is defined as an intervention 'that contains several interacting components, but they have other characteristics that evaluators should take into account' (Craig et al., 2013). These characteristics include the number of interacting components, the number and difficulty of behaviours required by the deliverers or receivers, the number of groups or organisational levels targeted, the number and variability of outcomes, and the degree of flexibility or tailoring of the intervention (Craig et al., 2013). ACV incorporates several of these characteristics.

Firstly, several interacting components can be challenging to control in an RCT, as evidenced by the RCT conducted by Pandian and colleagues. In particular, the variation in tracheostomy weaning within and between patients because of different clinical approaches may interact with the ACV treatment. Indeed there are general concerns within the ICU community that 'control groups' can be problematic because other interventions received may influence the outcomes (Hodgson and Cuthbertson, 2016). Interventions in the ICU can also be impacted by varying standards of care or staff morale; standardisation can be difficult to achieve in an ICU setting (Chiche and Angus, 2008; Hillman et al., 2009). Secondly, the HCPs involved in ACV assessment and delivery must consider and manage many factors when using it with patients. They need to consider contraindications and risks of adverse events, such as airway patency issues, which are not always easy to predict or detect. They must consider titration and optimisation of airflow while liaising with the patient to ensure comfort and optimal patient and tracheostomy positioning. Many clinicians are also managing the airflow delivery with the thumb port, attempting to synchronise the airflow application with the ventilator or the patients breathing, and needing to pause airflow during swallowing. They have to provide education and training to the patient, family, and other staff to optimise effectiveness, ensure safety, and prevent maladaptive vocal behaviours that might lead to vocal strain. Thirdly, ACV is suitable for many heterogeneous patient groups in intensive care, and there may be differences in how different patients respond to it. Fourthly, ACV addresses multiple purposes and requires an array of outcome measures, including swallowing, communication, cough, and QoL. The

specific benefits obtained from ACV appears to vary between patients. Fifthly, there is a need to tailor the intervention to the individual, as the airflow tolerated seems to depend on the patient, the tracheostomy, and the position of both. Therefore, ACV meets the definition of a complex intervention.

The process of intervention development, especially a complex intervention, is typically an iterative one (O'Cathain et al., 2019). When developing a complex intervention, it is vital to understand the mechanism of action of the intervention, issues with the implementation of the intervention, and the variability in the effectiveness of the intervention between individuals and groups (Craig et al., 2013). The critical evaluation of the research literature for ACV reveals that certain key elements of the intervention development and evaluation process are missing. Missing elements include (i) testing the intervention procedures; (ii) estimating recruitment and retention; (iii) determining sample size; (iv) surveillance and monitoring; (v) long-term follow-up; (vi) identifying the mechanism of action; and (vii) assessing the cost-effectiveness (Craig et al., 2013; Fletcher et al., 2016). Furthermore, the majority of the evidence reviewed in Chapter 3 does not describe the intervention delivery in detail and, as such, is not reproducible. The survey findings and interview studies reinforce that there are issues with clinical translation and implementation which is potentially contributing to the wide variation in practice. The next steps for ACV research must focus on developing evidence in these areas and recognising that the adoption and implementation of complex interventions can be much more complicated than simple interventions (Ferlie et al., 2005).

The research undertaken in the thesis has helped to further develop this complex intervention. O'Cathain and colleagues, in their guidance on how to develop complex interventions, outlined various important aspects of intervention development addressed in this research (O'Cathain et al., 2019). They highlighted the importance of reviewing published research evidence to improve understanding of each component of the intervention, collecting qualitative data to understand the context of intervention delivery, understanding facilitators and barriers, working with stakeholders to understand the issues and problem-solve, and considering future ACV use and sustainability (O'Cathain et al., 2019). In the research presented in the thesis the systematic review comprehensively describes the research and some issues with the evidence base and the intervention itself. The survey and interview study have provided opportunities to engage with stakeholders. This has led to an improved understanding of the context, the issues and barriers surrounding ACV implementation and application, and has helped to identify potential solutions. Furthermore, the DAM has enabled the consideration of the cost-effectiveness of ACV and identified critical areas for further research. This research should reduce the uncertainties identified, ensuring that ACV use is optimised and sustainable. To that end, this research has helped to further develop the ACV intervention by: improving understanding of the

complexities of ACV, defining more clearly the different parameters of application, improving understanding of the potential causes for variation, understanding the need for clinicians to expand the purpose of ACV, recognising the need for terminology change, and describing trouble-shooting strategies. This research should provide some immediate guidance for ACV implementation and application, as well as helping to guide future research.

7.4.2 Theoretical insights for the uncertainty, subjectivity, and variation

The origin of the uncertainty and the variation in purpose, approach, and opinions may be the result of a combination of factors. These include peoples' interpretation and understanding of the evidence; their personal experiences; their perceptions of the experiences of others; the application approach they use; the primary purpose for which they use ACV; the tracheostomy weaning approach taken in their service; their staffing levels; the brand of tracheostomy tube used; and the type and complexity of the patients they manage. An individual's mental model and how they understand a specific aspect of how the world works (in this case, ACV) influences how they respond to and deal with complexity and make decisions (Holtrop et al., 2021). An individual's particular perspectives and experiences influence their opinions and how they react in different situations or scenarios (McComb and Simpson, 2014). HCPs will have different mental models dependent on who they are as an individual. Their mental model will also be influenced by their professional background and their experiences and opinions about a range of related issues (Piquette et al., 2009).

Some fundamental theoretical insights have been developed throughout the thesis that may explain some of the uncertainty, subjectivity, and variation observed in the systematic review, the survey, the interview study, and the DAM. These insights are: 1) the brand and design of the tracheostomy tube may impact the forces applied to the laryngo-tracheal mucosa; 2) ACV application is likely to impact intra-luminal pressures; 3) the position of the subglottic port exit may impact on safety and effectiveness of ACV; and 4) the use of cuff deflation prior to ACV trials may impact on the effectiveness of ACV. These theories provide potential explanations for the varying benefits observed, the varying patient and clinician experience, and the varying application of ACV. Each theory will be discussed in turn.

7.4.2.1 Impact of the tracheostomy tube design on forces applied to the laryngo-tracheal mucosa

Different brands of tracheostomy tubes have different designs for their subglottic ports. For example, the subglottic port of the Portex® tube has a 2mm lumen with a single lateral exit, whereas the TRACOE® tube has a 4mm lumen with bilateral exits (Figure

18). When airflow travels through a tube with a smaller diameter, there are higher airflow pressures and greater airflow resistance compared to airflow travelling through a larger diameter tube (Hannallah et al., 1996; Pryor, Baldwin, et al., 2016). During ACV, airflow passes from the oxygen bubble tubing (this wavy tubing has a diameter that ranges from approximately 4mm to 8mm) into the smaller diameter of the subglottic port tubing of 2 to 4mm. The diameters of the oxygen tubing and the subglottic port tubing are all considerably smaller than the diameter of a trachea, which has a lower limit of mean diameter of 10mm for women and 13mm for men (Breatnach et al., 1984). Therefore, similar airflow rates through a healthy normal trachea may have much higher pressures when entering a trachea partially blocked by a tracheostomy via a narrow subglottic port. The variation in the number and position of the subglottic port exits may also impact the turbulence of the airflow. The altered pressure and turbulence of the airflow could alter the forces applied to the laryngo-tracheal mucosa and, consequently, the comfort of the patient receiving ACV.

Figure 18 Different tracheostomy tube designs. *Left:* Portex® tracheostomy tube with 2mm subglottic port diameter and single, lateral exit. *Right:* TRACOE® tracheostomy tube with 4mm subglottic port diameter with bilateral exits on the midline.

These factors are likely to impact the airflow rates that are tolerated by patients, with many patients only finding lower flows acceptable. However, these flows may be insufficient to facilitate intelligible, acceptable, or good quality speech. One interview participant who reported using airflows of up to 15 L/min described his rationale, stating that the average airflow rates for speech in healthy individuals were much higher than 6 L/min. Therefore, he believed that ACV should be used with airflows more comparable to that usually used during speech. The mean airflow during everyday speech is 11.4 L/min for men and 8.4 L/min for women (Holmberg et al., 1988). The mean anterior-

posterior diameter of a trachea for men is 20.8mm and for women is 15.5mm, and the mean transverse diameter of a trachea for men is 21.4mm and for women is 17.8mm (Kamel et al., 2009). An airflow of 15 L/min travelling through an average-sized trachea will probably have much lower pressures than when applied via a subglottic port tube with a 2 or 4mm diameter. Therefore, the ACV airflow will presumably exert much more force against laryngo-tracheal tissue than normal airflow travelling through a healthy trachea. This participant reported that their patients had tolerated airflows of 15 L/min via a TRACOE® tracheostomy tube. Possibly the 4mm diameter subglottic port, in combination with bilateral exits, reduces the pressure to the extent that patients tolerate it. In summary, the different designs of different tracheostomy tubes may explain some of the differences in outcomes seen in the systematic review with different ACV applications, the differences in opinions about optimal ACV application, and the differences in HCPs' opinions about acceptability and who benefits from ACV.

7.4.2.2 Impact of the application of ACV on intra-luminal pressures

During normal swallowing, there is a period of apnoea, where exhalation pauses while the vocal folds adduct to protect the airway from secretions, food, or drink. In healthy adults, this period of apnoea ranges from approximately 0.74-1.41 seconds depending on age and sex (Hiss et al., 2001). For adults with dysphagia, this apnoea ranges from 1.38-2.41 seconds (Butler et al., 2007). A build-up of subglottic pressure of approximately 5.5-10.76 cmH_2O occurs during swallowing in healthy individuals, and this subglottic pressure is believed to be vital to facilitate effective and efficient swallowing (Eibling and Gross, 1996; Gross et al., 2006; Gross et al., 2012).

However, when airflow is applied continuously, there is nowhere for the applied airflow to escape during this period of apnoea. It is hypothesised that with continuous airflow application, the subglottic pressure in the intra-luminal space between the closed glottis and the inflated tracheostomy cuff will increase steadily and quickly instead of remaining static in that beneficial and normal range. Increasing intra-luminal pressure has the potential to increase discomfort, cause harm to the laryngo-tracheal structures, and reduce swallowing frequency in patients attempting to avoid the discomfort associated with pressure build-up. Additionally, the build-up of pressure could force vocal fold abduction and glottic opening to provide a release of pressure which might leave the patient vulnerable to aspiration and could actively prevent vocal fold adduction. The higher the applied airflow, the greater the pressure build-up in this subglottic space.

Approximately half of the survey respondents and 42% of interview participants stated that they were using continuous airflow application some or all of the time. Furthermore, four of 13 studies included in the systematic review used continuous airflow application, and a further four studies did not specify whether they used

intermittent or continuous airflow application. If this theory of intra-luminal pressure build-up is correct, it could explain the variation in patient acceptability reported by HCPs and the differing opinions on how effective and valuable ACV is.

7.4.2.3 Impact of the position of the subglottic port exit on safety and effectiveness

The impact of patient and tracheostomy positioning on ACV effectiveness and safety has been raised in several research studies, including the systematic review in Chapter 3 (Leder and Astrachan, 1989; Leder and Traquina, 1989; Leder, 1990b; Akhtar and Bell, 1993; Calamai et al., 2018; Mills, Michou, King, et al., 2022). Additionally, 46% of survey respondents stated that poor tracheostomy positioning should be a contra-indication for ACV use, and a large proportion of respondents used the techniques of adjusting the position or posture of the patient (62%) or the tracheostomy (40%) to improve success with ACV. Several of the interview participants also stated that tracheostomy tube positioning was a safety concern and that re-positioning the patient helped to improve success. Furthermore, some interview participants raised concerns about the individual variability of ACV and that patients could achieve a voice in one session yet in other session be unable to vocalise.

One theory for this intra-patient variability in effectiveness and safety is related to the positioning of the exit of the subglottic port. If the subglottic port exit is positioned against the tracheal wall, it likely prevents airflow from reaching the vocal folds. In such a circumstance, it is unclear what happens with the airflow and whether the exit blockage causes the oxygen flow meter at the wall to stop releasing oxygen or whether high-pressured air is directed against the tracheal mucosa. If it is the latter, there is potential for tracheal mucosal damage. Prior to the survey of HCPs, there had been no reports of bleeding associated with the use of ACV. However, the survey revealed that HCPs occasionally observe bleeding around the stomal site or via the subglottic port. This bleeding could result from tracheal mucosal damage caused by high pressure airflow directed against the tracheal wall because of poor tracheostomy positioning. Turbulent airflow applied in a constricted space has been shown to increase the frictional stress applied to airway mucosa and this could result in tissue damage (Nucci et al., 2003; Lin et al., 2007).

An improved understanding of the mechanics of ACV is crucial to appreciate the risks better and effectively mitigate them. Similarly, better understanding of the mechanics of ACV might help to improve the design of tracheostomy tubes. For example, optimising the positioning of the subglottic port exit could reduce the likelihood of occlusion, improving safety and consistency of vocalisation.

7.4.2.4 The use of cuff deflation prior to ACV trials may impact on ACV effectiveness

The survey and the interview study demonstrated the substantial impact of varying tracheostomy management on ACV use. One theory for the variation in the effectiveness of ACV observed is due to variation in the process prior to ACV application. In addition to the survey and interview study revealing that a tracheostomy tube change to one with a subglottic port is often necessary prior to ACV being possible, the systematic review revealed that this was also the case for the only RCT of ACV (Pandian et al., 2020). In this RCT, all patients underwent cuff deflation trials before ACV was considered, and their tracheostomy tube was changed to a subglottic tube. If patients succeeded with cuff deflation, a subglottic tube was generally not required. Cuff deflation and a period of restored airflow through the larynx may better prepare patients for ACV and improve communication success with ACV. Most interview participants reported that they thought both swallowing and communication outcomes were better with cuff deflation and one-way valve (OWV) than with ACV, probably due to greater and more normalised trans-laryngeal airflow. Receiving a more normalised airflow prior to ACV may better prime the patient for improved vocal fold movement, and this theory should be explored in future research.

7.5 Strengths and Limitations

The strengths and limitations of each research study have been discussed in detail in each chapter. Therefore, this section will provide an overview of the main strengths and limitations of this body of research.

The overall strength of the research is in assembling all the research evidence available for ACV. The systematic review provides the first critical appraisal of the literature; the survey and interview studies provide the first research exploring stakeholder views on ACV practice; and the DAM provides the first early-stage cost-effectiveness analysis. This research has facilitated improved understanding of the complexities of ACV and will help to shape future research.

The main limitations of the research were related to the impact of the COVID-19 pandemic. Firstly, the changes to the research plan mean that the patient perspective on ACV was limited to input from the research PCPI group and the patient representative input into the expert elicitation for the DAM. It would have been beneficial to hear from patients and relatives about their experiences and opinions about ACV. This is an important area for future research.

Secondly, the original cost-effectiveness analysis and the feasibility study were impossible due to the COVID-19 pandemic. Developing an early-stage DAM using available published data rather than trial data provided considerable challenges. The

limited and low-quality data introduced a high level of uncertainty into the model as various assumptions had to be made. It also led to a dependence on expert elicitation to provide parameter estimates. The patient expert utility data depended on just one patient, because there was insufficient time to obtain ethical approval to recruit additional patients, which could have led to biased utility estimates.

Despite these limitations and the need for cautious interpretation of the results, this model provides essential information about key drivers of cost and QoL and will help to refine and direct future research. Furthermore, the requirement to defer the RCT may have been beneficial. The research revealed significant uncertainty about ACV application, and it is clear that further refinement of the intervention process is needed before a robust protocol can be developed for testing in an RCT.

Another potentially limiting factor for this research was that all studies were conducted in English. The systematic review excluded non-English language studies, the survey was written in English, the interviews were conducted in English, and the rapid reviews conducted for the DAM also excluded non-English language studies. These choices were made due to the time and cost limitations of the research. However, it could have resulted in the omission of crucial research and biased responses if HCPs were excluded from responding to the survey or participating in interviews. Future research should factor in the inclusivity of language and representation, and ensure finances are available for translation and interpretation.

7.6 Clinical Implications

The systematic review, survey, and interview all highlighted the adverse events and complications that can occur with ACV and the need for caution with implementation and application. In particular, the survey and interview studies emphasised the need for guidelines, competencies, and education packages to help support HCPs to use ACV safely. Simulation was also suggested as a potential facilitator to overcome some of the issues faced by HCPs regarding staff training. The systematic review and survey also suggested involvement of SLTs or voice specialists was essential to minimise laryngeal complications.

The parameters of application have been clearly defined for the first time. This information may inform record-keeping and ensure that patient-specific guidelines incorporate all the relevant application information, which may improve safety. This research has also facilitated the collation of troubleshooting recommendations from researchers and HCPs. Given the lack of guidance available for ACV, this information could be beneficial for clinical practice.

Throughout the research there is a perception amongst researchers and clinicians that ACV is primarily for communication, and there was a lack of prioritisation for other

purposes. By acknowledging the multi-faceted nature of ACV and widening the focus of ACV's purpose to include communication and swallowing, this may help widen the potential pool of patients that may benefit from ACV (Figure 19). As well as potentially increasing both the extent of the benefits for patients and the number of patients accessing the intervention, this may also improve the ability of services to deliver ACV as there will be more patients receiving ACV to support training and the development and maintenance of competencies.

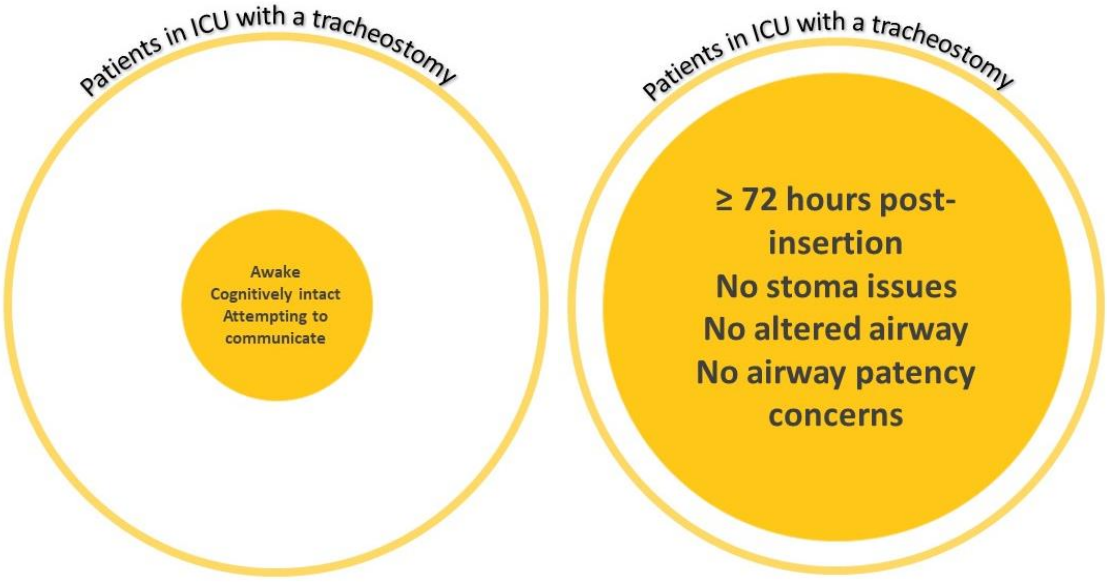

Figure 19 Widening the focus of purpose from communication only (*Left*) to include swallowing (*Right*)

The health economic DAM suggests that the ongoing adoption of ACV into clinical practice is appropriate given the cost-effectiveness data currently available. Nonetheless, further research is essential to reduce the level of uncertainty in the data. Issues with inadequate or inconsistent use of outcome measures were identified throughout the research. Routine use of validated outcome measures in clinical practice could form a valuable additional contribution to the evidence-base.

7.7 Future research

This body of work has helped to close some of the research gaps and answer key research questions for ACV. It has also identified additional gaps, and the health economic DAM has identified areas of uncertainty that are the key drivers of cost-effectiveness. Given the current evidence base and the conclusion that ACV is a complex intervention, it is important that the next steps of research include preclinical, Phase I, Phase II, and Phase III studies (Campbell et al., 2000). There is a need for Phase I studies, including benchtop and computer modelling studies to further define the different components of the intervention to support the design of an intervention

protocol that can be tested. Qualitative studies addressing patient and relative opinions and experience are also required to ensure that any intervention protocol is acceptable to patients. Phase II studies are needed to test the feasibility of an RCT and its acceptability to patients and clinicians. Finally, phase III studies will allow the defined intervention protocol to be tested, and ideally this should also incorporate qualitative methods to evaluate the implementation processes (Campbell et al., 2000). The use of a mixed-methods approach integrating both quantitative and qualitative methods is vital when evaluating and implementing a complex intervention (Noyes et al., 2019). There are a range of specific research questions which should be the focus of future research in these different phase studies. These are separated into the following topics, which will be discussed in turn: short-term effects, long-term effects, safety considerations, and cost-effectiveness.

7.7.1 Short-term effects

There is a lack of large-scale, high-quality evidence for the short-term effectiveness of ACV for different patient groups for a range of outcomes. Most outcomes were subjective, and the lack of consistency in using outcome measures, made comparison of studies difficult. The variation in focus in the purpose of the research also means that it is difficult to make firm conclusions about the effectiveness of ACV. Some participants raised the potential for ACV to impact on LoS due to potential benefits in the reduction of delirium as a result of improved communication, and only one study included in the systematic review reported data on this outcome. The interview study and the DAM revealed that ACV might generate process utility, which is when there are QoL benefits to the patient even when there are no functional gains (e.g., reassurance, humanisation, and identity). Future research must capture any process utilities gained by patients. The key research questions in this area are:

1. How effective is ACV in improving communication, swallowing, cough, time to decannulation, ICU LoS, hospital LoS, and QoL for patients with a tracheostomy in intensive care?
2. What process utilities does ACV generate for patients?
3. Does improving communication in the ICU with ACV help to reduce delirium and the use of sedatives and anti-psychotics?

To evaluate these questions effectively, studies must employ core outcome sets and clearly describe the planned and delivered intervention. However, there is currently no core outcome set available for dysphagia or communication for the ICU population. These are priority research areas to improve the quality of ICU studies by reducing the heterogeneity of outcome measures used (Dinglas et al., 2020; Zaga, Cigognini, et al., 2020; Duncan et al., 2023). Furthermore, to provide robust utility data for future cost-

effectiveness analysis, appropriate QoL outcome measures, like the EQ-5D, must be used to ensure easy conversion of values to a utility index value.

In the context of needing to apply implementation science to ACV to improve uptake, one option for a future RCT would be to employ an 'effectiveness-implementation hybrid design' which would evaluate both the effectiveness of ACV while exploring the facilitators and barriers to implementation (Barr et al., 2021).

7.7.2 Long-term effects

There is no evidence of any long-term effectiveness provided by ACV. The systematic review revealed that all the studies only evaluated the immediate effects of ACV. However, the DAM indicates that if ACV impacts which end state a patient reaches and whether they are decannulated or have dysphagia, then this can considerably impact the overall cost-effectiveness, particularly the QALYs gained in the long-term stage. There is currently no evidence to suggest whether ACV impacts long-term outcomes related to decannulation or dysphagia. Furthermore, if ACV has additional QoL benefits after the intervention is stopped, this will also substantially impact cost-effectiveness and the QALYs gained in the longer term. The key research questions in this area are:

1. Does improving communication in the ICU help improve long-term QoL and reduce post-intensive care syndrome, post-traumatic stress disorder, and anxiety?
2. Does ACV lead to earlier commencement of oral intake?
3. Does ACV lead to earlier decannulation?
4. Does ACV lead to an increased likelihood of decannulation?
5. Does ACV reduce the severity of dysphagia in the long term?
6. Does ACV reduce the likelihood of dysphagia in the long term?
7. Does ACV reduce ICU and hospital LoS?
8. How does ACV impact long-term destination (e.g., rehabilitation, nursing home, home with care, and home without care)?

7.7.3 Safety considerations

One of the topics that frequently arose in each study is the concern that clinicians and researchers have regarding the potential for ACV to cause drying of the laryngo-tracheal mucosa. In combination with practical issues in setting up humidification of airflow, these concerns appear to lead to limits being placed on the duration of ACV to reduce the potential risks for patients. Another safety consideration is whether there is trauma occurring to the laryngo-tracheal mucosa either as a result of poor positioning of the tracheostomy tube – with the subglottic port funnelling high pressured airflow directly against the tracheal wall – or because of the use of high airflows. If this mucosal damage is occurring due to the airflow, it could be the source of bleeding

identified by survey respondents at the stomal site and in the subglottic port. There is also a lack of clarity regarding whether intermittent or continuous application is more effective and safer for patients. One concern raised by some interview participants was related to potential discomfort for patients during swallowing with continuous application of ACV. The theory developed regarding the potential for increasing intra-luminal pressures in the subglottic space, between the inflated cuff and the closed glottis, could be a safety issue for patients.

The key research questions for safety are:

1. At what dose of ACV using non-humidified oxygen or medical air does laryngo-tracheal mucosal drying occur?
2. Can a cheap, simple humidification system be developed?
3. At what dose of ACV, using humidified oxygen or medical air, does laryngo-tracheal mucosal drying occur?
4. What forces are applied to the vocal folds and the tracheal mucosa with varying airflow rates delivered with different brands and designs of tracheostomy tubes?
5. If the tracheostomy tube is badly positioned, and the subglottic port is flush against the tracheal wall, does that stop the airflow, or is a greater force being applied to the tracheal tissue?
6. What intra-luminal pressures build up in the subglottic space between the inflated cuff and the adducted vocal folds during swallowing with a continuous application of different airflow rates, with different sizes and designs of tracheostomy tubes?

The candidate is currently collaborating with the Mechanical Engineering department at the University of Leeds to develop benchtop studies and computer simulation models to explore some of these research questions. These answers will provide a greater understanding of the mechanism of ACV action and should help to provide robust guidance for clinical implementation and application to improve patient safety. Specifically, it would provide guidance regarding whether continuous airflow application should be avoided and whether airflow application should be paused during swallowing. It should guide safe upper airflow rate limits for different tracheostomy brands and designs. The information provided should be sufficient to facilitate the development of competencies and safety training. Having a clearer understanding of the mechanism of action and optimal approach from a safety perspective will also help to guide the development of an ACV protocol for a future RCT.

7.7.4 Cost-effectiveness

In order to continue the development of the early-stage health economic DAM, better quality data is needed for the model parameters. Research addressing the above

questions specific to ACV will obtain some of these parameters. However, broader gaps in the research need to be filled for both UC and ACV. These gaps include utility data for all patients with a tracheostomy from insertion to death and mortality data for all patients with a tracheostomy from insertion to death.

The key research questions for cost-effectiveness are:

1. What impact does ACV have on ICU and ward LoS?
2. What impact does ACV have on speed of tracheostomy weaning?
3. What is the mortality risk for patients with a tracheostomy at each stage of the weaning process during their ICU stay (e.g., 'tracheostomy maintenance', 'tracheostomy and ventilator weaning', 'decannulated', 'not decannulated')?
4. What is the mortality risk for patients with a tracheostomy (or who have had a tracheostomy) when located on the ward?
5. What is the mortality risk for patients with a tracheostomy (or who have had a tracheostomy) when in rehabilitation, in a nursing home, at home with care, or at home without care?
6. What utilities do patients with a tracheostomy have at each stage of the weaning process during their ICU stay (e.g., 'tracheostomy maintenance'; 'tracheostomy and ventilator weaning'; 'decannulated'; 'not decannulated')?
7. What utilities do patients with a tracheostomy (or who have had a tracheostomy), have when located on the ward?
8. What utilities do patients with a tracheostomy (or who have had a tracheostomy) have when in rehabilitation, in a nursing home, at home with care, or at home without care?

Answering these research questions would be beneficial for other critical care DAMs as well as ACV cost-effectiveness analysis.

7.8 Conclusion

ACV shows the potential to improve outcomes for patients with a tracheostomy and is potentially cost-effective according to the limited and low-quality data available. Several new theoretical insights have been developed that might explain some of the findings of this research, and further research is needed to explore these theories. Critical areas for future research have been identified, and it is vital to reduce the level of uncertainty in the data to enable a more robust cost-effectiveness analysis and provide more guidance for clinicians regarding ACV adoption decisions and optimal clinical implementation and application.

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Appendix A Systematic Review Search Strategy

Ovid MEDLINE(R) <1946 to May Week 4 2020>

Date searched: 3 June 2020

1 Tracheostomy/ (7322)
2 tracheotomy/ (8348)
3 tracheostom*.tw,kw. (12537)
4 tracheotom*.tw,kw. (6286)
5 or/1-4 [tracheostomy] (23509)
6 ((talk* or speak* or speech* or communicat* or voice* or verbal* or vocal*) adj4 (tube* or trach*)).tw,kw. (1819)
7 ((sub-glott* or subglott*) adj4 (airflow* or air-flow*)).tw,kw. (85)
8 or/6-7 [above cuff vocalisation] (1902)
9 5 and 8 [ACV in tracheosotomy] (509)
10 ("above cuff" adj4 vocal*).tw,kw. (1)
11 9 or 10 (510)

Database and Dates covered	**Date searched**	**Hits**
AMED (Allied and Complementary Medicine) <1985 to May 2019	7/5/19	13
CINAHL Wednesday, May 08, 2019 5:29:08 AM	8/5/19	190
Cochrane Central Register of Controlled Trials Issue 5 of 12, May 2019 37 (no other hits)	7/5/19	37
Embase Classic+Embase <1947 to 2019 May 03>	7/5/19	692
Ovid MEDLINE(R) <1946 to April Week 4 2019>	7/5/19	498
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to May 03, 2019	7/5/19	548
Web of science	7/5/19	31
SCOPUS	8/5/19	764
Web of science	7/5/19	452

Clinical trials.gov	10/5/19	32
ICTRP	10/5/19	10
Prospero	10/5/19	8
	Total	**3277**

Appendix B Survey Questions

The Leeds Teaching Hospitals NHS Trust

UNIVERSITY OF LEEDS

International Survey about Above Cuff Vocalisation

Participant Information

Title	**The ACoUSTiC Study – Exploring the potential benefits of Above CUff VocaliSation in TraCheostomy**
Version	2.0
Date	8 January 2019
REC No.	18-037

We would like to invite you to take part in a University of Leeds and Leeds Teaching Hospitals NHS Trust research study. This research is funded through a personal National Institute for Health Research Clinical Doctoral Research Fellowship.

Before you decide whether you would like to take part, it is important for you to understand why the research is being done, what it would involve for you and how the information you provide will be used. Please take time to read the Participant Information Sheet carefully and decide whether or not you wish to take part and complete this online survey.

If there is anything that is not clear, or you would like more information you can contact us:

Claire Mills

NIHR Clinical Doctoral Research Fellow & Speech and Language Therapy Critical Care Lead at Leeds Teaching Hospitals NHS Trust

Telephone: +44 (0)113 343 2702

Email: c.s.mills@leeds.ac.uk

Consent Form

1. Consent to Participate - select the statements below to proceed with the survey

	Select your agreement to proceed to the survey.
	Agree
I confirm that I have read and understand the information provided above for this online survey and have had an opportunity to ask questions	○
I understand that my participation is voluntary and that I am free to withdraw at any point during the completion of the survey, up until pressing submit. I understand that if I withdraw my legal rights will not be affected. I understand that once I have submitted the survey, data cannot be withdrawn because it is anonymous and the analysis will have already begun.	○
I understand that all data which identifies me will be kept strictly confidential and will be kept on a secure database. No identifiable information will be included in any outputs from this study. I understand that the data collected is covered by the General Data Protection Regulation (2018) and the Data Protection Act (2018) and will be stored appropriately	○
I understand that the anonymised data produced will be stored in a Research Repository for a minimum of 10 years and that there will be restricted access to this by other researchers	○

2. I agree to take part in this survey.

- ○ Agree
- ○ Disagree

Participant Information

3. Which country do you work in?

4. What is the name of the hospital in which you work?

5. What is your profession?

- Advanced Critical Care Practitioner
- Advanced Nurse Practitioner
- Doctor/Physician
- Health Care Assistant
- Nurse
- Occupational Therapist
- Physiotherapist
- Psychologist
- Respiratory Therapist
- Speech & Language Therapist/Speech-Language Pathologist/Speech Pathologist
- Other

5.a. If you selected Other, please specify:

6. What area do you work in?

- Critical Care
- Acute wards
- Rehabilitation wards
- Long-term nursing or residential care
- Community

Tracheostomy management in your hospital

7. In the last calendar month approximately how many patients did you have with a tracheostomy in your critical care units/wards?

- ○ 1-5
- ○ 6-10
- ○ 11-15
- ○ 16-20
- ○ 21-25
- ○ 26-30
- ○ 31-35
- ○ 36-40
- ○ 41-45
- ○ 46-50
- ○ >50
- ○ don't know

8. What types of patients with tracheostomies do you see?

- ☐ Cardiothoracic
- ☐ ECMO
- ☐ General
- ☐ Neurological
- ☐ Spinal
- ☐ Respiratory
- ☐ Oncology
- ☐ Other

8.a. If you selected Other, please specify:

9. What is the earliest that cuff deflation will be considered at your hospital?

- <1 hr post-trache insertion
- 1-6 hrs post-trache insertion
- 7-12 hrs post-trache insertion
- 13-24 hrs post-trache insertion
- 25-48 hrs post-trache insertion
- 49-72 hrs post-trache insertion
- >72 hrs post-trache insertion
- dependent on patient
- dependent on Consultant on duty
- no defined earliest time
- don't know

10. What is the highest level of PEEP at which it is usually considered suitable to deflate the tracheostomy cuff at your hospital?

- 0 cmH20
- 1 cmH20
- 2 cmH20
- 3 cmH20
- 4 cmH20
- 5 cmH20
- 6 cmH20
- 7 cmH20
- 8 cmH20
- 9 cmH20
- 10 cmH20
- 11 cmH20
- 12 cmH20
- 13 cmH20
- 14 cmH20
- 15 cmH20
- dependent on patient
- dependent on Consultant on duty
- no defined highest level of PEEP
- don't know

11. What is the highest level of pressure support at which it is typically considered suitable to deflate the tracheostomy cuff at your hospital?

- 0 cmH20
- 1 cmH20
- 2 cmH20
- 3 cmH20
- 4 cmH20
- 5 cmH20
- 6 cmH20
- 7 cmH20
- 8 cmH20
- 9 cmH20
- 10 cmH20
- 11 cmH20
- 12 cmH20
- 13 cmH20
- 14 cmH20
- 15 cmH20
- 16 cmH20
- 17 cmH20
- 18 cmH20
- 19 cmH20
- 20 cmH20
- 21 cmH20
- 22 cmH20
- 23 cmH20
- 24 cmH20
- 25 cmH20
- 26 cmH20
- 27 cmH20
- 28 cmH20
- 29 cmH20
- 30 cmH20
- dependent on patient
- dependent on consultant on duty
- no defined highest Pressure Support level
- don't know

12. How many days post-tracheostomy insertion do you **typically** first trial tracheostomy cuff deflation?

- <1
- 1-5
- 6-10
- 11-20
- 21-30
- >30
- don't know
- depends on patient
- depends on consultant

13. Are there SLT(s) that provide input to your critical care/ward service at least 5 days per week?

- Yes
- No
- Don't know

14. Do you have access to Fibreoptic Endoscopic Evaluation of Swallowing (FEES) in your critical care units?

- Yes
- No
- Don't know

15. On average, how often is the **first** tracheostomy tube inserted usually one with a sub-glottic port?

- 0%
- 1-25%
- 26-50%
- 51-75%
- 76-99%
- 100%

Prevalence of ACV Use

16. Is Above Cuff Vocalisation (ACV) used in your hospital?

- Yes
- No

Prevalence of ACV Use

17. In the last calendar month, approximately how many patients in your hospital used ACV?

- 0
- 1-5
- 6-10
- 11-15
- 16-20
- 21-25
- 26-30
- 31-35
- 36-40
- 41-45
- 46-50
- >50
- Don't know

18. Approximately how long has your hospital been using ACV for?

- <1 year
- 1-2 years
- 3-4 years
- 5-6 years
- 7-8 years
- 9-10 years
- 11-15 years
- 16-20 years
- >20 years
- Don't know

Practicalities of using ACV in your hospital

19. Are any of the following in use in your hospital for ACV?

	Yes	No	In development	Don't know
Guidelines for the use of ACV	○	○	○	○
Standard Operating Procedure for ACV	○	○	○	○
Protocol for ACV	○	○	○	○
Patient-specific guidelines for ACV	○	○	○	○
Patient-specific record sheet for ACV	○	○	○	○
Competencies for staff assessing patients for ACV	○	○	○	○
Competencies for staff delivering ACV treatment	○	○	○	○

19.a. If you answered yes to any of the questions above, which professional groups were involved in producing them? (select all that apply)

- ☐ ACCP
- ☐ Doctor
- ☐ Health Care Assistant
- ☐ Nurse
- ☐ Occupational Therapist
- ☐ Physiotherapist
- ☐ Psychotherapist
- ☐ Speech and Language Therapist
- ☐ Not applicable
- ☐ Don't know
- ☐ Other

19.a.i. If you selected Other, please specify:

Practicalities of using ACV in your hospital

20. Is training provided at your hospital for staff **delivering ACV** treatment to patients?

- ○ Yes
- ○ No
- ○ Don't know

Practicalities of using ACV in your hospital

21. Which professional groups **receive** this training for delivering ACV treatment? (select all that apply)

- ☐ Advanced Critical Care Practitioner
- ☐ Doctor
- ☐ Health Care Assistant
- ☐ Nurse
- ☐ Occupational Therapist
- ☐ Physiotherapist
- ☐ Psychologist
- ☐ Speech and Language Therapist
- ☐ Don't know
- ☐ Other

21.a. If you selected Other, please specify:

22. Which professional groups **deliver** the training? (select all that apply)

- ☐ Advanced Critical Care Practitioner
- ☐ Doctor
- ☐ Health Care Assistant
- ☐ Nurse
- ☐ Occupational Therapist
- ☐ Physiotherapist
- ☐ Psychologist
- ☐ Speech and Language Therapist
- ☐ Don't know
- ☐ Other

22.a. If you selected Other, please specify:

Practicalities of using ACV in your hospital

23. Is training provided at your hospital for staff carrying out the **initial assessment** for ACV?

- ○ Yes
- ○ No
- ○ Don't know

Practicalities of using ACV in your hospital

24. Which professional groups **receive** this training for initial assessment for ACV? (select all that apply)

- ☐ Advanced Critical Care Practitioner
- ☐ Doctor
- ☐ Health Care Assistant
- ☐ Nurse
- ☐ Occupational Therapist
- ☐ Physiotherapist
- ☐ Psychologist
- ☐ Speech and Language Therapist
- ☐ Don't know
- ☐ Other

24.a. If you selected Other, please specify:

25. Which professional groups **deliver** the training? (select all that apply)

- ☐ Advanced Critical Care Practitioner
- ☐ Doctor
- ☐ Health Care Assistant
- ☐ Nurse
- ☐ Occupational Therapist
- ☐ Physiotherapist
- ☐ Psychologist
- ☐ Speech and Language Therapist
- ☐ Don't know
- ☐ Other

25.a. If you selected Other, please specify:

Practicalities of using ACV in your hospital

26. What is the **earliest** that ACV is ever introduced with patients in your hospital after tracheostomy insertion?

- 0-24 hrs
- 25-48 hrs
- 49-72 hrs
- >72 hrs
- Don't know

27. How long post-tracheostomy insertion is ACV **typically** introduced with patients?

- 0-24 hrs
- 25-48 hrs
- 49-72 hrs
- >72 hrs
- Don't know

28. What reasons do you have for not introducing ACV earlier with patients? (select all that apply)

- Concerns regarding risk of subcutaneous emphysema
- Direct experience of incidents of subcutaneous emphysema when used earlier
- Level of alertness of patient
- Based on research evidence
- Based on guidance from other hospitals
- Lack of training
- Lack of available staff to assess
- Other
- Don't know

28.a. If you selected Other, please specify:

29. Do you have a contraindications or exclusions list for ACV use?

- Yes
- No
- Don't know

Practicalities of using ACV in your hospital

30. What contraindications or exclusions are included in your list? (select all that apply)

- Known upper airway patency issues
- Altered upper airway
- Tracheostomy not in optimal position
- Not attempting to mouth to communicate
- Inability to mouth clearly (e.g dysarthria)
- Low levels of alertness/Too drowsy
- Fluctuating levels of alertness
- Patients in a disorder of consciousness
- < 72 hours post-tracheostomy insertion
- < 48 hours post-tracheostomy insertion
- < 24 hours post-tracheostomy insertion
- Surgical tracheostomy
- Issues at the tracheostomy stoma site e.g. bleeding
- Requiring continuous sub-glottic suction
- Only with tracheostomy tubes licensed for ACV use
- Sepsis
- Unwell
- Don't know
- Other

30.a. If you selected Other, please specify:

Practicalities of using ACV in your hospital

31. Who makes the decision about whether or not a patient is suitable for ACV? (select all that apply)

- ☐ Advanced Critical Care Practitioner
- ☐ Doctor
- ☐ Health Care Assistant
- ☐ Nurse
- ☐ Occupational Therapist
- ☐ Physiotherapist
- ☐ Psychologist
- ☐ Speech and Language Therapist
- ☐ Tracheostomy MDT
- ☐ Don't know
- ☐ Other

31.a. If you selected Other, please specify:

32. Is an assessment carried out with patients to check they are safe and appropriate for ongoing delivery of ACV?

- ○ Yes
- ○ No
- ○ Don't know

Practicalities of using ACV in your hospital

33. Which professional group usually carries out ACV assessments? (select all that apply)

- ☐ Advanced Critical Care Practitioner
- ☐ Doctor
- ☐ Health Care Assistant
- ☐ Nurse
- ☐ Occupational Therapist
- ☐ Physiotherapist
- ☐ Psychologist
- ☐ Speech and Language Therapist
- ☐ Don't know
- ☐ Other

33.a. If you selected Other, please specify:

Practicalities of using ACV in your hospital

34. Who most commonly delivers the ACV treatment to patients?

- Advanced Critical Care Practitioner
- Doctor
- Family members
- Health Care Assistant
- Nurse
- Occupational Therapist
- Physiotherapist
- Psychologist
- Speech and Language Therapist
- Don't know
- Other

34.a. If you selected Other, please specify:

35. How often do you allow the patient's family to assist in ACV delivery (e.g. have control of the thumb port)?

- Always
- Very often
- Sometimes
- Rarely
- Never
- N/A
- Don't know

36. What is the upper airflow limit that you use for ACV?

- 1 L/min
- 2 L/min
- 3 L/min
- 4 L/min
- 5 L/min
- 6 L/min
- 7 L/min
- 8 L/min
- 9 L/min
- 10 L/min
- 11 L/min
- 12 L/min
- 13 L/min
- 14 L/min
- 15 L/min
- no upper limit
- don't know

37. What type of air do you usually use for ACV?

- Humidified oxygen
- Non-humidified oxygen
- Medical air
- Don't know

37.a. Why do you use this type of air? (select all that apply)

- No access to humidified oxygen for ACV
- No access to medical air for ACV
- Not allowed to use medical air due to concerns regarding safety (e.g medical air then being used in an emergency instead of oxygen)
- Reduced risk of drying of laryngeal mucosa
- Improved voice quality
- Improved comfort for patients
- Ability to use for longer periods of time with patients
- Ease of access/availability
- Don't know
- Other

37.a.i. If you selected Other, please specify:

38. What type(s) of airflow delivery do you use with patients?

- Intermittent (using a thumb port)
- Continuous (oxygen connected directly to sub-glottic port)
- Both intermittent and continuous (with equal frequency)
- Both intermittent and continuous (with intermittent used more frequently)
- Both intermittent and continuous (with continuous used more frequently)
- Don't know

38.a. If intermittent airflow is used, do you leave the oxygen tubing connected, via the thumb port, throughout the day to allow patients to use as desired?

- Always
- Very often
- Sometimes
- Rarely
- Never
- N/A
- Don't know

39. Do you have an upper limit for the total amount of time that patients can have ACV for each day?

- Yes
- No
- Don't know

39.a. What is this upper limit of total airflow duration per day in minutes?

- <15 mins
- 15-30 mins
- 31-60 mins
- 61-90 mins
- 91-120 mins
- >120
- Don't know

40. What is the typical total daily duration of ACV delivery in minutes?

- ○ <15 mins
- ○ 15-30 mins
- ○ 31-60 mins
- ○ 61-90 mins
- ○ 91-120 mins
- ○ >120 mins
- ○ Don't know

41. What advice is usually given on the number of ACV episodes during the day?

- ☐ no advice given
- ☐ hourly
- ☐ 1-2 times daily
- ☐ 3-4 times daily
- ☐ 5-6 times daily
- ☐ >6 times daily
- ☐ when requested by patient
- ☐ whenever staff communicate with patient
- ☐ when relatives visit
- ☐ Don't know
- ☐ Other

41.a. If you selected Other, please specify:

42. How long do patients typically have ACV for?

- ○ ≤1day
- ○ 2-3 days
- ○ 4-5 days
- ○ 6-7 days
- ○ 1-2 weeks
- ○ 3-4 weeks
- ○ >1 month
- ○ ongoing (e.g. long-term tracheostomy)
- ○ Don't know

43. What would make you stop a session of ACV treatment? (select all that apply)

- [ ] no voice produced
- [ ] excessive secretions
- [ ] stomal air escape
- [ ] burping/aerophagia
- [ ] subcutaneous emphysema in neck/face/head
- [ ] air trapping
- [ ] patient reported discomfort or pain
- [ ] bleeding at stoma site
- [ ] blood in sub-glottic port
- [ ] infection at stoma site
- [ ] lack of evidence of air passing through upper airway
- [ ] patient fatigue
- [ ] no criteria for stopping ACV
- [ ] excessive coughing that doesn't settle
- [ ] don't know
- [ ] Other

43.a. If you selected Other, please specify:

44. What would make you discontinue ACV treatment altogether e.g. allow no further sessions of ACV? (select all that apply)

- [ ] no voice produced
- [ ] excessive secretions
- [ ] stomal air escape
- [ ] burping/aerophagia
- [ ] subcutaneous emphysema in neck/face/head
- [ ] air trapping
- [ ] patient reported discomfort or pain
- [ ] bleeding at stoma site
- [ ] blood in sub-glottic port
- [ ] infection at stoma site
- [ ] lack of evidence of air passing through upper airway
- [ ] patient fatigue
- [ ] achieves cuff deflation
- [ ] no criteria for stopping ACV
- [ ] excessive coughing that doesn't settle
- [ ] don't know
- [ ] Other

44.a. If you selected Other, please specify:

45. Where do you record ACV delivery and any complications? (select all that apply)

- [ ] no record made
- [ ] bedside charts
- [ ] nursing notes
- [ ] specially designed ACV record sheet
- [ ] medical notes
- [ ] physio notes
- [ ] SLT notes
- [ ] incident form/report
- [ ] don't know
- [ ] Other

45.a. If you selected Other, please specify:

46. Whose responsibility is it to monitor the ACV records and ensure ACV is stopped if needed?

- ○ Advanced Critical Care Practitioner
- ○ Doctor
- ○ Health Care Assistant
- ○ Nurse
- ○ Occupational Therapist
- ○ Physiotherapist
- ○ Psychologist
- ○ Speech and Language Therapist
- ○ No-one
- ○ Don't know
- ○ Other

46.a. If you selected Other, please specify:

47. Do you collect outcome measures for ACV?

- ○ Yes
- ○ No
- ○ Don't know

47.a. If yes, what are they? (select all that apply)

- ☐ voice Therapy Outcome Measures (voiceTOMs)
- ☐ tracheostomy Therapy Outcome Measures (tracheTOMs)
- ☐ Penetration Aspiration Score (PAS) of secretions if FEES carried out
- ☐ Penetration Aspiration Score (PAS) of oral intake if FEES carried out
- ☐ Secretion Severity Rating Score (SSRS) if FEES carried out
- ☐ New Zealand Secretion Scale (NZSS) if FEES carried out
- ☐ Functional Oral Intake Scale (FOIS)
- ☐ Australian Therapy Outcome Measures (AusTOMs)
- ☐ Royal Brisbane Hospital Outcome Measures for Swallowing (RBHOMS)
- ☐ American Speech-Language-Hearing Association National Outcome Measurement System (ASHA NOMS)
- ☐ EQ-5D
- ☐ Quality of life questionnaire for Mechanically Ventilated Patients (QOL-MV)
- ☐ Don't know
- ☐ Other

47.a.i. If you selected Other, please specify:

48. Do you use Fibreoptic Endoscopic Evaluation of Swallowing to monitor the outcomes and safety of ACV?

- ○ never
- ○ rarely
- ○ sometimes
- ○ often
- ○ always
- ○ Don't know

Resource use for ACV

49. For patients who are receiving ACV treatment, how much time would staff (e.g. therapist or nurse) typically spend with a patient assisting in the delivery of ACV over the course of one day?

- <15 mins
- 15-30 mins
- 31-60 mins
- 61-90 mins
- 91-120 mins
- 121-150 mins
- >150 mins
- don't know

50. How often is the tubing for ACV delivery changed?

- daily
- every 2-3 days
- once per week
- once per month
- once every 2-3 months
- never
- don't know

51. How often do you change the thumb port used for intermittent ACV delivery?

- daily
- every 2-3 days
- once per week
- once per month
- once every 2-3 months
- never
- don't know

52. Do you usually have to change the tracheostomy tube before ACV is possible?

- Yes
- No
- Don't know

Your experience of ACV

53. Are you involved in the use of ACV in your hospital?

- ○ Yes
- ○ No

53.a. How long have you been involved in the use of ACV?

- ○ <6 months
- ○ 6-12 months
- ○ 1-2 years
- ○ 3-4 years
- ○ ≥5 years

53.b. What are your roles with ACV? (select all that apply)

- ☐ Assessment
- ☐ Treatment
- ☐ Monitoring
- ☐ Training

53.c. How many patients have you been involved with for ACV assessment, treatment or monitoring?

- ○ <10
- ○ 10-50
- ○ 51-100
- ○ >100
- ○ Don't know

54. What positive benefits of ACV have you personally observed? (select all that apply)

- ☐ improved communication
- ☐ increased frequency of swallowing
- ☐ reduced volume of secretions removed from above the cuff via the sub-glottic port
- ☐ improved laryngeal sensation
- ☐ earlier commencement of oral intake
- ☐ coughing secretions to mouth/back of throat
- ☐ improved mood
- ☐ none of the above
- ☐ don't know
- ☐ Other

54.a. If you selected Other, please specify:

55. What complications or symptoms have you personally observed that you suspect may have been due to ACV? (select all that apply)

- [ ] subcutaneous emphysema
- [ ] air trapping
- [ ] aerophagia (swallowing air and burping)
- [ ] air escape via stoma
- [ ] excessive secretions
- [ ] patient reported discomfort
- [ ] patient reported pain
- [ ] bleeding at stoma site
- [ ] blood in the sub-glottic port
- [ ] infection at the stoma site
- [ ] nausea
- [ ] gagging
- [ ] vomiting
- [ ] strained vocal quality
- [ ] dizziness
- [ ] drying of the laryngeal mucosa
- [ ] none of the above
- [ ] don't know
- [ ] Other

55.a. If you selected Other, please specify:

56. What other complications or side-effects of ACV have occurred at your hospital that you are aware of? (select all that apply)

- [ ] subcutaneous emphysema
- [ ] air trapping
- [ ] aerophagia (swallowing air and burping)
- [ ] air escape via stoma
- [ ] excessive secretions
- [ ] patient reported discomfort
- [ ] patient reported pain
- [ ] bleeding at stoma site
- [ ] blood in the sub-glottic port
- [ ] infection at the stoma site
- [ ] nausea
- [ ] gagging
- [ ] vomiting
- [ ] strained vocal quality
- [ ] dizzyness
- [ ] drying of the laryngeal mucosa
- [ ] none of the above
- [ ] don't know
- [ ] Other

56.a. If you selected Other, please specify:

57. How many times have more serious complications occurred since the use of ACV first started in your hospital/place of work?

	Number of episodes of complications that have occurred since ACV was first introduced in your hospital									
	0	1-2	3-4	5-6	7-8	9-10	11-20	21-30	>30	Don't know
Subcutaneous emphysema	○	○	○	○	○	○	○	○	○	○
Air trapping	○	○	○	○	○	○	○	○	○	○
Bleeding	○	○	○	○	○	○	○	○	○	○

58. In your hospital, what strategies are in place to avoid or reduce the risk of complications before they occur? (select all that apply)

- [ ] all patients receive endoscopy/FEES to check airway patency
- [ ] high risk patients receive endoscopy/FEES to check airway patency
- [ ] contraindications list used in selecting patients for trials of ACV
- [ ] all patients assessed by trained/competent assessor
- [ ] only trained/competent staff delivering ACV on day-to-day basis
- [ ] don't know
- [ ] Other

58.a. If you selected Other, please specify:

59. What techniques are used in your hospital to improve the effectiveness or success of ACV? (select all that apply)

- ☐ manually adjusting tracheostomy position
- ☐ adjusting position/posture of patient
- ☐ increasing the size of the tracheostomy tube
- ☐ decreasing the size of the tracheostomy tube
- ☐ SLT training the patient in how to use ACV (e.g. vocal exercises)
- ☐ other staff training the patient in how to use ACV
- ☐ don't know
- ☐ Other

59.a. If you selected Other, please specify:

Your opinion of ACV

60. How effective do you think ACV is for each of the following domains?

	extremely effective	very effective	moderately effective	slightly effective	not at all effective	don't know
improving communication	○	○	○	○	○	○
improving mood	○	○	○	○	○	○
improving saliva management e.g. increased swallow frequency	○	○	○	○	○	○
improving cough/clearance of saliva	○	○	○	○	○	○
reducing quantities of saliva removed from above the cuff	○	○	○	○	○	○
improving laryngeal sensation	○	○	○	○	○	○
leading to earlier commencement of oral intake	○	○	○	○	○	○
leading to earlier decannulation	○	○	○	○	○	○
reducing ICU length of stay	○	○	○	○	○	○

61. How effective do you think ACV is for the following patient groups?

	extremely effective	very effective	moderately effective	slightly effective	not at all effective	don't know
patients in a disorder of consciousness	○	○	○	○	○	○
patients receiving ECMO	○	○	○	○	○	○
respiratory patients	○	○	○	○	○	○
cardiac patients	○	○	○	○	○	○
general surgery patients	○	○	○	○	○	○
neuro patients	○	○	○	○	○	○
spinal patients	○	○	○	○	○	○
oncology patients	○	○	○	○	○	○

62. What do you think is the **optimal** type of airflow delivery?

- intermittent (using thumb port) with continual access during the day
- intermittent (using thumb port) for a certain number of episodes each day
- continuous (no thumb port) continually applied during the day
- continuous (no thumb port) for a certain number of episodes each day
- patient dependent
- don't know

63. Do you think there should be an upper limit of airflow rate for ACV?

- Yes
- No
- Don't know

63.a. If yes, what do you think the upper limit should be?

- 1 L/min
- 2 L/min
- 3 L/min
- 4 L/min
- 5 L/min
- 6 L/min
- 7 L/min
- 8 L/min
- 9 L/min
- 10 L/min
- 11 L/min
- 12 L/min
- 13 L/min
- 14 L/min
- 15 L/min
- Don't know

64. Do you think there should be an upper limit of total time of ACV per day?

- Yes
- No
- Don't know

64.a. If yes, what do you think the upper limit should be?

- <30 minutes per day
- 30-60 minutes per day
- 1-2 hours per day
- 3-4 hours per day
- 5-6 hours per day
- 7-8 hours per day
- 9-10 hours per day
- 11-12 hours per day
- Don't know

65. Do you think there should be an upper limit on the number of episodes of ACV per day?

- Yes
- No
- Don't know

65.a. If yes, what do you think the upper limit should be?

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- ≥13
- Don't know

Your opinion of ACV

66. Does your hospital use ACV guidelines, protocols or patient-specific guidelines?

- ○ Yes
- ○ No
- ○ Don't know

66.a. Do you think it would be beneficial to introduce ACV guidelines, protocols or patient-specific guidelines in your hospital?

- ○ Yes
- ○ No
- ○ Don't know

66.a.i. Why do you think it would be beneficial? (select all that apply)

- ☐ provide clarity on approach to ACV
- ☐ ensure evidenced based practice
- ☐ maximise safety
- ☐ minimise risk
- ☐ improve quality
- ☐ improve outcomes
- ☐ ensure competence of staff involved in ACV
- ☐ reduce variation in practice
- ☐ ensures patients receive ACV more regularly
- ☐ don't know
- ☐ Other

66.a.i.a. If you selected Other, please specify:

Your opinion of ACV

67. How beneficial are these ACV guidelines, protocols or patient-specific guidelines?

- ○ Extremely
- ○ Very
- ○ Moderately
- ○ Slightly
- ○ Not at all

67.a. Why do you think they are beneficial? (select all that apply)

- ☐ provide clarity on approach to ACV
- ☐ ensure evidenced based practice
- ☐ maximise safety
- ☐ minimise risk
- ☐ improve quality
- ☐ improve outcomes
- ☐ ensure competence of staff involved in ACV
- ☐ reduce variation in practice
- ☐ ensures patients receive ACV more regularly
- ☐ Other

67.a.i. If you selected Other, please specify:

Your opinion on ACV

68. Do you think staff should receive training to assess for ACV and/or deliver ACV treatment?

	Yes	No
to assess for ACV	○	○
to deliver ACV treatment	○	○

69. Which professional group(s) do you think are best placed to carry out assessments for ACV? (select all that apply)

- ☐ Advanced Critical Care Practitioner
- ☐ Doctor
- ☐ Health Care Assistant
- ☐ Nurse
- ☐ Occupational Therapist
- ☐ Physiotherapist
- ☐ Psychologist
- ☐ Speech and Language Therapist
- ☐ Don't know
- ☐ Other

69.a. If you selected Other, please specify:

70. Why do you think this professional group(s) is best placed to carry out assessments for ACV?

71. Do you think competencies are needed for staff who assess patients for ACV?

- ○ Yes
- ○ No
- ○ Don't know

71.a. Why do you think competencies are needed for staff who assess patients for ACV? (select all that apply)

- [ ] ensure consistency of approach
- [ ] maximise safety
- [ ] minimise risk
- [ ] improve quality
- [ ] improve outcomes
- [ ] reduce variation in practice
- [ ] don't know
- [ ] Other

71.a.i. If you selected Other, please specify:

71.a.ii. How important is it for each of the following elements to be included in competencies for staff assessing patients for ACV? (rate each item)

	Rate importance				
	Not important	Slightly important	Moderately important	Important	Very important
completed reading of ACV literature	○	○	○	○	○
knowledge of indications and contraindications for ACV	○	○	○	○	○
knowledge of process of ACV	○	○	○	○	○
knowledge of different types of airflow delivery and associated risks	○	○	○	○	○
knowledge of complications of ACV and how to avoid/prevent them	○	○	○	○	○
knowledge of how to problem-solve and train patients to use ACV	○	○	○	○	○
knowledge of recommendations for ACV for handover	○	○	○	○	○
practical skills in delivering ACV	○	○	○	○	○
practical skills in assessing for ACV	○	○	○	○	○
practical skills in avoiding/preventing ACV complications	○	○	○	○	○
practical skills in therapeutic approaches to support patients in ACV use	○	○	○	○	○
practical skills in assessment of voice, cough, swallow with ACV	○	○	○	○	○
practical skills in training others in ACV delivery	○	○	○	○	○

Your opinion of ACV

72. Do you think competencies are needed for staff who deliver ACV treatment?

- ○ Yes
- ○ No
- ○ Don't know

72.a. Why do you think competencies are needed for staff who deliver ACV treatment? (select all that apply)

- ☐ ensure consistency of approach
- ☐ maximise safety
- ☐ minimise risk
- ☐ improve quality
- ☐ improve outcomes
- ☐ reduce variation in practice
- ☐ don't know
- ☐ Other

72.a.i. If you selected Other, please specify:

72.a.ii. How important is it for each of the following elements to be included in competencies for delivering ACV treatment? (rate each item)

	Rate importance				
	Not important	Slightly important	Moderately important	Important	Very important
completed reading of ACV literature	○	○	○	○	○
knowledge of indications and contraindications for ACV	○	○	○	○	○
knowledge of process of ACV	○	○	○	○	○
knowledge of different types of airflow delivery and associated risks	○	○	○	○	○
knowledge of complications of ACV and how to avoid/prevent them	○	○	○	○	○
knowledge of how to problem-solve and train patients to use ACV	○	○	○	○	○
knowledge of recommendations for ACV for handover	○	○	○	○	○
practical skills in delivering ACV	○	○	○	○	○
practical skills in assessing for ACV	○	○	○	○	○
practical skills in avoiding/preventing ACV complications	○	○	○	○	○
practical skills in therapeutic approaches to support patients in ACV use	○	○	○	○	○
practical skills in assessment of voice, cough, swallow with ACV	○	○	○	○	○
practical skills in training others in ACV delivery	○	○	○	○	○

Barriers to ACV use

73. How much of a barrier are the following factors to ACV being used in your hospital? (rate each factor)

	Rate each factor			
	Not a barrier	Somewhat of a barrier	Moderate barrier	Extreme barrier
lack of evidence to support its use	○	○	○	○
lack of evidence to support its effectiveness	○	○	○	○
lack of evidence to support safety	○	○	○	○
lack of evidence/guidance to support how ACV should be implemented	○	○	○	○
lack of access to SLT	○	○	○	○
lack of access to Fibreoptic Endoscopic Evaluation of Swallowing	○	○	○	○
lack of time to implement	○	○	○	○
belief that it is not beneficial to patients	○	○	○	○
not using tracheostomy tubes with sub-glottic port	○	○	○	○
cost of delivering ACV	○	○	○	○
lack of access to staff with knowledge to implement	○	○	○	○
lack of access to training	○	○	○	○
difficulty maintaining skills of staff	○	○	○	○
lack of time to train staff	○	○	○	○
lack of appropriate patients	○	○	○	○
tracheostomy cuff deflated early and no need for ACV	○	○	○	○

Final comments

74. Do you have any other comments about ACV?

Request for further involvement

We would like to carry out telephone/Skype interviews to further explore this topic with some individuals.

75. If you would be willing to participate in a telephone/Skype interview (approximately 30 minutes in duration) please provide your email below:

Your email address will only be used for the purposes of providing you with a Participant Information Sheet and Consent Form, and to arrange a convenient time for the interview, it will be deleted following completion of this project.

Final page

Thank you for taking the time to complete this survey.

Appendix C List of professional networks and societies that disseminated the survey

Association of Chartered Physiotherapists in Respiratory Care

British Association of Critical Care Nurses

Critical Care Leadership Forum

European Society for Swallowing Disorders

ICU Recovery Network

Intensive Care Society

Members of Special Interest Group 3 and 13, American Speech-Language-Hearing Association

National Institute for Health Research Critical Care Specialty Group

Royal College of Speech and Language Therapists

Royal College of Speech and Language Therapists Tracheostomy Clinical Excellence Network

Scottish Intensive Care Society

Speech Language and Audiology Canada

UK Allied Health Professional and Nurses Network for Critical Care Research

UK Critical Care Nursing Alliance

UK Critical Care Research Forum

World Federation of Critical Care Nurses

Welsh Intensive Care Society

Appendix D Topic Guide

Title	**The ACoUSTiC Study – Exploring the potential benefits of Above CUff VocaliSation in TraCheostomy**
Version	4.0
Date	24 February 2021
REC No.	18-037

The Leeds Teaching Hospitals NHS
NHS Trust

UNIVERSITY OF LEEDS

Interview Topic Guide

Introduction [suggested dialogue]:

- Introduce self
- Thank you for completing the online survey and for agreeing to discuss your experience and opinions of using Above Cuff Vocalisation (ACV). Your input is vital to explore how ACV is being used and to develop an ACV treatment protocol for a feasibility study.
- This discussion should take approximately 30 minutes and if at any time you need a break, please let me know.
- If there is anything that you would rather not answer, please let me know.
- The session is being audio-recorded for the sole purpose of producing a transcript of the discussion for analysis. The only people who will listen to the recording will be members of the research team and the transcriber. The recording will be downloaded onto a secure computer and erased from the audio-recorder.
- All the information that you provide will remain confidential and you will not be identifiable in any reports, papers or other outputs from this study
- Do you have any questions before I switch on the recorder and begin?

SWITCH ON THE AUDIO-RECORDER

These are a list of suggested topics and questions that may prompt discussion. However, participants will be encouraged to speak openly and freely about their experiences and opinions of ACV.

Elicit information about professional background, number of years practicing, brand of tracheostomy used etc

Questions:

- **Can you tell me about your experience of using ACV?**
  - Prompts: different experiences/problems encountered/what type of patients/barriers to use/laryngeal drying
- **Can you tell me a bit about how ACV is managed in your setting?**
  - Prompts: training/monitoring/competencies/who does assessments/use of protocols/complications /approaches
- **How do you feel about using ACV?**
  - Prompts: confidence/consensus across setting in use/negatives/benefits/evidence
- **Would you recommend it as an intervention?**
  - Prompts: colleagues/patients/family members
- **Do you think ACV has an impact on length of stay?**
  - Prompts: positive/negative

- **What impact has COVID-19 had on ACV use in your setting?**
    - Prompts: plans to restart/altered opinion of ACV

- **What needs to happen next with ACV?**
    - Prompts: in your setting/research

Closing:

- Is there anything else that you'd like to add?
- Thank you for time and participating in this study.
- Would you be happy for me to contact you again if I have any further questions?
- If you would like a summary of the interviews conducted, or the full study findings when it is completed, please let me know

Appendix E Search Strategy and Results for Health Economic Modelling in Tracheostomy, Decannulation, and Extubation

Ovid MEDLINE(R) all <1946 to March 08, 2021

1 Tracheostomy/ (7796)

2 Tracheotomy/ (8442)

3 Intubation, intratracheal/ (36753)

4 Airway extubation/ (1716)

5 (Tracheotom* or tracheostom*).tw. (20987)

6 endotracheal.tw. (21765)

7 intubat*.tw. (58649)

8 (extubat* or decannulat*).tw. (16616)

9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 (111166)

10 models, economic/ or models, econometric/ (15465)

11 markov chain/ (14817)

12 decision trees/ (11431)

13 decision support techniques/ (20975)

14 value-based purchasing/ (889)

15 microsimulat*.tw. (1354)

16 (patient level adj8 simulat*).tw. (139)

17 (simulat* adj3 model*).tw. and decision*.mp. (2798)

18 (discrete event* adj5 simulat*).tw. (852)

19 (discrete event* adj8 model*).tw. (701)

20 (decision* adj5 model*).tw. (17761)

21 (model* adj5 markov*).tw. (15832)

22 ((econom* or cost or costs) adj6 model*).tw. (27448)

23 "state transition model*".tw. (609)

24 ("transition probabilit*" and (state or states or model*)).tw. (2503)

25 "value of information".tw. (1234)

26 "health state*".tw. (6836)

27 ("disease state*" and (econom* or cost* or qaly* or utilit*)).tw. (1750)

28 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 (108191)

29 9 and 28 (314)

Database and Dates covered	**Date searched**	**Hits**
Ovid MEDLINE(R) all <1946 to March 08, 2021	09/03/2021	314
Embase Classic+Embase <1947 to 2021 March 12>	15/03/2021	442
CINAHL Tuesday, March 09, 2021 11:34:36 AM	09/03/2021	121
EconLit Wednesday, March 10, 2021 4:40:26 AM	10/03/2021	1
Web of science	10/03/2021	546
NHS EED CRD assessed economic evaluation (bibliographic and full abstract) & HTA in progress and published	15/03/2021	350
	Total	**1774**

Appendix F Search Strategy and Results for Parameters for the Health Economic Model

Tracheostomy weaning and costs

Ovid MEDLINE(R) ALL <1946 to February 14, 2023>

1 tracheostomy/ 8684

2 tracheotomy/ 8576

3 (Tracheotom* or tracheostom*).tw,kf.23859

4 1 or 2 or 3 [Trache] 29424

5 device removal/ 14853

6 airway extubation/ 2297

7 decannulat*.tw,kf. 3000

8 ventilator weaning/ 4389

9 wean*.tw,kf. 55799

10 extubat*.tw,kf. 16441

11 or/5-10 [weaning] 88448

12 4 and 11 [Trache and weaning] 3627

13 exp "Costs and Cost Analysis"/ 262740

14 (econom* or cost*).tw,kf. 1076727

15 13 or 14 [economic terms] 1177317

16 12 and 15 [trache weaning costs] 199

17 Deglutition/ 11373

18 cough/ 18284

19 ((cough* or airway*) adj3 (impair* or disorder* or reduc* or weak*)).tw,kf. 8103

20 Airway protect*.tw,kf. 1039

21 dystus*.tw,kf. 23

22 ((ICU* or intensive care or critical care) adj3 (re-admission or readmission or readmit*)).tw,kf. 904

23 (fail* adj3 decannulat*).tw,kf. 131

24 ((re-insert* or reinsert* or recannulat* or re-cannulat*) adj3 tracheostom*).tw,kf. 11

25 Deglutition Disorders/ 23396

26 dysphag*.tw,kf. 34284

27 (swallow* adj3 (impair* or disorder* or reduc* or difficult*)).tw,kf. 6981

28 deglutition.tw,kf. 4892

29 or/17-28 [other issues] 80949

30 12 and 29 [trache weaning and other issues] 431

31 16 or 30 [trache weaning/costs or trache weaning/issues] 604

32 (exp Child/ or Adolescent/ or exp Infant/) not exp Adult/ 2110530

33 (extracorporeal or extra corporeal or ECMO).tw,kf. 50212

34 32 or 33 2153788

35 31 not 34 454

36 limit 35 to yr="2002 -Current" 390

Quality Adjusted Life-Years and tracheostomy in the ICU

Ovid MEDLINE(R) ALL <1946 to February 14, 2023>

1 Tracheostomy/ (8684)

2 Tracheotomy/ (8576)

3 (Tracheotom* or tracheostom*).tw,kf. (23859)

4 1 or 2 or 3 [trache] (29424)

5 Critical Care/ (59677)

6 (intensive care or critical care).tw,kf. (214692)

7 exp Intensive Care Units/ (103670)

8 or/5-7 [ICU] (270275)

9 4 and 8 [trache patients ICU] (4148)

10 Quality-Adjusted Life Years/ (15425)

11 (quality adjusted or adjusted life year$).tw,kf. (22465)

12 (qaly$ or qald$ or qale$ or qtime$).tw,kf. (14090)

13 (illness state$1 or health state$1).tw,kf. (8122)

14 (hui or hui1 or hui2 or hui3).tw,kf. (1914)

15 (multiattribute$ or multi attribute$).tw,kf. (1262)

16 (utility adj3 (score$1 or valu$ or health$ or cost$ or measur$ or disease$ or mean or gain or gains or index$)).tw,kf. (19431)

17 utilities.tw,kf. (9093)

18 (eq-5d or eq5d or eq-5 or eq5 or euro qual or euroqual or euro qual5d or euroqual5d or euro qol or euroqol or euro qol5d or euroqol5d or euro quol or euroquol or euro quol5d or euroquol5d or eur qol or eurqol or eur qol5d or eur qol5d or eur?qul or eur?qul5d or euro$ quality of life or european qol).tw,kf. (16528)

19 (euro$ adj3 (5 d or 5d or 5 dimension$ or 5dimension$ or 5 domain$ or 5domain$)).tw,kf. (5734)

20 (sf36$ or sf 36$ or sf thirtysix or sf thirty six).tw,kf. (26032)

21 (time trade off$1 or time tradeoff$1 or tto or timetradeoff$1).tw,kf. (2316)

22 Disability-Adjusted Life Years/ (165)

23 (DALY? or disability adjusted life year$).tw,kf. (5733)

24 Healthy Life Expectancy/ (46)

25 (HALY? or health adjusted life year$).tw,kf. (688)

26 (sf20$ or sf 20$ or sf twenty).tw,kf. (432)

27 (sf12$ or sf 12$ or sf twelve).tw,kf. (6691)

28 (sf8$ or sf 8$ or sf eight).tw,kf. (747)

29 "health-related quality of life".tw,kf. (57435)

30 (HRqol or HR-QoL or HRQL or HR QL).tw,kf. (26948)

31 or/10-30 [QALY] (139769)

32 9 and 31 [QALYs trache patients ICU] (35)

33 (cardiac or coronary or heart).tw,kf. (1610447)

34 Coronary Care Units/ (4489)

35 33 or 34 [cardiac] (1611748)

36 8 and 31 and 35 [Cardiac ICU QALY] (238)

37 (exp Child/ or Adolescent/ or exp Infant/) not exp Adult/ (2110530)

38 (extracorporeal or extra corporeal or ECMO).tw,kf. (50212)

39 37 or 38 (2153788)

40 32 or 36 [Cardiac ICU QALY or QALYs trache patients ICU] (271)

41 40 not 39 (228)

42 limit 41 to yr="2002 -Current" (208)

Quality-Adjusted Life-Years and dysphagia in the ICU

Database: Ovid MEDLINE(R) ALL <1946 to February 14, 2023>

1 Cough/ (18284)

2 ((cough* or airway*) adj3 (impair* or disorder* or reduc* or weak*)).tw,kf. (8103)

3 airway protect*.tw,kf. (1039)

4 dystus*.tw,kf. (23)

5 (fail* adj3 decannulat*).tw,kf. (131)

6 ((re-insert* or reinsert* or recannulat* or re-cannulat*) adj3 tracheostom*).tw,kf. (11)

7 ((ICU* or intensive care or critical care) adj3 (re-admission or readmission or readmit*)).tw,kf. (904)

8 Deglutition Disorders/ (23396)

9 (dysphag* or oropharyngeal dysphag*).tw,kf. (34284)

10 (swallow* adj3 (impair* or disorder* or reduc* or difficult*)).tw,kf. (6981)

11 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 [cough or dysphagia] (73701)

12 Quality-Adjusted Life Years/ (15425)

13 (quality adjusted or adjusted life year$).tw,kf. (22465)

14 (qaly$ or qald$ or qale$ or qtime$).tw,kf. (14090)

15 (illness state$1 or health state$1).tw,kf. (8122)

16 (hui or hui1 or hui2 or hui3).tw,kf. (1914)

17 (multiattribute$ or multi attribute$).tw,kf. (1262)

18 (utility adj3 (score$1 or valu$ or health$ or cost$ or measur$ or disease$ or mean or gain or gains or index$)).tw,kf. (19431)

19 utilities.tw,kf. (9093)

20 (eq-5d or eq5d or eq-5 or eq5 or euro qual or euroqual or euro qual5d or euroqual5d or euro qol or euroqol or euro qol5d or euroqol5d or euro quol or euroquol or euro quol5d or euroquol5d or eur qol or eurqol or eur qol5d or eur qol5d or eur?qul or eur?qul5d or euro$ quality of life or european qol).tw,kf. (16528)

21 (euro$ adj3 (5 d or 5d or 5 dimension$ or 5dimension$ or 5 domain$ or 5domain$)).tw,kf. (5734)

22 (sf36$ or sf 36$ or sf thirtysix or sf thirty six).tw,kf. (26032)

23 (time trade off$1 or time tradeoff$1 or tto or timetradeoff$1).tw,kf. (2316)

24 Disability-Adjusted Life Years/ (165)

25 (DALY? or disability adjusted life year$).tw,kf. (5733)

26 Healthy Life Expectancy/ (46)

27 (HALY? or health adjusted life year$).tw,kf. (688)

28 (sf20$ or sf 20$ or sf twenty).tw,kf. (432)

29 (sf12$ or sf 12$ or sf twelve).tw,kf. (6691)

30 (sf8$ or sf 8$ or sf eight).tw,kf. (747)

31 "health-related quality of life".tw,kf. (57435)

32 (HRqol or HR-QoL or HRQL or HR QL).tw,kf. (26948)

33 or/12-32 [QALY] (139769)

34 Critical Care/ (59677)

35 (intensive care or critical care).tw,kf. (214692)

36 exp Intensive Care Units/ (103670)

37 34 or 35 or 36 [ICU] (270275)

38 Coronary Care Units/ (4489)

39 (cardiac or coronary or heart).tw,kf. (1610447)

40 38 or 39 [cardiac] (1611748)

41 40 or 37 [cardiac or ICU patients] (1841094)

42 11 and 33 and 41 [QALYs in cardiac or ICU patients with dysphagia or dystussia] (30)

43 (exp Child/ or Adolescent/ or exp Infant/) not exp Adult/ (2110530)

44 (extracorporeal or extra corporeal or ECMO).tw,kf. (50212)

45 43 or 44 (2153788)

46 42 not 45 [QALYs in cardiac and ICU patients with dysphagia and dystussia excl paeds and ECMO] (26)

47 limit 46 to yr="2002-Current" (26)

Quality-Adjusted Life-Years in the ICU

Ovid MEDLINE(R) ALL <1946 to February 20, 2023>

1 (exp Child/ or Adolescent/ or exp Infant/) not exp Adult/ 2110824

2 (extracorporeal or extra corporeal or ECMO).tw,kf. 50278

3 1 or 2 2154142

4 *Critical Care/ 34635

5 (intensive care or critical care).ti. 63306

6 exp *Intensive Care Units/ 44000

7 4 or 5 or 6 [ICU] 100366

8 Quality-Adjusted Life Years/ 15424

9 (quality adjusted or adjusted life year*).tw,kf.22471

10 (qaly* or qald* or qale* or qtime*).tw,kf. 14097

11 (eq-5d or eq5d or eq-5 or eq5 or euro qual or euroqual or euro qual5d or euroqual5d or euro qol or euroqol or euro qol5d or euroqol5d or euro quol or euroquol or euro quol5d or euroquol5d or eur qol or eurqol or eur qol5d or eur qol5d or eur?qul or eur?qul5d or euro$ quality of life or european qol).tw,kf. 16534

12 (euro* adj3 (5 d or 5d or 5 dimension* or 5dimension* or 5 domain* or 5domain*)).tw,kf. 5745

13 8 or 9 or 10 or 11 or 12 [qaly] 42796

14 7 and 13 266

15 14 not 3 242

16 limit 15 to yr="2002 -Current" 222

Database and Dates covered	**Date searched**	**Concept search strategy**	**Hits**
Ovid MEDLINE(R) all <1946 to March 08, 2021	15/02/2023	Tracheostomy weaning and costs; QALY and tracheostomy in the ICU; QALY and dysphagia in the ICU; QALY in the ICU	846
Embase Classic+Embase (Ovid) <1947 to 2021 March 12>	15/02/2023	Tracheostomy weaning and costs; QALY and tracheostomy in the ICU; QALY and dysphagia in the ICU; QALY in the ICU	1,464
# Web of Science Search Strategy (v0.1) # Database: Web of Science Core Collection	15/02/2023	Tracheostomy weaning and costs; QALY and tracheostomy in the ICU; QALY and dysphagia in the ICU; QALY in the ICU	895
International Network of Agencies for Health Technology Assessment (INAHTA)	28/02/2023	Tracheostomy weaning and costs; QALY and tracheostomy in the ICU; QALY and dysphagia in the ICU; QALY in the ICU	3
		Total	**3208**

Appendix G Expert Elicitation Survey Questions for SLTs

Background information

What is your profession?
- Doctor
- Nurse
- Speech and Language Therapist
- Physiotherapist

How many years have you worked in critical care?
- <1 year
- 1-5 years
- 6-10 years
- 10-15 years
- 15-20 years
- >20 years

Which specialty critical care units have you worked on?
- general
- cardiac
- neuro/neurosurgery
- burns
- spinal
- Other

If you selected Other, please specify:

Usual Care

Wait for instructions

What do you think is the lowest plausible percentage of patients in general ICU that would regress from 'tracheostomy and ventilator weaning' back to the 'tracheostomy maintenance' state?

What do you think is the highest plausible percentage of patients in general ICU that will regress back from 'tracheostomy and ventilator weaning' to 'tracheostomy maintenance'?

What is your best guess for the percentage of patients in general ICU that will regress from 'tracheostomy and ventilator weaning' to 'tracheostomy maintenance'?

How confident are you that your interval, from lowest to highest, captures the true value of the percentage of patients in general ICU that regress from 'tracheostomy and ventilator weaning' to 'tracheostomy maintenance' state? (Please enter a number between 50% and 100%)

What do you think are the top reasons for patients to regress back to the 'tracheostomy maintenance' state?

When patients regress back to 'tracheostomy maintenance', what do you think is the lowest plausible number of days that a patient in general ICU would spend in the

'tracheostomy maintenance' state before moving on to 'tracheostomy and ventilator weaning'?

When patients regress back to 'tracheostomy maintenance', what do you think is the highest plausible number of days that a patient in general ICU would spend in 'tracheostomy maintenance' before moving on to 'tracheostomy and ventilator weaning'?

What is your best guess for the number of days that a patient in general ICU would spend in 'tracheostomy maintenance' after regressing to this state, before moving onto 'tracheostomy and ventilator weaning'?

How confident are you that your interval, from lowest to highest, captures the true value of the number of days spent by patients in general ICU in the 'tracheostomy maintenance' state after regressing? (Please enter a number between 50% and 100%)

ACV - time in 'tracheostomy maintenance'
Wait for instructions

Do you think if patients receive ACV during 'tracheostomy maintenance' it will alter the time spent in the 'tracheostomy maintenance' state (e.g., by impacting saliva management/swallowing function/risk of VAP/communication function/use of sedatives/use of anti-psychotics)?

- Increase the time spent in 'tracheostomy maintenance'
- Reduce the time spent in 'tracheostomy maintenance'
- No effect on the time spent in 'tracheostomy maintenance

ACV - Increase the time spent in 'tracheostomy maintenance'
If yes, what is the lowest plausible number of days that the time spent in 'tracheostomy maintenance' would be increased by?

What do you think is the highest plausible number of days that the time spent in 'tracheostomy maintenance' would be increased by?

What is your best guess for the number of days that the time spent in 'tracheostomy maintenance' would be increased by?

How confident are you that your interval, from lowest to highest, captures the true value of the number of days that the time spent in 'tracheostomy maintenance' would be increased by? (Please enter a number between 50% and 100%)

ACV - Reduce the time spent in 'tracheostomy maintenance'
If yes, what is the lowest plausible number of days that the time spent in 'tracheostomy maintenance' would be reduced by?

What do you think is the highest plausible number of days that the time spent in 'tracheostomy maintenance' would be reduced by?

What is your best guess for the number of days that the time spent in 'tracheostomy maintenance' would be reduced by?

How confident are you that your interval, from lowest to highest, captures the true value of the number of days that the time spent in 'tracheostomy maintenance' would be reduced by? (Please enter a number between 50% and 100%)

ACV - time in 'tracheostomy and ventilator weaning'
Do you think if patients receive ACV during 'tracheostomy and ventilator weaning' it will alter the time spent in 'tracheostomy maintenance' state (e.g., by impacting saliva management/swallowing function/risk of VAP/communication function/use of sedatives/use of anti-psychotics)?

- Increase the time spent in 'tracheostomy and ventilator weaning'
- Reduce the time spent in 'tracheostomy and ventilator weaning'
- No effect on the time spent in 'tracheostomy and ventilator weaning'

ACV - Increase the time spent in 'tracheostomy and ventilator weaning'
If yes, what is the lowest plausible number of days that the time spent in 'tracheostomy and ventilator weaning' would be increased by?

What do you think is the highest plausible number of days that the time spent in 'tracheostomy and ventilator weaning' would be increased by?

What is your best guess for the number of days that the time spent in 'tracheostomy and ventilator weaning' would be increased by?

How confident are you that your interval, from lowest to highest, captures the true value of the number of days that the time spent in 'tracheostomy and ventilator weaning' would be increased by? (Please enter a number between 50% and 100%)

ACV - Reduce the time spent in 'tracheostomy and ventilator weaning'
If yes, what is the lowest plausible number of days that the time spent in 'tracheostomy and ventilator weaning' would be reduced by?

What do you think is the highest plausible number of days that the time spent in 'tracheostomy and ventilator weaning' would be reduced by?

What is your best guess for the number of days that the time spent in 'tracheostomy and ventilator weaning' would be reduced by?

How confident are you that your interval, from lowest to highest, captures the true value of the number of days that the time spent in 'tracheostomy and ventilator weaning' would be reduced by? (Please enter a number between 50% and 100%)

ACV - risk of regression
Wait for instructions

Balancing the potential for ACV to increase risk of some complications and reduce the risk of other complications, do you think that patients receiving ACV could have altered risk of regression back to 'tracheostomy maintenance' compared to usual care?

- Increase the risk of regression to 'tracheostomy maintenance'
- Reduce the risk of regression to 'tracheostomy maintenance'
- No effect on the risk of regression to 'tracheostomy maintenance'

ACV - Increase the risk of regression to 'tracheostomy maintenance'
What is the lowest plausible percentage increase in risk of regression to 'tracheostomy maintenance' for patients receiving ACV compared to usual care?

What is the highest plausible percentage increase in risk of regression to 'tracheostomy maintenance' for patients receiving ACV compared to usual care?

What is your best guess for the percentage increase in risk of regression to 'tracheostomy maintenance' for patients receiving ACV compared to usual care?

How confident are you that your interval, from lowest to highest, captures the true value of the percentage increase in risk of regression to 'tracheostomy maintenance' for patients receiving ACV compared to usual care? (Please enter a number between 50% and 100%)

ACV - Reduce the risk of regression to 'tracheostomy maintenance'
What is the lowest plausible percentage reduction in risk of regression to 'tracheostomy maintenance' for patients receiving ACV compared to usual care?

What is the highest plausible percentage reduction in risk of regression to 'tracheostomy maintenance' for patients receiving ACV compared to usual care?

What is your best guess for the percentage reduction in risk of regression to 'tracheostomy maintenance' for patients receiving ACV compared to usual care?

How confident are you that your interval, from lowest to highest, captures the true value of the percentage reduction in risk of regression to 'tracheostomy maintenance' for patients receiving ACV compared to usual care? (Please enter a number between 50% and 100%)

ACV - Percentage decannulation
Wait for instructions

Do you think that the percentage of patients decannulated will be impacted by ACV compared to usual care?

- reduce the percentage of patients decannulated
- increase the percentage of patients decannulated
- no effect on the percentage of patients decannulated

ACV - reduce the percentage decannulated
What do you think is the lowest plausible absolute percentage reduction of patients decannulated in general ICU because they have received ACV (e.g., the difference between the percentage of UC patients decannulated and the percentage of ACV patients decannulated)?

What do you think is the highest plausible absolute percentage reduction of patients decannulated in general ICU because they have received ACV?

What is your best guess for the absolute percentage reduction of patients decannulated in general ICU because they have received ACV?

How confident are you that your interval, from lowest to highest, captures the true value of the absolute percentage reduction of patients decannulated in general ICU because they have received ACV? (Please enter a number between 50% and 100%)

ACV - increase the percentage decannulated
What do you think is the lowest plausible absolute percentage increase of patients decannulated in general ICU because they have received ACV (e.g., the difference between the percentage of UC patients decannulated and the percentage of ACV patients decannulated)?

What do you think is the highest plausible absolute percentage increase of patients decannulated in general ICU because they have received ACV?

What is your best guess for the absolute percentage increase of patients decannulated in general ICU because they have received ACV?

How confident are you that your interval, from lowest to highest, captures the true value of the absolute percentage increase of patients decannulated in general ICU because they have received ACV? (Please enter a number between 50% and 100%)

ACV - mortality
Wait for instructions

Do you think that patients in general ICU receiving ACV will have an altered risk of death because they receive ACV (e.g. by increasing/reducing the risk of VAP or increasing/decreasing the risk of complications)?

- Reduced risk of mortality
- Increased risk of mortality
- No effect on risk of mortality

ACV - Reduce the risk of mortality
What is the lowest plausible percentage absolute risk reduction in mortality for patients receiving ACV compared to usual care because they receive ACV (e.g., the difference in risk of mortality between ACV and usual care)?

What is the highest plausible percentage absolute risk reduction in mortality for patients receiving ACV compared to usual care because they receive ACV?

What is your best guess for the percentage absolute risk reduction in mortality for patients receiving ACV compared to usual care because they receive ACV?

How confident are you that your interval, from lowest to highest, captures the true value of the percentage absolute risk reduction in mortality for patients receiving ACV compared to usual care because they receive ACV? (Please enter a number between 50% and 100%)

ACV - Increase the risk of mortality
What is the lowest plausible percentage absolute risk increase in mortality for patients receiving ACV compared to usual care because they receive ACV (e.g., the difference in risk of mortality between ACV and usual care)?

What is the highest plausible percentage absolute risk increase in mortality for patients receiving ACV compared to usual care because they receive ACV?

What is your best guess for the percentage absolute risk increase in mortality for patients receiving ACV compared to usual care because they receive ACV?

How confident are you that your interval, from lowest to highest, captures the true value of the percentage absolute risk increase in mortality for patients receiving ACV compared to usual care because they receive ACV? (Please enter a number between 50% and 100%)

ACV - dysphagia after decannulation
Wait for instructions

Do you think that patients in general ICU receiving ACV will have an altered risk of dysphagia after decannulation because of having received ACV?
- Reduced risk of dysphagia
- Increased risk of dysphagia
- No effect on risk of dysphagia

ACV - Reduce the risk of dysphagia
What is the lowest plausible percentage absolute risk reduction in dysphagia after decannulation for patients receiving ACV compared to usual care because of having received ACV (e.g., the difference in risk of dysphagia between ACV and usual care)?

What is the highest plausible percentage absolute risk reduction in dysphagia after decannulation for patients receiving ACV compared to usual care because of having received ACV?
What is your best guess for the percentage absolute risk reduction in dysphagia after decannulation for patients receiving ACV compared to usual care because of having received ACV?

How confident are you that your interval, from lowest to highest, captures the true value of the percentage absolute risk reduction in dysphagia after decannulation for patients receiving ACV compared to usual care because of having received ACV? (Please enter a number between 50% and 100%)

ACV - Increase the risk of dysphagia
What is the lowest plausible percentage absolute risk increase in dysphagia after decannulation for patients receiving ACV compared to usual care because of having received ACV (e.g., the difference in risk of dysphagia between ACV and usual care)?

What is the highest plausible percentage absolute risk increase in dysphagia after decannulation for patients receiving ACV compared to usual care because of having received ACV?

What is your best guess for the percentage absolute risk increase in dysphagia after decannulation for patients receiving ACV compared to usual care because of having received ACV?

How confident are you that your interval, from lowest to highest, captures the true value of the percentage absolute risk increase in dysphagia after decannulation for patients receiving ACV compared to usual care because of having received ACV? (Please enter a number between 50% and 100%)

ACV - dysphagia not decannulated
Wait for instructions

Do you think that patients in general ICU receiving ACV who were not decannulated will have an altered risk of dysphagia because of having received ACV?
- Reduced risk of dysphagia
- Increased risk of dysphagia
- No effect on risk of dysphagia

ACV - Reduce the risk of dysphagia in not decannulated
What is the lowest plausible percentage absolute risk reduction in dysphagia for patients receiving ACV who were not decannulated compared to usual care because of having received ACV (e.g., the difference in risk of dysphagia between ACV and usual care)?

What is the highest plausible percentage absolute risk reduction in dysphagia for patients receiving ACV who were not decannulated compared to usual care because of having received ACV?

What is your best guess for the percentage absolute risk reduction in dysphagia for patients receiving ACV who were not decannulated compared to usual care because of having received ACV?
How confident are you that your interval, from lowest to highest, captures the true value of the percentage absolute risk reduction in dysphagia for patients receiving

ACV who were not decannulated compared to usual care because of having received ACV? (Please enter a number between 50% and 100%)

ACV - Increase the risk of dysphagia
What is the lowest plausible percentage absolute risk increase in dysphagia for patients receiving ACV who were not decannulated compared to usual care because of having received ACV (e.g., the difference in risk of dysphagia between ACV and usual care)?

What is the highest plausible percentage absolute risk increase in dysphagia for patients receiving ACV who were not decannulated compared to usual care because of having received ACV?

What is your best guess for the percentage absolute risk increase in dysphagia for patients receiving ACV who were not decannulated compared to usual care because of having received ACV?

How confident are you that your interval, from lowest to highest, captures the true value of the percentage absolute risk increase in dysphagia for patients receiving ACV who were not decannulated compared to usual care because of having received ACV? (Please enter a number between 50% and 100%)

Final page
Thank you for taking part in this expert elicitation survey

Appendix H Expert Elicitation Survey Questions for Doctors and Nurses

Background information

What is your profession?
- Doctor
- Nurse
- Speech and Language Therapist
- Physiotherapist

How many years have you worked in critical care?
- <1 year
- 1-5 years
- 6-10 years
- 10-15 years
- 15-20 years
- >20 years

Which specialty critical care units have you worked on?
- general
- cardiac
- neuro/neurosurgery
- burns
- spinal
- Other

If you selected Other, please specify:

Usual Care

Wait for instructions

What do you think is the lowest plausible percentage of patients in general ICU that would regress from 'tracheostomy and ventilator weaning' back to the 'tracheostomy maintenance' state?

What do you think is the highest plausible percentage of patients in general ICU that will regress back from 'tracheostomy and ventilator weaning' to 'tracheostomy maintenance'?

What is your best guess for the percentage of patients in general ICU that will regress from 'tracheostomy and ventilator weaning' to 'tracheostomy maintenance'?

How confident are you that your interval, from lowest to highest, captures the true value of the percentage of patients in general ICU that regress from 'tracheostomy and ventilator weaning' to 'tracheostomy maintenance' state? (Please enter a number between 50% and 100%)

What do you think are the top reasons for patients to regress back to the 'tracheostomy maintenance' state?

When patients regress back to 'tracheostomy maintenance', what do you think is the lowest plausible number of days that a patient in general ICU would spend in the

'tracheostomy maintenance' state before moving on to 'tracheostomy and ventilator weaning'?

When patients regress back to 'tracheostomy maintenance', what do you think is the highest plausible number of days that a patient in general ICU would spend in 'tracheostomy maintenance' before moving on to 'tracheostomy and ventilator weaning'?

What is your best guess for the number of days that a patient in general ICU would spend in 'tracheostomy maintenance' after regressing to this state, before moving onto 'tracheostomy and ventilator weaning'?

How confident are you that your interval, from lowest to highest, captures the true value of the number of days spent by patients in general ICU in the 'tracheostomy maintenance' state after regressing? (Please enter a number between 50% and 100%)

Appendix I Expert Elicitation Survey Questions for the Patient representative

Quality of Life - Usual Care
Wait for instructions

What is the lowest plausible utility value that you think a patient would have who was in the 'tracheostomy maintenance' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'tracheostomy maintenance' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'tracheostomy maintenance' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'tracheostomy maintenance' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the lowest plausible utility value that you think a patient would have who was in the 'tracheostomy and ventilator weaning' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'tracheostomy and ventilator weaning' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'tracheostomy and ventilator weaning' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'tracheostomy and ventilator weaning' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the lowest plausible utility value that you think a patient would have who was in the 'decannulated' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'decannulated' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'decannulated' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'decannulated' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the lowest plausible utility value that you think a patient would have who was in the 'not decannulated' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'not decannulated' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'not decannulated' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'not decannulated' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the lowest plausible utility value that you think a patient would have who was in the 'decannulated, no swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'decannulated, no swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'decannulated, no swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'decannulated, no swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the lowest plausible utility value that you think a patient would have who was in the 'decannulated, with swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'decannulated, with swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'decannulated, with swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'decannulated, with swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the lowest plausible utility value that you think a patient would have who was in the 'not decannulated, no swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'not decannulated, no swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'not decannulated, no swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'not decannulated, no swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the lowest plausible utility value that you think a patient would have who was in the 'not decannulated, with swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'not decannulated, with swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'not decannulated, with swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'not decannulated, with swallowing issues' state? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

Quality of Life - Above Cuff Vocalisation
Wait for instructions

What is the lowest plausible utility value that you think a patient would have who was in the 'tracheostomy maintenance' state and receiving ACV? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'tracheostomy maintenance' state and receiving ACV? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'tracheostomy maintenance' state and receiving ACV? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'tracheostomy maintenance' state and receiving ACV? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the lowest plausible utility value that you think a patient would have who was in the 'tracheostomy and ventilator weaning' state and receiving ACV? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is the highest plausible utility value that you think a patient would have who was in the 'tracheostomy and ventilator weaning' state and receiving ACV? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

What is your best guess for the utility value that you think a patient would have who was in the 'tracheostomy and ventilator weaning' state and receiving ACV? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

How confident are you that your interval, from lowest to highest, captures the true value of the utility value that a patient would have who was in the 'tracheostomy and ventilator weaning' state and receiving ACV? [This should be a number between -0.594 (worse than dead) and 1(perfect health)]

Final page

Thank you for taking part in this expert elicitation survey