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ECONOMIC EVALUATION OF HEALTH INTERVENTIONS

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An Early-Stage Decision-Analytic Health Economic Model of Above Cuff Vocalization: What Do We Know and What Do We Need to Resolve?

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OBJECTIVES: Above cuff vocalization (ACV) is used in patients with a tracheostomy in the ICU despite limited evidence. This early-stage decision-analytic model (DAM) for ACV evaluates the expected cost-effectiveness exploring the impact of uncertainty to identify key drivers of cost and effect and critical further research priorities.

PERSPECTIVE: U.K. National Health Service.

SETTING: Hypothetical cohort of general ICU patients with a tracheostomy, 63 years old, 64% male.

METHODS: A de novo decision-analytic health economic model comparing ACV to usual care (UC). Model parameters were acquired from the literature review and expert opinion. One-way sensitivity analyses were conducted to identify key drivers of cost-effectiveness.

RESULTS: The daily cost of ACV in the ICU ranged from £75 to 89 (USD 101–120), with most of this cost attributable to staff resources for delivery. The base-case scenario revealed ACV is potentially cost-effective, dominating UC with cost savings of £9,488 (USD 12,808) and 0.395 Quality-Adjusted Life Years gained. Most sensitivity analyses revealed that ACV dominated UC, costing less and being more effective. When ACV had a negative impact on ICU and ward length of stay (LoS), or had no effect on the speed of weaning, it was not cost-effective. The primary driver of cost was whether ACV affected the speed of weaning and ICU LoS. The two primary drivers of effect were: i) whether ACV impacted which end state a patient transitioned to and ii) whether ACV had a sustained positive impact on quality of life.

CONCLUSIONS: Despite the substantial input required from speech-language pathologists—a typically scarce resource in ICU settings—ACV demonstrates strong potential for cost-effectiveness. There is no reason for decision-makers to de-adopt ACV, and delaying adoption may result in loss of opportunity costs. Improved reporting of mortality and utility data in critical care research would increase the reliability of early-stage DAMs.

KEYWORDS: critical care; deglutition disorders; healthcare economics and organizations; quality of life; tracheostomy

Globally, approximately 250,000 tracheostomies are inserted annually (1). The impact of tracheostomy on patients in the ICU can be profound (2). An inflated tracheostomy cuff prevents airflow through the laryngopharynx preventing verbal communication and reducing laryngopharyngeal sensation, a crucial component of effective and safe swallowing. This can lead to severely reduced quality of life (QoL) (3, 4). Above cuff vocalization (ACV), the application of an external airflow via the subglottic port, is

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KEY POINTS

Question: This study evaluated the cost-effectiveness of the above cuff vocalization for the first time.

Findings: This early-stage decision-analytic health economic model demonstrates that above cuff vocalization is potentially cost-effective.

Meaning: There is no reason for decision-makers to de-adopt above cuff vocalization and delaying adoption may result in loss of opportunity costs.

one potential option to reestablish laryngopharyngeal airflow, facilitate vocalization, and improve swallowing (5, 6). A recent systematic review highlighted the limited and low-quality evidence available for ACV (6, 7), and a survey reported low uptake (8). There is a lack of cost-effectiveness evaluation (5, 6) which could support decision-makers to make informed choices about whether to adopt ACV regardless of the quantity or quality of the evidence (9–11).

A decision-analytic model (DAM) is a mathematical framework used to estimate the consequences of healthcare decisions in terms of costs and effects (12). DAMs can support decision-making for interventions even where data are limited and there is uncertainty associated with outcomes (13, 14). Early-stage DAMs can help to reduce the risks associated with early adoption of an intervention in the context of limited and uncertain evidence (14). Arguably, the most important reason for early-stage DAM is to identify critical evidence gaps and the key drivers of cost-effectiveness to direct future research (14). Early-stage models can provide a foundation and direction for future robust modeling once more evidence is generated, ensuring research funding is directed appropriately and used efficiently (15, 16). We developed an early-stage DAM for ACV and evaluated the expected cost-effectiveness exploring uncertainty in sensitivity analyses to identify information gaps, inform adoption decisions, and direct future research.

MATERIALS AND METHODS

Ethical approval was not required as the study did not fall under the board's guidelines for human subjects research. Model parameters were obtained from the research literature and expert opinion. This analysis followed the National Institute for Health and Clinical Excellence (NICE) recommendations for undertaking cost-effectiveness analyses for technology appraisals (17) and is reported according to the Consolidated Health Economic Evaluating Reporting Standards statement (**Appendix 1**, https://links.lww.com/CCX/B579) (18).

Model Design

A rapid review identified no models suitable for use or adaptation (**Appendix 2**, https://links.lww.com/CCX/B579). Therefore, a de novo model was developed and refined through multiple iterations from feedback and input from experts.

Model Structure

A lifetime perspective was deemed appropriate, with the model broken down into short-, medium-, and long-term components. The complex model structure was required to incorporate the complexity of the tracheostomy weaning pathway from the ICU to death and pragmatically incorporate the limited but focused data available (**Fig. 1**).

The "tracheostomy and ventilator weaning" state included either or both of tracheostomy weaning (i.e., cuff deflation) and ventilatory weaning (i.e., reducing ventilatory support). The model commenced 72 hours after tracheostomy insertion, with a lifetime horizon. Cycle length was 1 day for the initial Markov model and one year for the final Markov model. A half-cycle correction—where adjustments are made to allow for patients who may transit partway 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, reflecting the current U.K. National Health Service (NHS) system of charging full ICU days no matter the time of ICU discharge. Various model assumptions were made (**Appendix 3**, https://links.lww.com/CCX/B579).

Patient Cohort

Patients included were those with a tracheostomy in the general ICU in the NHS, 63 years old, and 64% male. These figures were derived from key papers contributing to the model (19–24). Although the

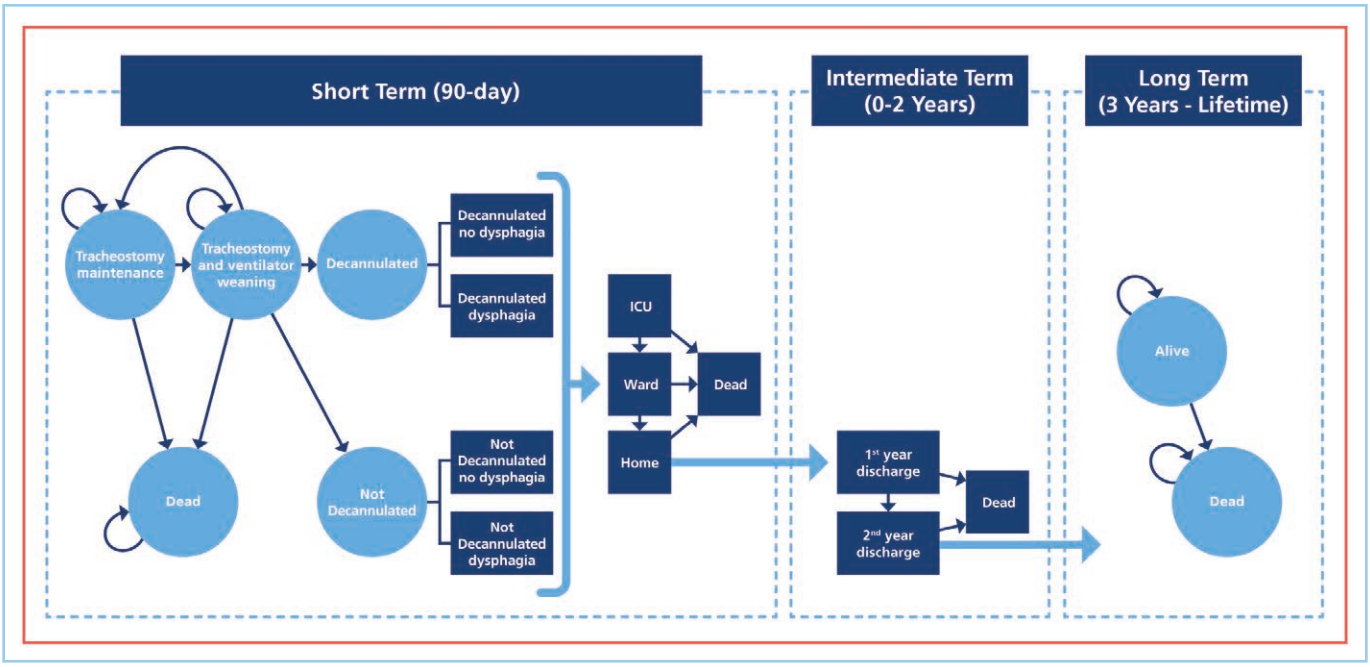

Figure 1. Decision-analytic model for above cuff vocalization illustrating the three stages of the model. 1) An initial Markov model—mapping the tracheostomy pathway from 72 hr after insertion to "decannulated" or "not decannulated" in the ICU; 2) A decision tree—mapping four end states in the ICU, the ward, and in the first two years after discharge from the hospital; and 3) A final Markov model—tracking potential outcomes for these end states until death. The Markov portions of the model have circular states, and the decision tree portion of the model has rectangular states.

model included hypothetical NHS patients, research from all countries was considered for model parameters, and this model is applicable to all healthcare perspectives (25).

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 included speech and language therapy support for communication, patients being nil-by-mouth when the tracheostomy cuff was inflated, and the potential for oral intake when actively weaning and having periods of cuff deflation (**Appendix 4**, https://links.lww.com/CCX/B579). Patients in the ACV cohort received a defined ACV intervention, developed from the evidence (6, 8), in both the "tracheostomy maintenance" and the "tracheostomy and ventilator weaning" states, in addition to UC (Appendix 4, https://links.lww.com/CCX/B579).

Parameter Acquisition

Parameters were acquired from the ACV systematic review (6) and a further rapid review (**Appendix 5**, https://links.lww.com/CCX/B579). Parameters included transition probabilities, utilities (Quality-Adjusted Life Years [QALYs]), and costs (healthcare costs until death), in line with NICE guidance (17). Where there was a lack of, or conflicting, evidence, expert opinion was elicited through structured, individual, online surveys (26–28) (**Appendix 6**, https://links.lww.com/CCX/B579). Resource use was obtained from the literature and a range of NHS sources (29) (**Appendix 7**, https://links.lww.com/CCX/B579).

Data Analysis and Reporting

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 (C.B.) checking the model. The cost of the intervention was calculated from staff and equipment resources required, and comparisons were made between speech-language pathologist (SLP) and nurse-delivered vs entirely SLP-delivered. For UC and ACV, QALYs, cost, incremental cost-effectiveness ratio, incremental net monetary benefit, and the incremental net health benefit (30) are

reported. The incremental cost for ACV is reported, and the difference in QALYs between ACV and UC is reported. An additional focus of the analysis was the univariate sensitivity analysis to identify key evidence gaps.

Sensitivity Analyses

One-way sensitivity analyses were conducted to evaluate the critical determinants for cost-effectiveness and identify key structural uncertainties in the model (31). These included sensitivity analysis of: 1) the effectiveness of ACV, 2) ICU costs, and 3) long-term outcomes after ACV.

RESULTS

Study Parameters

Study parameters were gathered from a range of critical care and dysphagia studies with variable quality of data reporting. Many 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 base-case estimates and the ranges used for sensitivity analyses included transition and survival probabilities, utilities, and resource unit costs (**Appendices 7**, **8**, and **9**, respectively, https://links.lww.com/CCX/B579). Other key model parameters are reported in **Appendix 10**, https://links.lww.com/CCX/B579.

Cost-effectiveness of ACV

The daily cost of ACV in the ICU was calculated at £75–£89 (USD 101–120), dependent on which staff group delivered the intervention and the frequency of consumable replacement. Patients receiving ACV transitioned through the first Markov model more quickly than those receiving UC in the base-case scenario, with a greater proportion of patients ending up in the optimal "decannulated-no dysphagia" state. Analysis revealed that ACV is potentially cost-effective, dominating UC with cost savings of £9,488.16 (USD 12,808) and 0.395 QALYs gained overall (**Table 1**).

Sensitivity Analyses

The findings for all sensitivity analyses compared with the base-case results are reported in **Appendix 11** (https://links.lww.com/CCX/B579); the parameter alterations are described in **Appendix 12** (https://links.lww.com/CCX/B579). Most of these analyses revealed that ACV continues to dominate UC in the short-term stage and overall, but with a reduced overall cost-effectiveness or cost saving. However, sensitivity analyses 2 and 3 showed that ACV was not cost-effective, where ACV had a negative impact on the ICU and ward length of stay (LoS), and where ACV did not have any impact on speed of transition through the model, which resulted in no reduction in ICU LoS, respectively.

DISCUSSION

This research presents the structure, parametrization, and results of the first early-stage DAM evaluating ACV against UC in the context of U.K. critically ill patients in the general ICU. There has been limited use of DAMs in critical care research or anesthesia, and this is the first use of a DAM for any pediatric or adult speech and language therapy intervention (32). Potential reasons for this include: 1) the paucity of data and research efforts required to enable the estimation of probabilities and utilities, 2) the complex treatment processes in critical care making the DAM challenging to map, and 3) potential challenges in obtaining utilities from patients in the ICU (33).

This early-stage DAM, applying sensitivity analysis, identified some critical areas of uncertainty that have the most significant impact on cost-effectiveness and directs future research to reduce levels of uncertainty. It provides a starting point for future cost-effectiveness analysis, which should be developed as new evidence regarding ACV accrues.

Cost-Effectiveness of ACV

The base-case scenario indicated that ACV is potentially cost-effective overall. ACV is more effective and less costly than UC when considered during the lifetime of the model and during the first 90 days. However, during the model's intermediate and long-term stages, ACV costs more than UC yet is more effective. The findings suggest substantial cost savings, probably due to reduced ICU LoS during the first 90

TABLE 1.
Base-Case Scenario Cost-Effectiveness for Short Term, Intermediate Term, Long Term, and Total

Outcome	Usual Care	ACV	Difference (ACV-UC)	Base-Case Results
Short term (90 d)				
90-d costs	£77,850.52	£66,508.55	90-d difference in costs	−£11,341.97
90-d QALYs	0.047	0.075	90-d difference in QALYs	0.028
			90-d ICER	ACV dominates
			90-d INMB (£20,000 WTP threshold)	£11,903
			90-d INHB (£20,000 WTP threshold)	0.595
Intermediate term (1-2 yr)				
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 yr 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

ACV = above cuff vocalization, ICER = incremental cost-effectiveness ratio, INHB = incremental net health benefit, INMB = incremental net monetary benefit, QALY = Quality-Adjusted Life-Year, WTP = willingness-to-pay.

days of the model and considerable improvements to the QoL of patients over their lifetime.

Most of the QALYs are gained during the long-term stage of the model. This is 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, 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 deceased patients generating no costs. The extent of the cost savings during the short-term stage, combined with the increase in QALYs throughout, outweighs the increased costs associated with ACV during the later stages.

Sensitivity Analyses

Sensitivity Analysis of the Effectiveness of ACV. Sensitivity analyses indicate that even if the effectiveness of ACV in accelerating transition to decannulation is substantially less than estimated by experts, and even when ACV is equivalent to UC for some parameters, it could still be cost-effective. 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, though they are much reduced. 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 weaning, it could still be cost-effective, with reduced cost savings.

Two analyses (2 and 3) indicated that ACV was not cost-effective. Analysis 2 used data from a randomized controlled trial (RCT) reporting an increase in ICU and ward LoS for patients receiving ACV, 20- and 25-day, respectively (34). RCT data are usually prioritized over expert opinion in health economic evaluations, and typically this would be used in the base-case scenario. However, all clinical experts believed ACV would have a neutral or positive effect on LoS, and a qualitative study supported this (35). Furthermore, there were several factors that could explain the unexpected finding of increased LoS. Most importantly, 40% of the control group proceeded to cuff deflation trials, in contrast to 0% of the ACV group. Early cuff deflation (≤ 24 hr) has been shown to accelerate the tracheostomy weaning process compared with standard care (≥ 48 hr), although it did not reduce LoS (36). The ACV trial restricted cuff deflation for 5 days of treatment, which is neither standard practice nor the defined ACV intervention used in this model, and may have adversely affected LoS (34, 36). A decision was made to apply this increased LoS estimate in a sensitivity analysis rather than in the base-case scenario. Analysis revealed a significant impact on cost-effectiveness, with UC dominating and being less costly and more effective than ACV. Analysis 3 evaluated ACV as having no impact on the transition probabilities in the initial Markov model—that is, having no impact on the speed of tracheostomy weaning—which means there is no reduction in ICU LoS.

These analyses 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. The key transition probabilities appearing to have the most influence on cost-effectiveness are from "tracheostomy maintenance" to "tracheostomy and ventilator weaning" and from "tracheostomy and ventilator weaning" to "decannulated."

Sensitivity Analysis of ICU Costs. Sensitivity analyses 7 and 8 explored the impact of altering ICU cost on the cost-effectiveness of ACV, by adjusting the costs of states or by reducing the ICU LoS, respectively. The only data reporting ICU LoS after decannulation reported a median of 11 days in the ICU (20). However, this duration is not in keeping with the experience of the clinical experts, who 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 (20, 21, 23, 37). Both analyses revealed that ACV still dominated in the short-term stage and overall, and resulted in more cost savings compared with the base-case scenario. ICU costs are generally uncertain and variable, dependent on the level of organ support. Therefore, the costs chosen for the base-case scenario hold a high level of uncertainty. However, the findings 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.

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 focuses on the immediate positive effects of ACV (6). Analyses 9 and 10 explored the potential impact of ACV eliciting a long-term positive effect after delivery is stopped, with substantial QALYs added to patients in the intermediate and long-term stages of the model. The findings suggest that if ACV provides sustained utilities beyond immediate delivery (e.g., if ACV improves ICU experience, it may reduce the prevalence or severity of post-intensive care syndrome and post-traumatic stress disorder), it could increase cost-effectiveness.

Key Drivers of Cost-Effectiveness

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. A shorter period with a tracheostomy resulted in a shorter ICU LoS. Therefore, 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. First, 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; "decannulated" and "no dysphagia" states had higher utilities and lower costs associated with them. The second is whether ACV has a sustained positive impact on QoL after treatment completion.

Strengths and Limitations

The major limitations of this study relate to the limited and low-quality data available for the various model parameters. Data selected and incorporated into the model were not all specifically related to patients with a tracheostomy or general ICU patients. Some data required manipulation to make it usable (e.g., conversion of the Visual Analogue Score of the European Quality-of-life 5-dimensions (EQ-5D) to a utility value). The limited data available meant that it was not possible to produce parametric distributions, carry out probabilistic sensitivity analysis, or produce confidence ellipses to demonstrate the level of uncertainty. The potential impact of ACV on utilities is highly uncertain due to poor quality of the QoL data available for tracheostomized ICU patients and the limited data for the specific impact of ACV on QoL. This model includes patient expert-elicited utilities, which appear to be more genuinely reflective of patients' ICU experiences. 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 (> 6 yr previous). Nonetheless, the patient had a clear recollection of her greater than 6-month ICU stay and had strong confidence in their utility value ratings, ranging from 80 to 90% confidence, in comparison to the expert healthcare professionals, whose confidence in their ratings ranged from 40% to 90%. Eight healthcare professionals provided expert opinion for various model parameters, where published data were lacking. Four of these individuals were involved in this project, sitting on the study advisory group due to their expertise in the area, and this may have resulted in some bias. However, there were no clear differences between the values provided by those who were on the study advisory group compared with those who were not, and confidence ratings suggest individuals were transparent about the uncertainty in the values they provided. In addition, using a large pool of experts, as recommended, should help to reduce the impact of any individual bias (38).

One of the model's strengths is the lifetime horizon, which is best practice in health economic modeling, as it captures all the potential long-term consequences of ACV (38). However, the ACV research only evaluates the immediate effects, 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 hospital stay.

Clinical Implications

Given the level of structural and parameter uncertainty in this model, the findings 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 a cost-effective intervention, likely because of its relatively low resource costs. 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 (6, 8, 39). In this model, four 15-minute sessions per day were costed, based on the evidence available and expert consultation. When delivered up to 60 minutes daily, ACV is a relatively low-cost intervention, mostly comprising SLP staff costs associated with ACV delivery, review, and monitoring. Given the low cost of the intervention, even if the intervention time was doubled, it would probably have minimal effect on overall costs or cost-effectiveness. However, SLPs are typically a scarce resource in ICU settings in the United Kingdom (40), and this research may help to provide information for decision-makers to ensure this limited SLP resource is used to deliver interventions that represent the best value for money.

For those clinical services that have already adopted ACV in the ICU, the findings of this study are unlikely to result in the decision to de-adopt ACV. 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 (41,42). Given the low cost, adopting ACV while continuing research to provide further information about the cost-effectiveness appears reasonable, given the potential for loss of opportunity costs if the decision to adopt is delayed. In addition, ACV is an intervention that could be easily and quickly de-adopted should the evidence base change.

Research Implications

The one-way sensitivity analyses revealed the key drivers of uncertainty for cost and effect in the model. Future research should focus on reducing this uncertainty to provide a more comprehensive and robust cost-effectiveness analysis. Specifically, 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 (e.g., issues with transfer/discharge, delayed cuff deflation trials). Many of these other factors are mitigable, whereas if ACV adversely affects the speed of weaning, it is unlikely to be cost-effective. If ACV does not positively impact weaning, then cost-effectiveness will presumably depend on the extent of the QALYs provided in the short-, intermediate-, and long-term stages.

TABLE 2.
Recommendations to Reduce Uncertainty in Decision-Analytic Modeling in Critical Care Research

Issues With Critical Care Research	Recommendation to Reduce Uncertainty
Unclear mortality rates at different times and stages of the critical care and tracheostomy weaning pathway.	Where possible, studies should report breakdown of mortality rates at each stage of the tracheostomy weaning process.
Unclear mortality rates and quality of life for different types of patients, i.e., tracheostomized vs. non-tracheostomized; general ICU vs. specialist ICU.	Studies should report breakdown of mortality and quality of life for subgroups.
Limited utility data available for patients during ICU stay, with many studies assuming utilities at baseline. Where utilities are assumed at baseline, this typically adopts a value of 0 (quality-of-life equivalent to death) (43). Utilities are more plausibly negative in this population (quality of life worse than death) because patients are often immobile, unable to perform self-care, unable to carry out usual activities, endure severe or extreme pain and discomfort, and experience severe anxiety and depression. Expert elicitation in this study confirms this, with most of the utilities provided in the early stages of tracheostomy weaning having negative values.	Quality of life should be assessed at baseline. Where patients are unable to complete a questionnaire due to sedation or delirium, proxy measures should be completed by healthcare professionals or relatives (44, 45).
Utility data are typically only collected after ICU discharge.	Further research is needed to provide a reference set for the health-related quality of life of patients at different stages of the critical care pathway, as well as after ICU discharge.
Some studies do not use a validated quality-of-life measure that can be used to calculate utilities.	All studies should use a validated generic utility measure that can be used to calculate utilities, e.g., EQ-5D-5L (43) alongside any disease-specific quality-of-life measures.
Where health-related quality-of-life data are available, it is reported in a way that has limited use for early-stage decision-analytic modeling.	Means of raw data should be reported (N.B. the visual analogue score of EQ-5D is insufficient).
Limited long-term utility data, with no studies reporting beyond five years.	Longitudinal health-related quality-of-life assessment, until death, is needed so that lifetime horizons with accurate and reliable data can be implemented in health economic evaluation.

EQ-5D = European quality-of-life 5-dimensions, QALY = quality-adjusted life-year.

Access to resources, such as SLP staff time to deliver ACV and time to provide training, has been identified as a major barrier to ACV implementation and use (8, 39). Further research 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 for delivery.

Specific issues were identified with the data available in the published critical care research. These issues led to increased uncertainty in this early-stage DAM. **Table 2** outlines these issues and recommendations for researchers, which would help to reduce uncertainty in future critical care DAMs.

CONCLUSIONS

This first evaluation of the cost-effectiveness of ACV, using DAM, reveals that ACV is potentially cost-effective. This is despite the substantial time resource required from speech-language pathologists—typically a scarce resource in ICU settings. There is no reason for decision-makers to de-adopt ACV, and there may be loss of opportunity costs in delaying adoption, particularly as it is easily reversible. However, there are considerable uncertainties in the model because of the limited and low-quality data available, and findings should be treated with caution. This study highlights the lack of utility and mortality data for patients with a tracheostomy in the ICU. Recommendations are provided to improve reporting in critical care research, which would increase the reliability of early-stage DAMs.

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Dr. Mills was involved in funding acquisition, conceptualization, data curation, formal analysis, methodology, project administration, validation, visualization, writing-original draft, and writing-review and editing. Dr. Bojke was involved in conceptualization, methodology, supervision, validation, and writing-review and editing. Drs. Michou, Brennan, Bellamy, and Siddle were involved in conceptualization, methodology, supervision, writing–review, and editing.

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