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Development, feasibility testing, and preliminary evaluation of the Communication with an Artificial airway Tool (CAT): Results of the Crit-CAT pilot study

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Abstract:	Background: A purpose built outcome measure for assessing communication effectiveness in patients with an artificial airway is needed. Objectives: To develop the Communication with an Artificial airway Tool (CAT) and to test the feasibility and preliminarily evaluate the clinical metrics of the tool. Methods: Eligible patients with an artificial airway in the Intensive Care Unit (ICU) were enrolled in the pilot study (Crit-CAT). The CAT was administered at least twice pre and post communication intervention. Item correlation analysis was performed. Participant and family member acceptability ratings and feedback were solicited. Qualitative thematic analysis was undertaken. Results: Fifteen patients with a mean age of 53 years (SD 19.26) were included. The clinician-reported scale was administered on 50 attempts (100%) with a mean completion time 4.5 (SD 0.77) minutes). The patient-reported scale was administered on 46 out of 49 attempts (94%) and took a mean of 1.5 (SD 0.39) minutes to complete. The CAT was feasible for use in the ICU, with patients with either an endotracheal or tracheostomy tube, whilst receiving invasive mechanical ventilation or not, and while using either verbal or non-verbal modes of communication. Preliminary establishment of responsiveness, validity, and reliability were made. The tool was acceptable to participants and their family members. Conclusion: The clinician-reported and patient-reported components of the were feasible for use. The CAT has the potential to enable quantifiable comparison of communication interventions for patients with an artificial airway. Future research is

	required to determine external validity and reliability.

7th June 2023

Dear Professor Marshall,

Thank you for taking the time to review our submission, “Development, feasibility testing, and preliminary evaluation of the Communication with an Artificial airway Tool (CAT): Results of the Crit-CAT pilot study”. We appreciate your receptiveness to our manuscript, based on prior correspondence.

Three quarters of patients admitted to the Intensive Care Unit (ICU) attempt to communicate. However, patients with an artificial airway (an endotracheal or tracheostomy tube) experience natural communication restriction, including loss of voice. To date, studies evaluating communication in this population have utilised tools that are not built-for-purpose, not validated in this population and that have not been developed considering the patient perspective.

This paper describes the development of the Communication with an Artificial airway Tool (CAT) and the study aimed to test the feasibility and preliminarily evaluate the clinical metrics of the tool.

The clinician-reported and patient-reported components of the CAT were feasible for use. The results of the CRIT-CAT pilot study indicate that the scale is responsive to change and has promising markers of clinical validity, content validity and reliability. The CAT has the potential to inform and improve clinical decision making and enable future research to objectively compare communication interventions for patients with an artificial airway. Future establishment of external validity and reliability is required.

We appreciate your consideration and look forward to reviewer comments.

Sincerely,

Charissa J. Zaga, MPH, Catherine S. Papasavva, MPH, Graham Hepworth, PhD, Amy Freeman-Sanderson, PhD, Mary Beth Happ, PhD, Jeannette D. Hoit, PhD, Brendan A. McGrath, PhD, Vinciya Pandian, PhD, Louise Rose, PhD, Anna-Liisa Sutt, PhD, Pieter R. Tuinman, PhD, Sarah Wallace, MPH, Rinaldo Bellomo, PhD, Adam P. Vogel, PhD, & Sue Berney, PhD.

Title Page (with Author details)

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Conceptualization – CJZ, RB, APV, SB; Data curation – CJZ, CSP; Formal analysis – CJZ, GH; Investigation – CJZ; Methodology – CJZ, CSP, AFS, MBH, JDH, BAM, VP, LR, ALS, PRT, SW, RB, APV, SB; Project administration – CJZ, APV, SB; Supervision – RB, APV, SB; Writing – original draft – CJZ; Writing – review & editing – CJZ, CSP, GH, AFS, MBH, JDH, BAM, VP, LR, ALS, PRT, SW, RB, APV, SB.

There are no acknowledgements.

Key words: communication, outcome measure, intensive care unit, artificial airway, speech, voice

Background

Three quarters of patients admitted to the Intensive Care Unit (ICU) attempt to communicate[1]. However, patients with an artificial airway (an endotracheal or tracheostomy tube) experience natural communication restriction, including loss of voice. This can lead to overwhelming frustration, anxiety, and reduced engagement in rehabilitation[2-4]. The communication impairment experienced is influenced by a constellation of factors, including the medical, physical, and cognitive status, the presence of fatigue and delirium and the artificial airway[5]. There can be a profound reduction in patients' independence and ability to connect with others. Healthcare professionals tend to guess what patients want and communicate less often with them[6-8]. An unequal balance of power exists between non-verbal patients attempting to communicate with healthcare professionals. Patients' communication is impacted by the communication methods used, the patient's needs and skills, the communication partner(s), the communication style of both the patient and the communication partner, and the ICU environment[9-11].

There are no patient or clinician reported outcomes purpose built for evaluating communication effectiveness of critically ill patients with an artificial airway[9]. Assessment of communication effectiveness should be part of routine daily care but requires an appropriate tool. To date, studies evaluating communication in this population have utilised tools that are not built-for-purpose, not validated in this population and that have not been developed considering the patient perspective[9].

Objectives

We developed a novel two-component clinician and patient reported outcome measure, the Communication with an Artificial airway Tool (CAT), that prioritises the patient's perspective, in addition to traditional clinician-driven measures. The CAT aims to 1) measure communicative effectiveness and function, 2) measure patient-reported satisfaction with their communication, and

3) inform progression of clinical care. This pilot study (Crit-CAT) sought to assess the feasibility, validity, reliability, and responsiveness of the CAT in a single ICU of a tertiary academic hospital in Australia. We also evaluated participant and family member acceptance of the tool. We hypothesised that the pilot study would demonstrate preliminary responsiveness and feasibility of the CAT.

Methods

CAT development

The CAT was developed by a multi-professional group comprising nurses, speech pathologists, and physicians with extensive experience with communication assessment and interventions, critical care, and clinical research. The group met via videoconference in January 2022 and continued to correspond via email to refine the scale. The items included in the CAT were based on the recently defined key elements of effective communication[8]. The CAT consists of a clinician-reported scale and a patient-reported scale.

The clinician-reported scale

The clinician-reported scale has six rating items (and components): 1) *Comprehension (Basic and Complex)*, 2) *Output (Content and Clarity)*, 3) *Rate,* 4) *Quantity*, 5) *Duration*, and 6) *Independence (Initiation, Set Up, and Use).* A short series of questions is used to facilitate the elicitation of a communication sample from the patient. This is then rated by a health care professional to derive a score of communication effectiveness (See **Figure 1**). The clinician-reported scale is scored from 0-3 per for each item and/or component therein, whereby 0 = no response and 3 = an effective response. The maximal total score is 30, with minimal total score of 0. The scoring represents the continuum of effective communication described in a previous study[8]. Two revisions were made to

the scale, one based on participant feedback (see **Supplementary Material e1**). As such, the maximum total score for some CAT administrations prior to the revision, was 27. The scale protocol and detailed description of the rating items and scoring guide can be found in the **Appendix**.

The patient-reported scale

The patient-reported scale comprises three rating items: 1) *Ease*, 2) *Satisfaction*, and 3) *Effort*. Using the CAT, a patient rates the degree of ease of communication, the degree of satisfaction with their communication, and the degree of effort required for the patient to communicate using a given communication intervention (See **Figure 1**). This patient rating was based on communication elicited during the clinician-reported scale administration of the CAT. The patient-reported scale is scored from 1-10 per rating item and incorporates the use of colour and emojis to support the written word descriptions. One (rating description in red with a frowning face emoji) is the worst score., five (orange) is a neutral score; ten is the best score (green with a smiling face emoji). The maximal total score is 30 and the minimal total score is 0. One revision to the scale was made based on participant feedback (see **Supplementary Material e1**).

The Crit-CAT pilot study

The pilot study was approved by the hospital ethics committee HREC/84457/Austin-2022. The study was conducted from August 2022 to January 2023 in the Austin Hospital general ICU. Participants were recruited during weekdays only. The inclusion criteria were: 1) adults ≥ 18 years old, 2) presence of an artificial airway, 3) if an endotracheal tube (ETT) in situ receiving mechanical ventilation for >48 hours and expected to continue mechanical ventilation for at least a further 48 hours, 4) sufficiently alert (Richmond Agitation and Sedation Score (RASS)[12] between -1 to +1), and 5) able to engage in communication intervention(s) as determined by the treating speech

pathologist(s). This was defined as patients who could maintain eye opening for at least 10-minute intervals. For pragmatic reasons, patients were excluded if non- English speakers.

Patient demographic data was collected including age, gender, Aboriginal and Torres Strait Islander background, APACHE II score, Charlson Comorbidity Index, and Body Mass Index recorded at the time of ICU admission or most recently recorded in relation to timing of enrolment in the study.

Procedure

Routine speech pathology care was provided by five ICU-trained speech pathologists. The cognitive-communication evaluation incorporated acknowledgement of the patient's cognitive-communicative pre-morbid history, current baseline function and their ability to engage with interventions including determining the patient's demonstrable intent to communicate and/or responsiveness to communication stimuli. The type of artificial airway, respiratory support required, physical capability (visual tracking, upper limb strength and dexterity) and patient goals and preferences guided the selection of communication interventions trialled with the patient (See **Supplementary Material Table e2)**.

One or both speech pathologists (CJZ and CSP) administered the CAT independently of routine speech pathology assessment. To determine responsiveness to change in performance and patient-reported outcomes the CAT was administered at least twice, at baseline and when there was a change in wakefulness as measured by the RASS, or a reported commencement or change in communication intervention documented in the electronic medical record. Where applicable, videorecording was performed via smartphone or smart tablet. The Confusion Assessment Method-ICU[13] score, a screening measure for the presence of delirium, which is routinely collected once per shift by nursing staff, was recorded for each shift that the CAT was administered.

Clinical metrics

As a gold standard reference measure was not available at the time of this pilot study[5,9], clinical validity was determined by the degree in which the participant's overall clinician-reported scale scores (out of 30) corresponded with the overall clinical impression of the treating speech pathologist(s) who were blinded to the scores.

Content validity was determined through participant feedback relating to the priority assigned to each rating tool and how well the tool covered all relevant parts (rating items) of the construct of effective communication[5].

Responsiveness was determined by the extent the tool measured change or lack of change over repeated administrations and how this corresponded with the overall clinical impression of the treating speech pathologist(s) who were blinded to the scores.

Inter-rater reliability was measured by two speech pathologists (CJZ and CSP) who were blinded to each other's rating of the same communication episode.

Feasibility was determined by evaluating the ability of users to practically administer the CAT in the target population and setting. We measured the proportion of completed administrations versus attempted administrations, the different artificial airway types, respiratory status, and communication methods used by participants with whom it was possible to administer the CAT with, and the time taken to administer the CAT.

Patient acceptance of the CAT and feedback on their experience communicating with an artificial airway was sought, using a modified questionnaire (see **Supplementary Material e3**), based on published works[14,15].

Statistical analysis

Descriptive statistics were used to report demographic characteristics. Continuous variables are summarised as mean (standard deviation) or median (inter-quartile range) depending on data distribution and categorical variables as proportion). We used Spearman's rho test to examine correlations between rating items, and between individual rating items and participant total scores to preliminarily guide item reduction, since the sample size was too small to conduct factor analysis. We performed crosstabulation of frequencies to examine the relationships between clinical conditions (e.g., delirium) and rating items or components (e.g., basic comprehension). Gamma was used to test the level of association for ordinal variables (e.g., between output (content) and delirium), and Fisher's exact test for variables where only two categories were observed (e.g., between basic comprehension and delirium). A linear mixed model with participant as a random effect was used to compare total scores between subgroups. IBM SPSS® Statistics for Windows, version 29 (IBM Corp: Armonk, NY) was used.

Thematic analysis

Qualitative thematic analysis[16] was undertaken to identify common themes from participant feedback on the CAT and the participants' experience of communicating with an artificial airway.

Results

Patient demographics are shown in **Table 1**. Eighteen adults were enrolled, and 15 participated in the pilot study (**Figure 2).** Participants underwent n= 50 administrations of the clinician-reported scale and n= 46 administrations of the patient-reported scale.

Clinician-reported scale

Following the revision of the clinician-reported scale, an additional rating item component was included meaning denominators were different for this result.

Feasibility

The CAT was able to be deployed in the ICU setting with patients with an artificial airway on 100% of occasions (**Table 2**). There were almost equal numbers of occasions of participants who used a verbal versus non-verbal communication mode (n=26 vs n=24 respectively) and no difference between the communication mode (verbal or non-verbal) and the participant total score (p=0.769).

Responsiveness

Multiple CAT administrations on the same participants were collected, generating 22 comparative scores which were analysed for responsiveness. Six participants used one communication method and nine participants used two communication methods (**Table 3**). The mean time between the 1st and 2nd administrations was 2.4 (SD 1.92) days with a mean of 12 (SD 7.81) days between 2nd and 3rd administrations. Other factors that influenced the timing of repeat administration included fluctuating clinical status, occasions of reduced access to patients due to nursing or other care, and no weekend study activity. The CAT was responsive to change and correlated with change was reported by the treating speech pathologist(s) who was blinded to the CAT scores (see **Table 2**). An improvement in communicative effectiveness corresponded with a progression of communication intervention and/or clinical impression (**Supplementary Material e4**).

Clinical validity and correlational analysis of the clinician-reported scale

Clinical validity was established through agreement between the overall total clinician-reported scale scores and the reported clinical diagnoses and impressions made by the treating speech pathologist(s) who were blinded to the Crit-CAT study (see **Table 3**). The construct of effective communication, as previously defined[8], was assessable in the pilot sample, with agreement between the CAT and the presence of absence of dysarthria, dysphonia, cognitive-communicative impairment, or aphasia diagnoses via screening through the communication sample where applicable. All participants who had a positive CAM-ICU score indicating the presence of delirium, were also recorded to have had a cognitive-communicative impairment (n=3) by the treating speech pathologist(s) (see **Table 2**). Correlations between rating items are described in **Supplementary Material e5**. Patients with delirium presented with less effective communication on the CAT.

Content validity

Content validity was established through participant feedback (n=5) that the content of both the clinician-reported and patient-reported scales in the CAT is inclusive of the construct of effective communication with an artificial airway[8] with patients who had viewed and used the scale (See **Table 2** and **Supplementary Material – Table e6**).

Inter-rater Reliability

Two speech pathologists (CJZ and CSP) independently rated nine out of fifty (18%) tool administrations to determine inter-rater reliability. Agreement was achieved for 87/89 (97.75%) of items rated. Discussion and clarification were sought for the two outstanding items; specifically, if rate using a whiteboard should be determined based on how the rate compares with voice production or compared with the expected rate that a person would write on a whiteboard. As a result of this discussion, the user guide was revised to minimise ambiguity (see **Appendix**). Six out of

fifteen (40%) participants declined videorecording of their communication. Three out of fifteen (20%) participants could not provide verbal consent for videorecording of their communication at the time of CAT administration due to presence of delirium, and inability to contact their medical treatment decision maker in a timely manner to coincide with their clinical suitability to participate (e.g., sufficiently alert).

Patient-reported scale scores

The patient-reported scale was administered on 46/49 (94%) attempts. Three attempts were not completed due to a participant's inability to engage with the scale due to delirium, and another who declined due to increasing fatigue. The comparison of overall total scores over time can be viewed in **Supplementary Material e7**.

Participant and family feedback and acceptability of the scale

Five participants agreed to provide feedback on the CAT. Two participants' family members provided general comments on their perceptions of the study and the participants' communication with an artificial airway. Thematic analysis of the participants' feedback revealed the following themes relating to the experience of communicating with an artificial airway: (1) the importance of the ability to express oneself and be understood, (2) the importance of the ability to be proactive with one's healthcare, (3) the initial difficulty with communication was part of the process of recovery, (4) the impact of being dependent on someone else to set up a communication method, and (5) the impact of social interactions on recovery (See **Supplementary Material – Table e8**). Two themes arose relating to participants' perception of the CAT: (1) the belief that the CAT will help the patient or someone like them in the future and (2) in contrast, reduced memory recall of the CAT in order to

provide specific feedback. Based on the feedback received, the CAT was considered acceptable to participants and their families.

Discussion

We provide a preliminary clinical evaluation of the CAT, which is the first outcome measure designed to assess the effectiveness of communication in patients with an artificial airway. The results of the CRIT-CAT pilot show that both the clinician-reported scale and the patient-reported scale of the CAT was feasible to administer. Preliminary establishment of clinical metrics included clinical validity, content validity, responsiveness, and reliability. The CAT was acceptable to both critically ill participants and their families. The CAT was brief and simple to use and was successfully deployed in the critical care environment during this pilot.

This pilot study demonstrated that it is feasible for patients with an artificial airway to participate in self-reporting and provide real-time feedback on their level of function and clinical status, which previous research has found to be challenging, particularly in reporting pain[17,18]. The scale could be administered in participants with different artificial airway types and communication modes (verbal and non-verbal) as well as multiple types of communication interventions (AAC and tracheostomy-related communication interventions). Previous studies have indicated overall low but emerging use of verbal communication methods while mechanically ventilated[19,20]. In this study, mechanically ventilated patients used both non-verbal and verbal methods to communicate suggesting communication interventions are safe, feasible and have utility in the critically ill population[21]. The CAT scores agreed with the clinician diagnosis of presence or absence of communication-related diagnoses and agreed with the CAM-ICU in identifying the presence of delirium in three participants over seven administrations. These findings indicate that the CAT has clinical utility for clinicians to measure clinical change over time across key elements of communication and can influence clinician selections of communication interventions and therapeutic recommendations.

The CAT rating items and components address the multi-dimensional and complex construct of communication in patients with an artificial airway, including those who receive mechanical ventilation[10]. The items within the scale target the elements beneath the broad communication umbrella; language, cognitive-linguistic, speech and voice features, within a respiratory context[22]. The CAT was developed by a group of experts in critical care, communication, and clinical research across a range of professions and four geographical locations. Participant feedback verified that items in the CAT scale were relevant and important for determining effectiveness of communication, and almost all (9/10) of the rating items of the CAT were confirmed to be either 'critical' or 'high priority' to be measured indicating a signal of content validity. Input from participants with current lived experience of communicating with an artificial airway while critically ill was favoured over co-design with patients who had past experience, given potential recall bias and post-traumatic stress disorder [23,24]. Feedback from participants about their experience communicating with an artificial airway was consistent with previous research which found that the ability to communicate while critically ill was extremely important to patients[6,7]. While the sample size limited further statistical analyses, there appeared to be concordance between rating items and the clinical impression and/or speech pathology diagnoses. Future examination of concurrent validity, criterion validity and clinical validity is needed.

Limitations and future directions

This promising work has several limitations. The pilot study had a small target sample of participants and only fifty and forty-six administrations of the clinician-reported and patient-reported scales of the CAT respectively. As such, the range of statistical analyses was limited and the association between delirium and *Basic Comprehension* may be overestimated. Similarly, the sub-group of patients with delirium as per CAM-ICU was small and therefore statistical significance may be

overstated. Thematic analysis was not rigorous given that it was limited to just five participants. Only two of the recruited patients had an endotracheal tube and further feasibility testing is required in that patient sub-group.

A large prospective multi-site study is needed to determine external validity and examine further the clinical metrics, especially the reliability of the scale. Scoring, factor analysis, weighting and item reduction will be undertaken with a larger future study. Administration of the scale was completed by speech pathologists during this pilot study, and future studies could explore the feasibility and reliability of other healthcare professionals administering the scale[25]. Non-English-speaking patients were excluded from this pilot study, and their inclusion with professional interpreters would enhance the generalisability and practicality in the future.

While the CAT was feasible to administer with participants who used a range of different communication interventions, communicative output measured was verbal or non-verbal expression via AAC device, excluding facial expression or gesture as sole methods of communication. Utterances made up only of vocalisations (production of phonemes – sounds only) are also not measurable using the CAT scale. These elements may be incorporated in a future revision prior to an external validity study. While a variety of verbal and non-verbal communication methods were used by participants in this study, some methods were not trialled in this pilot, such as above cuff vocalisation, one-way valve in-line with the ventilator or electrolarynx.

In-depth analysis of the patient-reported scores were out of scope for this pilot study, and the results indicate that there is much to examine in future research. There appeared to be a trend towards participants' initial high rating of satisfaction with their communication, followed by a reduction over repeat CAT administration. This could be associated with an initial contentment with being able to communicate, compared to not, followed by a reduction in satisfaction over time due to factors such as using a non-verbal method to communicate, or feeling confronted by the presence of their dysarthria or dysphonia[26]. Patient satisfaction using individual communication interventions

has been measured previously[27,28]; however, this pilot is the first of its kind to measure patient satisfaction with their communication over time, using a fit-for-purpose outcome measurement tool.

Conclusion

It was feasible to administer the clinician-reported component and engage critically ill participants with an artificial airway in the patient-reported component of the newly developed CAT scale. The results of the CRIT-CAT pilot study indicate that the scale is responsive to change and has promising markers of clinical validity, content validity and reliability. The CAT has the potential to inform and improve clinical decision making and enable future research to objectively compare communication interventions for patients with an artificial airway. Future establishment of external validity and reliability is required.

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Table, Figure, Appendix and Supplementary Material Legends

Table 1 – Patient demographics

Table 2 – Summary of preliminary clinical metrics

Table 3 – Clinician-reported scale: Comparison of total scores

Figure 1 – CAT Clinician-reported scale and patient-reported scale

Figure 2 – Consort diagram

Appendix – CAT user guide

Supplementary Material e1 – Revisions to the tool

Supplementary Material e2 - Routine ICU speech-language pathology assessment

Supplementary material e3 – Examples of responsiveness

Supplementary material e4 - Feedback questionnaire

Supplementary Material e5 – Rating item correlations

Supplementary Material e6 – Participant ratings of CAT items

Supplementary Material e7 – Patient-reported scale: Comparison of total scores

Supplementary Material e8 – Participant and family feedback

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Figure 1 – Communication with an Artificial airway Tool (CAT)

Clinician-reported scale

Item	Component	Scoring			
		0- Ineffective	1	2	3 - Effective
Comprehension	Basic	No response (Unreliable)	No correct answers (Unreliable)	Some correct answers (Unreliable)	Correct answers (Reliable)
	Complex	No response (Unreliable)	No correct answers (Unreliable)	Some correct answers (Unreliable)	Correct answers (Reliable)
Output	Content	None	Small (<25%)	Part (25-75%)	Most-All (75-100%)
	Clarity	None	Small (<25%)	Part (25-75%)	Most-All (75-100%)
Rate		Not applicable	Fast/Slow/Variable, resulting in difficulty following the communication	Fast/Slow/Variable which does not result in difficulty following the communication	Expected rate
Quantity		None	Single words	Phrases	Short-full sentences
Duration		Not applicable	Yes, significantly (1–10 minute periods)	Yes, somewhat (To certain periods of the day)	No (Unrestricted)
Independence	Initiation	No			Yes
	Set up	No	Yes, to an extent		Yes
	Use	No			Yes
Total out of 30					

Patient-reported scale

How easy or difficult is it to communicate?

Extremely difficult — Neutral — ☺ Extremely easy

1 2 3 4 5 6 7 8 9 10

How satisfied are you with your communication?

Highly dissatisfied — Neutral — ☺ Highly satisfied

1 2 3 4 5 6 7 8 9 10

How effortful or tiring is it to communicate?

Extremely effortful				Neutral				☺ Not at all effortful	
1	2	3	4	5	6	7	8	9	10

Figure 2 – Consort diagram

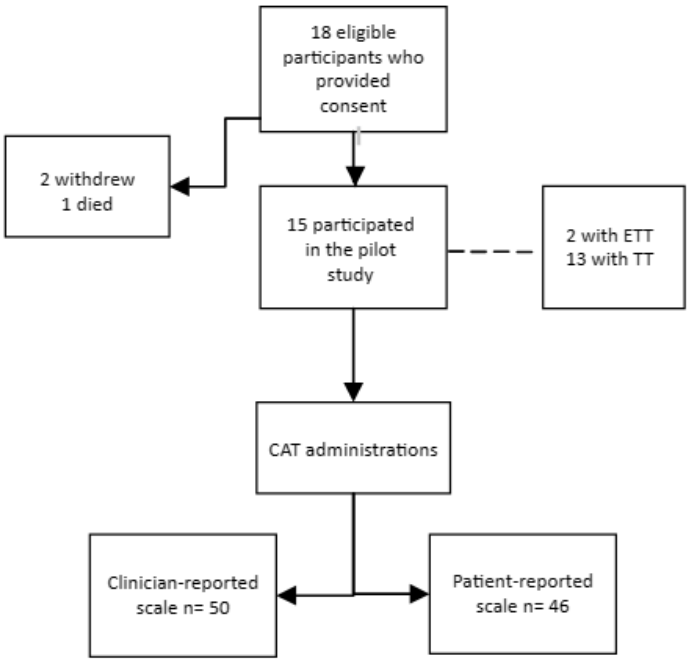


Table 1 – Patient demographics

Demographics	**n (CAT admins)**	**Mean (SD)**	**% (CAT admins)**
Age	15	53.1 (19.3)	
Male	11		73.0
Aboriginal & Torres Strait Islander status	0		
APACHE II score	15	14.1 (5.2)	
Charlson Comorbidity Index	15	2.5 (2.9)	
Body Mass Index	14	24.7 (4.1)	
Admission unit			
Cardiac Surgery	1		
Ear, Nose & Throat Surgery	2		
Neurology	2		
Neurosurgery	1		
Oral-Maxillo-Facial Surgery	3		
Spinal	4		
Thoracic Surgery	1		
Victorian Respiratory Support Service	1		
Pre-hospital location			
Home	8		53.3

Acute hospital transfer	7	46.7
Pre-hospital employment		
Working	10	66.7
Not working	4	26.7
Unknown	1	6.7
Pre-morbid level of function		
Independent	14	93.0
Home with carer assistance	1	7.0
CAM-ICU		
Positive	3 (7)	14.0
Negative	12 (43)	86.0
Respiratory and airway status		
Mechanically ventilated	6(14)	28.0
Spontaneously ventilated	12(36)	72.0
Endotracheal tube	2	13.0
Tracheostomy tube	13	87.0

APACHE= Acute Physiology and Chronic Health Evaluation, CAM-ICU= Confusion Assessment Method-Intensive Care Unit

Table 2 – Summary of preliminary clinical metrics

Feasibility	Clinical validity	Content validity	Responsiveness	Inter-rater Reliability
Clinician-reported scale was completed on all fifty attempts (100%)	Rating item scores corresponded to the clinical impression of the treating speech pathologist(s). Including lower score for Clarity and presenting with dysarthria.	3/5 participants agreed to rate the degree of importance of the rating items and components within both the clinician-reported and patient-reported components on a four-point scale ranging from critical to lower priority.	Measured change over time, where change was recorded by the treating speech pathologist(s) who was blinded to the CAT scores	9/50 (18%) of attempts were rated independently by two speech pathologists via 7 occasions at the bedside and 2 occasions via videorecording.
Clinician-reported scale had a mean completion time of 4.5 (SD 0.77) minutes	Two participants who were clinically recorded to have presented with aphonia, scored a 1 for *Clarity* over two observations, compared with 45 occasions (94%) without aphonia recorded where the *Clarity* rating was 2 or 3 (p=0.133).	Nine out of ten items were rated between *critical* and *high priority* by all patients. One item was rated as *high-lower priority* by one patient.	14/22 (64) of repeated overall total scores indicated improvement in communicative effectiveness which corresponded with a progression of communication intervention and/or clinical recommendations as assessed by the treating speech pathologist(s)	Agreement was achieved for 87/89 (98%) of items rated
Patient-reported scale was completed on 46/49 attempts (94%)	71% of participants with delirium received a score of 2 for *Content*, compared with 77% of participants without delirium who scored a 3 for *Content* (p=0.011).	One participant reported that he could not recall the tool while the other responded that he didn't know how to answer the questions asked.	6/22 (27%) of repeated overall total scores did not change, corresponding with no reported change in presentation	
Patient-reported scale had a mean completion time of 1.5 (SD 0.39) minutes	Seventy-one percent of observations of participants with delirium scored a 3 for *Basic Comprehension*, and 29% scored a 2, compared with 100% of observations of participants without delirium who scored a 3 (p=0.017).		1/22 (4.5%) of repeated overall total scores worsened, corresponding with a reported deterioration in clinical presentation	
CAT was administered with patients • with either an endotracheal tube (n=2) or tracheostomy tube (n=13) • of either sex (male n=11, female n=4) • using invasive mechanical ventilation (n=3) spontaneous ventilation (n=6) or both (n=3) • using either verbal (n=3) or non-verbal (n=7) modes of communication or both (n=3) • Using a range of communication interventions – AAC and tracheostomy-related (n=6)	Just under half of participants with delirium (43%) scored 3 for *Complex Comprehension*, and 57% scored 2, compared with 98% of occasions of participants without delirium who scored a 3 (p=0.001).		1/22 (4.5%) of repeated overall total scores was variable, which corresponded with a variable clinical presentation	

Table 3 – Clinician-reported scale: Comparison of total scores

Explanatory notes: Following the revision of the clinician-reported scale, an additional rating item component (Content) was included. That meant that denominators were different for this result.

Participant	Communication Mode/Method	1st administration				2nd administration				3rd administration				Days between admin	Overall
		1st score	Treating speech pathologist's impression	RASS score	CAM-ICU score	2nd score	Treating speech pathologist's impression	RASS score	CAM-ICU score	3rd score	Treating speech pathologist's impression	RASS score	CAM-ICU score		
1	Non-verbal/ Mouthing	21/27	Limited assessment due to cuff inflation; Moderate dysarthria suspected	0	Negative	23/27	Limited assessment due to cuff inflation; Mild dysarthria suspected	0	Negative	N/A	N/A	N/A	N/A	2	Improvement
1	Non-verbal/ Partner-assisted scanning with alphabet board	17/27	Limited assessment due to cuff inflation; Moderate dysarthria suspected	0	Negative	18/27	Limited assessment due to cuff inflation; Mild dysarthria suspected	0	Negative	N/A	N/A	N/A	N/A	2	Improvement
2	Verbal/ One-way valve off the ventilator	21/30	Moderate cognitive-communicative impairment	+1	Positive	26/30	Moderate cognitive-communicative impairment	+1	Positive	N/A	N/A	N/A	N/A	1	Improvement
3	Non-verbal/ Whiteboard	23/30	Limited assessment due to ETT; nil gross impairment but slowed informational processing as	-1	Negative	26/ 30	Limited assessment due to ETT; nil gross impairment but improved informational processing and	0	Negative	N/A	N/A	N/A	N/A	1	Improvement

			sedative agent weaned 30 mins prior to CAT administration				rate of communicating								
4	Non-verbal/ Whiteboard	28/30	Limited assessment due to cuff inflation; Severe dysarthria suspected	0	Negative	26/30	Limited assessment due to cuff inflation; Severe dysarthria	-1	Negative	N/A	N/A	N/A	N/A	1	Reduction
5	Non-verbal/ Partner-assisted scanning with alphabet board	21/30	Limited assessment due to cuff inflation; Mild dysarthria suspected	0	Negative	21/30	Limited assessment due to cuff inflation; Mild dysarthria suspected	0	Negative	N/A	N/A	N/A	N/A	1	No change
5	Verbal/ One-way valve off the ventilator	18/30	Aphonia	0	Negative	26/30	Mild dysphonia	0	Negative	27/30	Resolved dysphonia	0	Negative	7 and 2	Improvement
6	Non-verbal/ QWERTY layout alphabet board	20/30	Anarthric	0	Negative	20/30	Anarthric	0	Negative	N/A	N/A	N/A	N/A	2	No change
7	Verbal/ One-way valve off the ventilator	25/30	Moderate cognitive-communicative impairment	0	Positive	26/30	Moderate cognitive-communicative impairment	-1	Positive	N/A	N/A	N/A	N/A	7	Improvement
7	Non-verbal/ Whiteboard	26/30	Moderate cognitive-communicative impairment	0	Positive	26/30	Moderate cognitive-communicative impairment	-1	Positive	N/A	N/A	N/A	N/A		No change
8	Non-verbal/ Partner-assisted scanning with alphabet board	21/30	Limited assessment due to ETT	0	Negative	23/30	Limited assessment due to ETT	0	Negative	N/A	N/A	N/A	N/A	2	Improvement
9	Non-verbal/ Whiteboard	26/30	Limited assessment due to cuff inflation; Severe dysarthria suspected	0	Negative	26/30	Limited assessment due to cuff inflation; Severe dysarthria suspected	0	Negative	N/A	N/A	N/A	N/A	3	No change
10	Non-verbal/ Mouthing	24/30	Limited assessment	-1	Negative	24/30	Limited assessment due to cuff inflation	-1	Negative	N/A	N/A	N/A	N/A	1	No change

			due to cuff inflation												
10	Verbal/ One-way valve off the ventilator	25/30	Mild dysphonia	-1	Negative	27/30	Slight dysphonia	0	Negative	27/30	Resolved dysphonia	0	Negative	1 and 6	Improvement
11	Non-verbal/ Whiteboard	27/30	Limited assessment due to cuff inflation	0	Negative	27/30	Limited assessment due to cuff inflation	0	Negative	N/A	N/A	N/A	N/A	6	No change
11	Verbal/ One-way valve off the ventilator	22/30	Severe dysarthria	0	Negative	22/30	Severe dysarthria	0	Negative	25/30	Moderate-severe dysarthria	0	Negative	6 and 17	Improvement
12	Verbal/ Ventilator-adjusted leak speech	23/30	Mild dysarthria, mild dysphonia	-1	Negative	25/30	Resolved dysarthria, mild dysphonia	0	Negative	26/30	Resolved dysarthria, mild dysphonia	0	Negative	3 and 16	Improvement
12	Verbal/ One-way valve off the ventilator	26/30	Slight dysphonia	0	Negative	27/30	Resolved dysphonia	0	Negative	N/A	N/A	N/A	N/A	3	Improvement
13	Verbal/ One-way valve off the ventilator	24/30	Moderate dysarthria, mild dysphonia	0	Negative	25/30	Moderate dysarthria, slight dysphonia	0	Negative	N/A	N/A	N/A	N/A	1	Improvement
14	Non-verbal/ Whiteboard	26/30	Moderate cognitive-communicative impairment	-1	Positive	27/30	Mild cognitive-communicative impairment	0	Negative	N/A	N/A	N/A	N/A	1	Improvement
15	Verbal/ Ventilator-adjusted leak speech	21/30	Moderate dysarthria, mild dysphonia	0	Negative	12/30	Aphonia	0	Negative	24/30	Mild dysarthria, mild dysphonia	0	Negative	4 and 3	Variable, overall improvement
15	Verbal/ One-way valve off the ventilator	22/30	Mild dysphonia	0	Negative	23/30	Resolved dysphonia	0	Negative	23/30	Resolved dysphonia	0	Negative	8 and 3	Improvement

Office for Research

Austin HEALTH

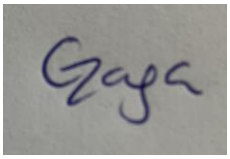
THIS EMAIL CONSTITUTES HUMAN RESEARCH ETHICS PROJECT APPROVAL AND AUSTIN HEALTH SITE SPECIFIC AUTHORISATION

Austin Site PI	Sue Berney
From	Human Research Ethics Committee
Project HREC Number	HREC/84457/Austin-2022
Austin Health SSA Reference Number *(if applicable)*	SSA/84457/Austin-2022
Protocol Number / Short Title *(if applicable)*	N/A
Project Title	The development and pilot of the ICU Communication Effectiveness Scale (ICE)
LEX ID (for agreements)	LEX 6620 • MACH Agreement Between Austin Health and the University of Melbourne - eCopy attached
Sites	• Austin Health
Submission Type	• Approval of New Project ○ HREA – 309696 ○ SSA - 305169
Approval Date	09 May 2022
Approved Documents	• Project description v3 March 2022 • VSM/84457/Austin-2022-312454(v1) • PICF-interventional-for-person-responsible-medical-treatment-decision-maker_ICE_v2 06.05.2022 • PICF-non-interventional-for-self.ICE_v2 06.05.2022 • ICU Communication Effectiveness Scale (ICE) V2 March 2022
Austin Site Specific Authorised Documents	• HIS Declaration form

Author Statement

I hereby state that all authors have approved the final article, agree to be accountable for all aspects of the work and acknowledge that all those entitled to authorship are listed as authors.

Sincerely,



Ms Charissa J. Zaga

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1-2
Objectives	3	State specific objectives, including any prespecified hypotheses	1-2
Methods			
Study design	4	Present key elements of study design early in the paper	2-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	2-6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	2-6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	2-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*2-6*
Bias	9	Describe any efforts to address potential sources of bias	4-5
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	n/a
		(*b*) Describe any methods used to examine subgroups and interactions	6
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	n/a

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	6
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	7
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	7
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*7*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(*b*) Report category boundaries when continuous variables were categorized	6
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7-8
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	n/a

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.