



# BMJ Open Protocol for a mixed method acceptability evaluation of a codesigned bundled COmmunication intervention for use in the adult ICU during the COVID-19 PandEmic: the COPE study

Laura Istanbulian <sup>1,2</sup>, Louise Rose,<sup>3,4</sup> Yana Yunusova,<sup>5,6</sup> Craig M Dale <sup>1,7</sup>

**To cite:** Istanbulian L, Rose L, Yunusova Y, *et al.* Protocol for a mixed method acceptability evaluation of a codesigned bundled COmmunication intervention for use in the adult ICU during the COVID-19 PandEmic: the COPE study. *BMJ Open* 2021;**11**:e050347. doi:10.1136/bmjopen-2021-050347

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-050347>).

Received 17 February 2021  
Accepted 31 August 2021



© Author(s) (or their employer(s)) 2021. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

**Correspondence to**  
Ms Laura Istanbulian;  
[laura.istanboulian@alum.utoronto.ca](mailto:laura.istanboulian@alum.utoronto.ca)

## ABSTRACT

**Introduction** Patients requiring invasive mechanical ventilation via an artificial airway experience sudden voicelessness placing them at risk for adverse outcomes and increasing provider workload. Infection control precautions during the COVID-19 pandemic, including the use of personal protective equipment (eg, gloves, masks, etc), patient isolation, and visitor restrictions may exacerbate communication difficulty. The objective of this study is to evaluate the acceptability of a codesigned communication intervention for use in the adult intensive care unit when infection control precautions such as those used during COVID-19 are required.

**Methods and analysis** This three-phased, prospective study will take place in a medical surgical ICU in a community teaching hospital in Toronto. Participants will include ICU healthcare providers, adult patients and their family members. Qualitative interviews (target n: 20–25) will explore participant perceptions of the barriers to and facilitators for supporting patient communication in the adult ICU in the context of COVID-19 and infection control precautions (phase 1). Using principles of codesign, a stakeholder advisory council of 8–10 participants will iteratively produce an intervention (phase 2). The codesigned intervention will then be implemented and undergo a mixed method acceptability evaluation in the study setting (phase 3). Acceptability, feasibility and appropriateness will be evaluated using validated measures (target n: 60–65). Follow-up semistructured interviews will be analysed using the theoretical framework of acceptability (TFA). The primary outcomes of this study will be acceptability ratings and descriptions of a codesigned COmmunication intervention for use during and beyond the COVID-19 PandEmic.

**Ethics and dissemination** The study protocol has been reviewed, and ethics approval was obtained from the Michael Garron Hospital. Results will be made available to healthcare providers in the study setting throughout the study and through publications and conference presentations.

## INTRODUCTION

Incapacities associated with critical illness and its treatment interfere with patient

## Strengths and limitations of this study

- The COmmunication intervention for use during and beyond the COVID-19 PandEmic (COPE) intervention will be the first stakeholder codesigned intervention to support intensive care unit (ICU) patient communication during COVID-19 infection control procedures.
- A key feature of the study is diverse ICU stakeholder involvement in all three phases.
- Using a mixed method study design will allow us to address contextually relevant practice-based barriers and facilitators influencing the acceptability of the COPE intervention.
- The primary limitation of this study is that it takes place in a single centre and therefore limits generalisability.

communication in the intensive care unit (ICU). For example, the placement of an advanced airway such as an endotracheal or tracheostomy tube to facilitate mechanical ventilation disrupts patient vocalisation leading to temporary and sometimes permanent voicelessness referred to as acquired communication impairment.<sup>1 2</sup> In the ICU, patient communication impairment may impede expression of physical and psychological support needs, as well as participation in medical decision making.<sup>3 4</sup> Misinterpretation of patient needs and other messaging may lead to poorly managed patient symptoms including anxiety, pain and agitation.<sup>5–8</sup> Unresolved patient communication difficulty may lead to increased workload, frustration and poor job satisfaction among ICU staff.<sup>9</sup> To address the wide-ranging need for communication support in the ICU, multifaceted bundled interventions, addressing both the individual and contextual needs of end users, are recommended.<sup>10–12</sup> Study of

Patient-Nurse Effectiveness with Assisted Communication (SPEACS) is an example of a multifaceted ICU communication programme that includes communication tools, a training programme and recommendations for speech specialist referral.<sup>13</sup>

Worldwide, to date, there have been over 200 million confirmed COVID-19 cases.<sup>14</sup> Respiratory illness associated with COVID-19 ranges from mild to severe, often requiring intubation and relatively long periods of mechanical ventilation.<sup>15 16</sup> Infection control precautions recommended for the care of patients with suspected or confirmed COVID-19 infection include droplet, contact and airborne precautions during aerosol generating procedures (eg, intubation, extubation and deep suction).<sup>17</sup> Personal protective equipment, clothing or equipment worn to protect against acquiring or transmitting infectious hazards such as COVID-19, include surgical masks or N-95 respirators, face shields, goggles, gown and gloves.<sup>18</sup> Additional infection control precautions for preventing spread of COVID-19 in ICUs include environmental controls such as placing patients in a single room and improving efficiencies in practice to limit unnecessary clinician–patient contact and visitor-related controls including the restriction of in-person family visitation.<sup>19</sup>

Prior to the COVID-19 pandemic, supporting patient communication in the adult ICU has been challenging suggesting unresolved barriers.<sup>9 20–22</sup> Though necessary to prevent spread of infection, infection control precautions potentially further complicate patient communication in the ICU as they may impede both verbal and non-verbal dimensions of communication. Although interventional studies have evaluated bundled communication programmes such as SPEACS in the adult ICU, none specifically address conditions including infection control precautions such as those during COVID-19.<sup>13 23–25</sup> It is, therefore, unclear how the design and implementation of a bundled communication programme should be adjusted for use in this context. Moreover, prior programmes have been evaluated by ICU nurses, omitting the perspectives of other key stakeholders such as ICU patients and their family members, as well as members of the allied healthcare team and physicians.<sup>10</sup> Stakeholder inclusivity in the design of interventions may improve their acceptability and adoption in healthcare.<sup>26</sup> We present the protocol for

a three-phase study to address gaps in the ICU communication evidence base, namely, the need for a bundled communication programme that is informed by diverse ICU stakeholders and that is acceptable for use during the COVID-19 pandemic and similar infection control precautions conditions.

## THEORETICAL FRAMEWORK

The Medical Research Council recommends that prior to large-scale effectiveness trials, complex interventions be designed and evaluated in a stepwise, phased and theoretically informed way that includes acceptability trials.<sup>27</sup> An intervention is complex when it contains several interacting components.<sup>27</sup> In addition to structural complexity, the current study will include patients, families, healthcare professionals and organisational processes of care.

This study will use the theoretical framework of acceptability (TFA), which defines ‘acceptability’ as a multifaceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate based on cognitive and emotional responses to the intervention.<sup>26</sup> The construct definitions provided by the developers of the TFA are provided in table 1.

## OBJECTIVE

The overall aim of this study is to produce a bundled ICU patient communication intervention that is designed by and deemed acceptable from the perspective of diverse stakeholders and tailored for use during the COVID-19 pandemic and similar infection control precautions conditions.

The following research objectives will guide each phase:

1. Establish baseline communication practices in this context (phase 1).
2. Explore barriers to and facilitators for supporting patient communication in this context from the perspective of key stakeholders (phase 1).
3. Use principles of codesign to develop an intervention and recommendations for implementation in this context (phase 2).

**Table 1** Construct definitions of the theoretical framework of acceptability

Construct	Definition
Affective attitude	How the individual feels about the intervention.
Burden	The perceived amount of effort that is required to participate in the intervention.
Ethicality	The extent to which the intervention has a good fit with the individual’s value system.
Intervention coherence	The extent to which the participant understands the intervention and how it works.
Opportunity costs	The extent to which benefits, profits or values must be given up engaging in the intervention.
Perceived effectiveness	The extent to which the intervention is perceived as likely to achieve its purpose.
Self-efficacy	The participant’s confidence that they can perform the behaviours required to participate in the intervention.



**Figure 1** Phases of the study (figure created by authors).

4. Implement and evaluate the acceptability of the intervention from the perspective of key stakeholders (phase 3).

### STUDY DESIGN

We propose a three-phase participant codesign approach to develop, revise and evaluate a bundled communication intervention for use in the adult ICU during and beyond the COVID-19 pandemic (see [figure 1](#)). In this study, a key design feature will be the formation of a codesign project advisory committee that includes diverse ICU stakeholders (ie, patients, family members, clinicians and researchers), led by the primary investigator (PI). Using results from phase 1, the advisory committee will provide oversight in the design of the intervention over a series of codesign meetings and create a revision of the intervention in phase 2. In phase 3, we will conduct a mixed method pilot trial of the acceptability of the codesigned intervention.

### SETTING

The study will be carried out from February 2021 to March 2022. Data will be collected from a single adult medical-surgical ICU at a large community teaching hospital in Toronto, Canada. This ICU has 17 beds and a multiprofessional healthcare workforce including registered nurses, allied healthcare providers (ie, respiratory therapists, physical and occupational therapists, speech language pathologist, social workers, registered dietitians,

pharmacists, etc), intensivists (ie, medical specialists) and clinical leadership.

### PARTICIPANTS

The target study populations for each phase are shown in [table 2](#).

#### Patients and family members

##### Inclusion criteria

This study will use convenience sampling of patients ≥18 years of age, treated with an advanced airway (ie, endotracheal or tracheostomy tube), English speaking, discharged from the ICU within the past year and having recollection of communication encounters while in ICU. Recall of ICU experiences will be confirmed by an affirmative answer to the screening question: do you recall anything about trying to communicate in the ICU? Adult English-speaking family members of patients who were admitted to the ICU during COVID-19 conditions are also eligible for participation.

##### Exclusion criteria

We will exclude patients who are unable to provide consent and are still in the ICU.

#### Healthcare professionals

##### Inclusion criteria

We will use convenience sampling of healthcare professionals working in the study setting. In phase 2, we will use purposive sampling to ensure diversity in the advisory committee.

##### Exclusion criteria

In phases 2, we will exclude casual staff to ensure availability for codesign meetings.

#### Phase 1: gathering experiences

##### Research objectives

1. Establish baseline communication practices in this context.

Table 2 Eligibility criteria (table created by authors)		
	Inclusion	Exclusion
Patients and caregivers	Phases 1, 2 and 3 1. Adult (>17). 2. Discharged from ICU within past year and can recall communication encounters. 3. Awake, oriented and able to provide consent. 4. Family member or adult caregiver of (2).	1. Currently in the ICU. 2. Unable to communicate in English.
HCP	Phase 1 1. Full-time, part-time and casual staff. 2. Nursing, allied, medicine, infection prevention and control, and leadership.	
	Phase 2 1. Full-time and part-time staff. 2. Nursing, allied, medicine, infection prevention and control, and leadership.	1. Casual staff.
	Phase 3 1. Full-time, part-time staff, and casual staff. 2. Nursing, allied, medicine and leadership.	

HCP, healthcare provider; ICU, intensive care unit.

2. Explore barriers to and facilitators for supporting patient communication in this context from the perspective of key stakeholders.

### Method

Patients, family members and healthcare providers will be recruited by email, study posters and face-to-face recruitment. A semistructured interview guide and brief demographic questionnaire will be piloted with an external sample of two to three ICU healthcare professionals from the study setting to evaluate comprehensibility and order of the interview questions. A question example for healthcare providers is: ‘What has helped you support communication for patients with mechanical ventilation in the ICU during COVID-19?’ A question example for patients is: ‘Can you tell me about your experiences trying to communicate when you were a patient in the ICU and on mechanical ventilation?’ Zoom or telephone interviews will be conducted by the PI at a time convenient to the participant, digitally recorded and then transcribed verbatim. The PI will conduct all interviews. A target of 20–25 participants (ie, healthcare providers, patients and family) will be set with recruitment for additional interviews as needed to reach thematic saturation.<sup>28</sup>

### Patient and public involvement

There was no patient or public involvement in the design of this study protocol.

### Analysis

Transcripts will be analysed by the PI using qualitative content analysis with deductive analysis using the TFA constructs, barriers and facilitators to using baseline communication supportive practices.<sup>29 30</sup> A codebook will be developed during the analysis of interview transcripts to create and describe codes.<sup>28</sup> Coding will occur concurrently with data collection. Code definitions will be shared with the research team with exemplars from the text throughout the entire data collection and coding process. Themes will be built out of patterns recognised in the coded content and continue until thematic saturation occurs (ie, when there is no additional information in terms of a higher level concept and definitions of concepts for the codebook).<sup>28</sup> NVivo V.12 software will be used to assist with management of coding.

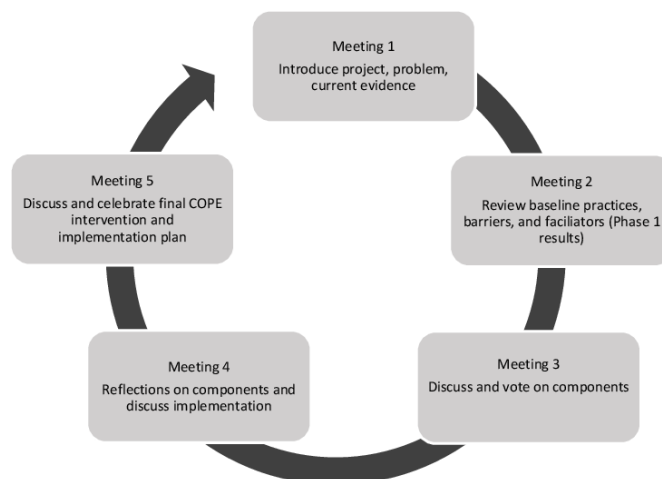
## PHASE 2: INTERVENTION CODESIGN

### Research objective

1. Use principles of participant codesign to develop an intervention and recommendations for implementation in this context.

### Method

Participant codesign principles will be used in phase 2 of this study. Codesign entails one or more groups of health stakeholders (eg, patients, family members, staff and researchers) reflecting on their experiences of a service, working together to identify improvement priorities, devising and implementing changes and then jointly



**Figure 2** Codesign meetings (figure created by authors).

reflecting on their achievements.<sup>31 32</sup> Diverse healthcare providers will be recruited by email, study poster distribution on approved ICU bulletin boards and staff meetings. Patients and caregivers will be recruited with the assistance of the unit supervisor who will identify and approach patients who are being discharged from ICU. All participants will be consented by the PI and demographics collected for each member. The target sample size for the advisory committee is 8–10, with purposive selection of diverse professional representation, at least one patient and family member and a member of the infection prevention and control committee.

A series of five codesign meetings using Zoom video-conferencing software will be held with the advisory committee to codesign the intervention (see figure 2). The PI will lead these meetings and invite all members to participate in the intervention design, reflection and consensus building. The PI will use anonymous voting after each meeting to ensure all members of the advisory committee feel they are able to contribute to the discussion and that the overall tone of the meetings is respectful. The PI will keep reflexive notes during the meetings, noting areas of clear agreement or disagreement and key decision points. In the first codesign meeting, the rationale for use of codesign to address this problem will be explored. The PI will provide a summary review of the current evidence about communication interventions and ICU specific implementation strategies. Over the next meetings, drawing from published evidence, phase 1 results and real-world experience, the advisory committee will iteratively design a COPE intervention and implementation strategy. The final COPE intervention will be developed through iterative steps of planning, discussion and reflection.

### Analysis

Data from the advisory committee meetings will be obtained as recorded meetings, PI notes and consensus decision points. The PI will transcribe the recorded meetings and summarise key decision points for the advisory committee between each meeting. An audit trail of the

advisory committee decisions leading to the final design of the COPE intervention and implementation plan will be recorded and reported.

### PHASE 3: PILOT ACCEPTABILITY EVALUATION

#### Research objective

1. Implement and evaluate the acceptability of the intervention from the perspective of key stakeholders.

#### Method

The COPE intervention will be implemented in the study setting over a minimum of six consecutive weeks to ensure staff exposure to the intervention followed by a convergent mixed method acceptability evaluation.<sup>33 34</sup> The implementation process will include recommended strategies for bundled interventions in the ICU (ie, multi-modal education, reminders and audit-feedback) and the suggestions of the advisory committee.<sup>35</sup> Convergent mixed method designs use two or more concurrent phases of data collection and analysis in one study and typically include a combination of quantitative and qualitative methods.<sup>34</sup>

#### Questionnaire

Healthcare providers will be recruited via direct email invitation to participate in a brief electronic questionnaire. Our target sample size for returned acceptability measures is 60–65 ICU healthcare providers. This target is based on the total number of potential participants in the study setting (ie, approximately 175), previous ICU clinician survey-based research and recommended targets of over 30% in the healthcare evidence base.<sup>36 37</sup> With a sample size of 63 the expected proportions of affirmative responses for the setting population can be estimated with 10% precision and 95% confidence.<sup>38</sup>

The validated Acceptability of Intervention Measure (AIM), Feasibility of Intervention Measure (FIM), and Appropriateness of Intervention Measure (IAM) will be sent via a secure online survey link to each participant<sup>39</sup> accompanied by a brief demographic questionnaire. The AIM, FIM and IAM are a set of validated measures created by Weiner *et al*<sup>39</sup> using Likert scale response values for each item ranging from 1 to 5, with 1=completely disagree, 2=disagree, 3=neither agree nor disagree, 4='agree' and 5='strongly agree'. A score of >3 is considered an affirmative response for acceptability, feasibility and appropriateness.<sup>39</sup>

The definitions for acceptability, feasibility and appropriateness in these measures align with the TFA constructs. 'Acceptability' in the AIM is defined as the perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable or satisfactory.<sup>39</sup> The definition for 'feasibility' in the FIM is the extent to which a new treatment, or an innovation, is perceived to be able to be successfully used or carried out within a given agency or setting.<sup>39</sup> The definition for 'appropriateness' is the perceived fit,

relevance or compatibility of the innovation or evidence-based practice for a given practice setting, provider or consumer and/or perceived fit of the innovation to address a particular issue or problem.<sup>39</sup>

#### Semistructured interviews

Questionnaire participants will be invited to participate in a follow-up interview. Discharged ICU patients who experienced the intervention and family members will also be invited to participate in an interview with the assistance of the unit supervisor. A target of 20–25 participants for qualitative interviews with patients (target n=5), family members (target n=5) and staff (target n=10–15) will be set with recruitment for additional interviews as needed to reach thematic saturation or until no novel results are being shared.<sup>28</sup> Semistructured interview questions and a brief demographic questionnaire will be piloted by the PI with a small external sample to evaluate comprehensibility and order of the interview questions. Zoom or telephone interviews will be conducted by the PI at a time convenient to the participant, recorded and then transcribed verbatim by a professional transcription service.

#### Analysis

##### Questionnaire

Descriptive statistics will be used to describe the study sample. Categorical data will be presented as frequency counts and percentages. Data distribution for continuous data will be checked and reported as means and SD or by medians and IQRs as appropriate. Mean (SD) scores for the AIM, FIM and IAM will be calculated.<sup>39</sup> A dichotomous variable will be created using a cut-off of >3 as an affirmative threshold for each measure. The number, proportion and 95% CIs of the sample who respond with an average score of >3 will be calculated and reported.<sup>38</sup>

##### Semistructured interviews

As reported in phase 1, transcripts will be analysed using qualitative content analysis with deductive analysis using the TFA constructs, barriers and facilitators.<sup>28</sup> Themes related to the acceptability of the COPE intervention will be created out of patterns recognised in the text. NVivo V.12 software will be used to assist with coding of all interview transcripts.

##### Mixed method analysis

Qualitative and quantitative data will be merged with mirrored content areas (ie, TFA constructs from qualitative results aligned with 'acceptability', 'feasibility' and 'appropriateness' scores from quantitative results) in order to compare, contrast and synthesise results in a joint table and discussion format.<sup>33 34</sup> Convergences (ie, similarities) and divergences (ie, differences) in the quantitative and qualitative data sets will be analysed.<sup>33 34</sup> Using a convergent mixed method analysis will permit the evaluation of and in what ways the codesigned intervention is acceptable, feasible and appropriate to support patient communication in this context.<sup>33 34</sup>



## ETHICS AND DISSEMINATION

Ethics approval has been obtained by Michael Garron Hospital (820–2010-Mis-347) research ethics board. Written informed consent will be obtained from patient, family member and healthcare provider participants in each study stage. Local knowledge translation will include presentation of the results at approved events and through the membership of an interdisciplinary communication committee in the study ICU. Publication in peer-reviewed journals and presentation at national and international conferences will also contribute to more widespread dissemination of results.

## DISCUSSION

This protocol describes a three-phase study to develop and evaluate an intervention responding to the problem of communication impairment in the adult ICU when infection control precautions such as those during the COVID-19 pandemic are in place. This study uses principles of codesign to design a bundled communication intervention and implementation plan. Evaluation of the intervention includes exploration of key theoretical constructs of acceptability grounded in the experiences of key stakeholders as they pertain to intervention design and delivery. Mixed method analysis will also explore convergences and divergences between quantitative and qualitative findings to enhance the trustworthiness of the results.<sup>34</sup> The results of this study will address gaps in previous ICU communication research including the impact of infection control precautions, lack of diverse inclusivity in design and evaluating intervention acceptability prior to full-scale studies.

### Strengths and limitations

Strengths of this study design include the use of diverse stakeholder participants in all three study phases. The oversight role of the advisory committee will ensure the needs and experiences of end users are considered in the design and implementation plan. Moreover, the mixed method design will ensure the intervention is optimised for the ICU context through the use of the validated AIM, FIM and IAM surveys and a theoretical framework (ie, TFA), whereby the constructs of acceptability will aid understanding of the delivery of the intervention.

The use of a single centre for the study setting, inclusion of only English-speaking participants with access to an internet connected computer for Zoom meetings (phase 2), and convenience sampling with self-report data collection methods are study design limitations decreasing generalisability of findings. These limitations will be acknowledged and discussed in the final reporting of the results.

### Contribution to practice and future research

This research has the potential to improve practice and contribute to future communication research in critical care. The participatory nature of codesign may increase

research and communication capacity among health-care professionals.<sup>32</sup> Evaluating the acceptability of an intervention prior to a resource intense adequately powered trial can help ensure the intervention and implementation strategy addresses real world challenges and is implementable.<sup>26 27</sup> The results of this study will inform the design of a future pilot study of an acceptable bundled communication intervention on patient reported outcomes (eg, anxiety, pain, satisfaction and ease of communication) in patients treated with mechanical ventilation in the adult ICU when infection control precautions are in place.

### Author affiliations

<sup>1</sup>Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, Ontario, Canada

<sup>2</sup>Provincial Centre for Excellence in Weaning, Toronto East Health Network Michael Garron Hospital, Toronto, Ontario, Canada

<sup>3</sup>Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care, King's College London, London, UK

<sup>4</sup>Critical Care and Lane Fox Respiratory Unit, Guy's and St Thomas' NHS Foundation Trust, London, UK

<sup>5</sup>Department of Speech Language Pathology, University of Toronto, Toronto, Ontario, Canada

<sup>6</sup>Toronto Rehabilitation Institute, Toronto, Ontario, Canada

<sup>7</sup>Tory Trauma Program, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada

**Twitter** Laura Istanbulian @laura\_lista and Craig M Dale @craig\_dale1

**Contributors** LI conceived and designed the study with advice from her supervision committee LR, YY and CMD. LI took the lead in drafting the study protocol manuscript, receiving input and feedback from LR, YY and CMD. All authors approved the final protocol manuscript.

**Funding** This study is supported by the Bertha Rosenstadt Health Research Fund, the Bluma Appel and Jeannie Butler Graduate Award in Nursing, the Mary Kathleen King Graduate Award, the Staples Family Graduate Student Award in Nursing, the TD Community Health Solutions Fund COVID-19 Research Grant, and the Canadian Nurses Foundation.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

### ORCID iDs

Laura Istanbulian <http://orcid.org/0000-0002-8831-587X>

Craig M Dale <http://orcid.org/0000-0002-5042-0332>

## REFERENCES

- 1 Happ MB, Seaman JB, Nilsen ML, *et al*. The number of mechanically ventilated ICU patients meeting communication criteria. *Heart Lung* 2015;44:45–9.
- 2 Menzel LK. Factors related to the emotional responses of intubated patients to being unable to speak. *Heart Lung* 1998;27:245–52.
- 3 Leung CCH, Pun J, Lock G, *et al*. Exploring the scope of communication content of mechanically ventilated patients. *J Crit Care* 2018;44:136–41.

- 4 Turnbull AE, Sahetya SK, Needham DM. Aligning critical care interventions with patient goals: a modified Delphi study. *Heart Lung* 2016;45:517–24.
- 5 Baumgarten M, Poulsen I. Patients' experiences of being mechanically ventilated in an ICU: a qualitative metasynthesis. *Scand J Caring Sci* 2015;29:205–14.
- 6 Guttormson JL, Bremer KL, Jones RM. "Not being able to talk was horrid": A descriptive, correlational study of communication during mechanical ventilation. *Intensive Crit Care Nurs* 2015;31:179–86.
- 7 Choi J, Campbell ML, Gélinas C, et al. Symptom assessment in non-vocal or cognitively impaired ICU patients: implications for practice and future research. *Heart Lung* 2017;46:239–45.
- 8 Radtke JV, Baumann BM, Garrett KL, et al. Listening to the voiceless patient: case reports in assisted communication in the intensive care unit. *J Palliat Med* 2011;14:791–5.
- 9 IJssennagger CE, Ten Hoorn S, Van Wijk A, et al. Caregivers' perceptions towards communication with mechanically ventilated patients: the results of a multicenter survey. *J Crit Care* 2018;48:263–8.
- 10 Istanbulian L, Rose L, Gorospe F, et al. Barriers to and facilitators for the use of augmentative and alternative communication and voice restorative strategies for adults with an advanced airway in the intensive care unit: a scoping review. *J Crit Care* 2020;57:168–76.
- 11 Ten Hoorn S, Elbers PW, Girbes AR, et al. Communicating with conscious and mechanically ventilated critically ill patients: a systematic review. *Crit Care* 2016;20:333.
- 12 Carruthers H, Astin F, Munro W. Which alternative communication methods are effective for voiceless patients in intensive care units? A systematic review. *Intensive Crit Care Nurs* 2017;42:88–96.
- 13 Happ MB, Garrett KL, Tate JA, et al. Effect of a multi-level intervention on nurse-patient communication in the intensive care unit: results of the SPEACS trial. *Heart Lung* 2014;43:89–98.
- 14 World Health Organization. Who coronavirus disease (COVID-19) Dashboard, 2021. Available: <https://covid19.who.int/>
- 15 McGrath BA, Ashby N, Birchall M, et al. Multidisciplinary guidance for safe tracheostomy care during the COVID-19 pandemic: the NHS national patient safety improvement programme (NatPatSIP). *Anaesthesia* 2020;75:1659–70.
- 16 Bhatraju PK, Ghassemieh BJ, Nichols M, et al. Covid-19 in Critically Ill Patients in the Seattle Region - Case Series. *N Engl J Med* 2020;382:2012–22.
- 17 Public Health Ontario. *IPAC recommendations for use of personal protective equipment for care of individuals with suspect or confirmed COVID-19*. Ontario, Canada: Public Health Ontario, 2020.
- 18 PIDAC. *Routine practices and additional precautions in all health care settings*. Ontario, Canada: Public Health Ontario, 2012.
- 19 Phua J, Weng L, Ling L, et al. Intensive care management of coronavirus disease 2019 (COVID-19): challenges and recommendations. *Lancet Respir Med* 2020;8:506–17.
- 20 Freeman-Sanderson A, Morris K, Elkins M. Characteristics of patient communication and prevalence of communication difficulty in the intensive care unit: an observational study. *Aust Crit Care* 2019;32:373–7.
- 21 Happ MB, Garrett K, Thomas DD, et al. Nurse-patient communication interactions in the intensive care unit. *Am J Crit Care* 2011;20:e28–40.
- 22 Mobasher MH, King D, Judge S, et al. Communication aid requirements of intensive care unit patients with transient speech loss. *Augment Altern Commun* 2016;32:261–71.
- 23 Happ MB, Sereika SM, Houze MP, et al. Quality of care and resource use among mechanically ventilated patients before and after an intervention to assist nurse-novocal patient communication. *Heart Lung* 2015;44:408–15.
- 24 Radtke JV, Tate JA, Happ MB. Nurses' perceptions of communication training in the ICU. *Intensive Crit Care Nurs* 2012;28:16–25.
- 25 Trotta RL, Hermann RM, Polomano RC, et al. Improving Nonvocal critical care patients' ease of communication using a modified SPEACS-2 program. *J Healthc Qual* 2020;42:e1–9.
- 26 Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17:88.
- 27 Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new medical Research Council guidance. *Int J Nurs Stud* 2013;50:587–92.
- 28 Ando H, Cousins R, Young C. Achieving saturation in thematic analysis: development and refinement of a codebook. *Comprehensive Psychology* 2014;3:03.CP.3.4–7.
- 29 Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res* 2005;15:1277–88.
- 30 Bengtsson M. How to plan and perform a qualitative study using content analysis. *NursingPlus Open* 2016;2:8–14.
- 31 Donetto S, Pierri P, Tsianakas V, et al. Experience-Based co-design and healthcare improvement: Realizing participatory design in the public sector. *The Design Journal* 2015;18:227–48.
- 32 Slattery P, Saeri AK, Bragge P. Research co-design in health: a rapid overview of reviews. *Health Res Policy Syst* 2020;18:17.
- 33 Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. *Health Serv Res* 2013;48:2134–56.
- 34 Creswell JW, Plano Clark VL. *Designing and conducting mixed methods research*. Third ed. Thousand Oaks, California: SAGE Publications, 2018.
- 35 Borgert MJ, Goossens A, Dongelmans DA. What are effective strategies for the implementation of care bundles on ICUs: a systematic review. *Implement Sci* 2015;10:119.
- 36 Rose L, Haslam L, Dale C, et al. Survey of assessment and management of pain for critically ill adults. *Intensive Crit Care Nurs* 2011;27:121–8.
- 37 Burns KEA, Duffett M, Kho ME, et al. A guide for the design and conduct of self-administered surveys of clinicians. *CMAJ* 2008;179:245–52.
- 38 Sample size calculator for estimating a single proportion. Available: <http://statulator.com/SampleSize/ss1P.html>
- 39 Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci* 2017;12:108.