





BMJ Open Core socioDemographic data variables in ICU Trials (CoDe-IT): a protocol for generating core data variables using a Delphi consensus process

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ABSTRACT

Introduction Sociodemographic variables influence health outcomes, either directly (ie, gender identity) or indirectly (eg, structural/systemic racism based on ethnoracial group). Identification of how sociodemographic variables can impact the health of critically ill adults is important to guide care and research design for this population. However, despite the growing recognition of the importance of collecting sociodemographic measures that influence health outcomes, insufficient and inconsistent data collection of sociodemographic variables persists in critical care studies. We aim to develop a set of core data variables (CoDaV) for social determinants of health specific to studies involving critically ill adults.

Methods and analysis We will conduct a scoping review to generate a list of possible sociodemographic measures to be used for round 1 of the modified Delphi processes. We will engage relevant knowledge users (previous intensive care unit patients and family members, critical care researchers, critical care clinicians and research co-ordinators) to participate in the modified Delphi consensus survey to identify the CoDaV. A final consensus meeting will be held with knowledge user representatives to discuss the final CoDaV, how each sociodemographic variable will be collected (eg, level of granularity) and how to disseminate the CoDaV for use in critical care studies.

Ethics and dissemination The University of Calgary conjoint health research ethics board has approved this study protocol (REB22-1648).

INTRODUCTION

Research shows that sociodemographic variables such as gender identity, race and ethnicity and socioeconomic status can influence health outcomes.^{1 2} There is a lack of consistent reporting of sociodemographic variables in adult intensive care unit (ICU) studies. To evaluate the impact of sociodemographic variables on health outcomes of critically ill adults, key knowledge users must inform a set of core data variables (CoDaV) of sociodemographic measures that can influence health outcomes. Marginalised

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ We engaged a diverse group of knowledge users from study inception.
- ⇒ Patient and family partners with lived intensive care unit (ICU) experience and from equity-deserving groups were involved in the design of this research.
- ⇒ Multiple data sources will be used to inform statements that will be rated and ranked during the modified Delphi consensus process.
- ⇒ The findings from this study may not be generalisable to other contexts outside of the ICU or outside of Canada.

groups in critical care medicine have worse health outcomes.^{3 4} Moreover, insufficient recruitment and retention of marginalised populations in clinical trials⁵⁻⁸ limit evidence-based findings to improve quality of care and outcomes for these populations. Understanding social determinants of health (SDoH) across all critical care clinical research requires representation of marginalised populations in clinical trials, as well as robust and standardised data collection of sociodemographic variables.

Despite the growing recognition of the importance of sociodemographic variables in clinical trials, sociodemographic characteristics of study populations are underreported in randomised controlled trials and observational studies.⁹ The most commonly reported sociodemographic variables include sex or gender identity (generally reported as binary variables) and race and ethnicity.⁹ Establishing a set of CoDaV is one strategy to encourage robust data collection of sociodemographic variables perceived to influence health outcomes of critically ill adults. While core outcome sets are commonly developed using the Delphi consensus method, such as

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for delirium prevention and management¹⁰ and for survivors of acute respiratory distress syndrome,¹¹ the modified Delphi process in this case will be used to identify core sociodemographic variables in critical care medicine.

Aims and objective

We aim to develop an evidence-informed and knowledge-user-informed standardised catalogue of sociodemographic variables that would be reported, at minimum, in all Canadian-led ICU critical care clinical trials and observational studies.

METHODS AND ANALYSIS

This protocol is registered online with the Open Science Framework (<https://osf.io/6da5m/>). Our study steering committee includes members of Equity, Diversity, and Inclusion and Patient and Family Partnership committees of the Canadian Critical Care Trials Group (CCCTG) reflecting diversity of age, gender identity, race and profession (past ICU patients and family members, critical care medicine researchers, clinicians and research co-ordinators).

Scope

The scope of the sociodemographic core variables set will specifically apply as follows:

1. Health condition: critical illness requiring treatment in an ICU.
2. Population: adult patients (≥ 16 years of age) admitted to an ICU.
3. Interventions: Any/no intervention/comparator (ie, for any study design).
4. Context: Primarily for adoption in Canadian critical care research and clinical trials evaluating the impact of SDoH. This includes, but is not restricted to, randomised controlled trials and observational cohort studies.

Knowledge users

The participant panel will comprise representatives from four key knowledge user groups: former ICU patients and family members, critical care researchers, critical care clinicians and research co-ordinators. There is currently no standard on the optimal panel size to achieve consensus when using a modified Delphi technique.¹² We will aim to recruit approximately 20 participants representing each knowledge user group (80 participants in total). We will oversample for the first round based on an estimated attrition of 30% across rounds. Letters of invitation to participate will be emailed to relevant organisations (see below) for each knowledge user group. The letter will outline the study, anticipated timelines, estimated time commitment and request for consent to participate. We will use maximum variability sampling to ensure diversity in the cohort and selectively recruit based on demographics to fill any gaps.

A range of expertise is an important quality criterion for the development of CoDaVs. We will seek to include representatives from four key knowledge user groups who would be interested in the CoDaV. This includes the following groups:

1. Former ICU patients and family members: This group of knowledge users will include patients or families who have been admitted to an adult ICU. We will aim to recruit across equity deserving groups (eg, race, gender identity, economic strata). This will include, but is not be limited to, recruiting from the patient partners who are part of patient-centred and family-centred care or advisory committees or are engaged with research programmes led by CCCTG members. This group will be recruited by emailing CCCTG members to ask if their patient partner would like to participate in this research programme. A limitation of existing patient and family partnerships is a lack of diversity. We will seek new partnerships and try to engage at the bedside if we see there is an unfilled gap in representation across a certain group/strata. We will follow the recent Trial Forge Guidance to ensure recruitment of equity deserving groups, which includes the following: (1) ensure recruitment strategies do not limit participation in ways we do not intend (eg, widen the recruitment settings, translate study materials into the top five languages spoken in Canada); (2) ensure recruitment materials are developed with inclusion in mind; (3) ensure staff are culturally competent; and (4) build trusting partnerships with community organisations that work with ethnic minority groups. ICU patients and family partners are important knowledge users to engage in the development of this CoDaV because they can provide their perspective on what might be the important sociodemographic variables for patients and/or families. While it may be important to report ethnicity/race in studies to understand health disparities and potential differences in treatment outcomes, it will be imperative to ensure this group of knowledge users includes representation from equity deserving groups to avoid unintended consequences of the CoDaV such as reinforcing stereotypes, oversimplifying/misinterpreting findings, disregarding intersectionality, perpetuating health disparities and excluding other important factors.
2. Critical care researchers: A critical care researcher will be defined as someone who holds an academic or clinical appointment or is an individual who conducts research under the supervision of an independent researcher (eg, graduate student, postdoctoral fellow, post-health professional degree fellow) and has at least one publication related to adult critical care. This group will be recruited from national professional organisations relevant to critical care (CCCTG), through snowball sampling, and identified from a systematic search of publications of Canadian-led ICU trials in PubMed and clinicaltrials.gov over the last 10 years. Critical care researchers are important knowledge users.

ers to include in the development of this CoDaV for their expertise on critical care outcomes and research data collection.

3. Critical care clinicians: A critical care clinician will include clinicians (ie, physicians, registered nurses, registered respiratory therapists) and allied healthcare professionals (eg, physical therapists, occupational therapists, speech and language pathologists, social workers) who have a primary role in a Canadian adult ICU and a minimum of 2 years' experience post their first clinical degree. We will ensure representations from community and academic centres. Clinicians will be recruited from national professional organisations relevant to critical care (eg, Canadian Critical Care Society (CCCS), CCCTG, Canadian Association of Critical Care Nurses (CACCN), Canadian Society of Respiratory Therapists (CSRT)). Critical care clinicians are at the bedside and have experience of what sociodemographic variables may influence the health outcomes of critically ill adults and are engaged knowledge users in which data could be helpful to improve equity in the care of critically ill adults and their families.
4. Research co-ordinators: Research co-ordinators will include research professionals responsible for conducting clinical trials in a Canadian ICU (eg, research assistants, clinical research co-ordinators) and have at least 2 years of work experience in critical care. Research co-ordinators will be recruited through the Canadian Critical Care Research Coordinators Group (CCCRCG) and through snowball sampling from CCCTG-sponsored trials. Research co-ordinators are important to include because they are recruiting critically ill adult populations for participation in studies and recognise the barriers and facilitators to engaging minoritised participants. This often includes collecting relevant sociodemographic data for ICU studies.

Information sources

A list of possible sociodemographic measures will be generated from six sources: (1) a published review of PubMed for critical care randomised trials (2010–2021)¹³; (2) a scoping review of demographic variables reported in Canadian-led studies conducted with a critically ill adult population, from January 2012; (3) a search of high impact critical care (*Intensive Care Medicine*, *American Journal of Respiratory Critical Care Medicine*, *Critical Care Medicine*, *Critical Care* and *CHEST*) and general medicine journal (*NEJM*, *The Lancet*, *JAMA*) websites for special issues relating to equity for sociodemographic variables associated with patient outcomes; (4) a search of the sociodemographic variables collected by the Canadian and provincial governments, institutions, organisations, CCCTG paediatric group (eg, universities, funding bodies) and selected international organisations (eg, National Institutes of Health, Athena Scientific Women's Academic Network); (5) variables mandated by high impact journals (eg, *Canadian Medical Association Journal (CMAJ)* and *NEJM*)^{14 15}; and (6) the Canadian Institute for Health Information.¹⁶ These will establish an initial comprehensive list of sociodemographic variables for round 1 of the modified Delphi consensus survey tailored to the Canadian setting.

We will conduct the scoping review using Arksey and O'Malley's methodological framework.¹⁷ The scoping review will be reported using the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for Scoping Reviews (online supplemental table 1).¹⁸ We will search MEDLINE, Embase and CINAHL for Medical Subject Headings (MeSH) terms related to the setting (ICU) and region (ie, Canadian provinces and territories) from January 2012. Studies published prior to 2012 will be excluded, as this review aims to identify a comprehensive and contemporary list of variables and terms currently used in Canadian critical care studies. The

Table 1 MEDLINE search strategy

Population	Canadian context
1. Critical care/ or Critical Illness/ or Intensive care units/ or ((intensive or critical or acute) adj2 (care* or therap*)).mp	6. Exp Canada/
2. (ICU* or ITU* or GICU* or CCU*).mp	7. (canad* or alberta or british columbia or colombie britannique or saskatchewan or manitoba or ontario or quebec or new brunswick or nouveau brunswick or nova scotia or nouvelle ecosse or prince edward island or ile du prince edward or PEI or newfoundland or terre neuve or labrador or nun\$vt\$ or territoires du nord ouest or northwest territories or nwt or yukon or ontario).mp.
3. ((critical* or severe or catastrophic* or acute*) adj2 (ill* or sick* or ail*)).mp	8. (edmonton or calgary or vancouver or victoria or prince george or kelowna or winnipeg or st* john?s or halifax or saint john or hamilton or waterloo or st catharines or sudbury or thunder bay or kingston or windsor or ottawa or toronto or mississauga or quebec city or montreal or trois?rivieres or sherbrooke or chicoutimi or moncton or saskatoon or western university).mp
4. ((critical* or severe or catastrophic* or acute*) adj2 (ill* or sick* or ail*)).mp	9. Or/6–8
5. Or/1–4	10. 5 and 9
	11. limit 10 to yr="2012 -Current"

Table 2 Eligibility criteria

Inclusion criteria	Exclusion criteria
<ol style="list-style-type: none"> 1. Study design: Any original, published study including randomised controlled trials (RCTs) and quasi RCTs, observational cohort studies (prospective/retrospective) and biobanking studies (if stand alone and not associated with a clinical trial manuscript) where social determinants of health could be linked with outcomes. 2. Language: Study is published in English or French. 3. Population of interest: Study includes adult ICU patients. 4. Country of origin: Study is Canadian led. The study can include sites from other countries but will be excluded unless the study is led or co-led by a Canadian investigative team (eg, corresponding author is Canadian). 5. Outcome of interest: Study reports participant sociodemographic information (eg, age, sex, gender identity, race/ethnicity, educational attainment, employment, etc). 	<ol style="list-style-type: none"> 1. Ineligible study design: We will exclude study protocols that do not report results, cross-sectional survey studies, secondary analyses of a study, cross-sectional studies, systematic reviews, scoping reviews, narrative reviews, editorials and opinion pieces, letters to the editor and conference abstracts. 2. Incorrect language: Study only available in a language other than English or French. 3. Ineligible study population: Study did not enrol adult ICU patients. 4. Incorrect country of origin: Study conducted solely outside of Canada. 5. No mention of outcome of interest: Study does not report any participant's sociodemographic information.

ICU, intensive care unit.

search strategy is adapted from a related study conducted by CCTG members (table 1).¹³ The full search strategies are available in online supplemental tables 2–4.

The results of the search will be combined and deduplicated in Covidence systematic review software (Veritas Health Innovation, Melbourne, Victoria, Australia) for title/abstract and full-text screening. Prior to title/abstract screening, 25 randomly selected articles will be screened by researchers, applying the inclusion/exclusion criteria. Any disagreements will be resolved through discussion. Following this pilot test, two researchers will independently screen titles/abstracts in duplicate. Any title/abstract included by at least one researcher will advance to full-text screening. Studies will be included if they meet the following criteria: (1) any original, published study (eg, randomised controlled trials, prospective or retrospective cohort studies, where SDoH could be linked with outcomes); (2) published in English or French; (3) includes adult ICU patients; (4) led or co-led by a Canadian investigative team (eg, corresponding author is Canadian); and (5) reports participant demographics. Complete inclusion/exclusion criteria are included in table 2.

Two researchers will screen full-text articles independently and in duplicate. Disagreements on whether to include articles will be resolved through discussion or by a third reviewer. Reference lists of included articles will be reviewed to identify additional studies. One researcher will extract data, which will include study characteristics (title, year of publication, journal, funding source, study design, stated objective, study date range, sample size, number of participating centres, regulatory information) and demographic variables. A second researcher will review the data for accuracy and omissions. In keeping with the descriptive objectives of this scoping review, we have not planned any quantitative summary analyses and will not complete critical appraisals of included studies.¹⁹

Sociodemographic variables will be sorted into eight domains using the PROGRESS-Plus health equity framework.²⁰ PROGRESS includes social variables that influence health outcomes: Place of residence, Race/ethnicity/culture/

language, Occupation, Gender identity, Religion, Education, Socioeconomic status and Social capital. 'Plus' includes three additional categories: (1) personal characteristics associated with discrimination (eg, age, frailty, disability); (2) features of relationships (eg, relationships that impact an individual's ability to assert their autonomy and self-manage such as social capital (eg, marital status, community networks, professional networks)); and (3) time-dependent relationships (eg, times of transitions where an individual may face increased risks for poor health management such as discharge from hospital).

Consensus process

We will conduct a modified Delphi consensus process for CoDaV development (flow of CoDaV development shown in figure 1). The modified Delphi consensus process will be informed by the RAND/University of California, Los Angeles (UCLA) appropriateness method²¹ and reported according to the conducting and reporting Delphi studies reporting guidelines.²² The modified Delphi consensus survey is a preferred method for CoDaV development because it is electronic (ie, panellists from across Canada can participate) and will allow participants to provide their anonymous views without influence from other panellists.¹²

We will use an online survey tool (Qualtrics, Provo, Utah, USA) to administer the survey. All surveys and participant-facing materials (ie, emails, informed consent forms, social media materials) will be developed and pilot-tested with eight individuals (two from each knowledge user group) prior to commencing the formal modified Delphi consensus survey to assess its flow, salience, acceptability and administrative ease.²³ Individuals will identify survey questions that are redundant, perceived as irrelevant or are poorly worded. Information obtained from pilot testing will be used to improve the survey. Surveys will be available in the five most commonly spoken languages in Canada after English/French: Mandarin, Punjabi, Yue (Cantonese), Spanish and Arabic.²⁴

During round 1, we will collect self-reported demographic data (ie, pronouns, age, sex, gender identity, race and

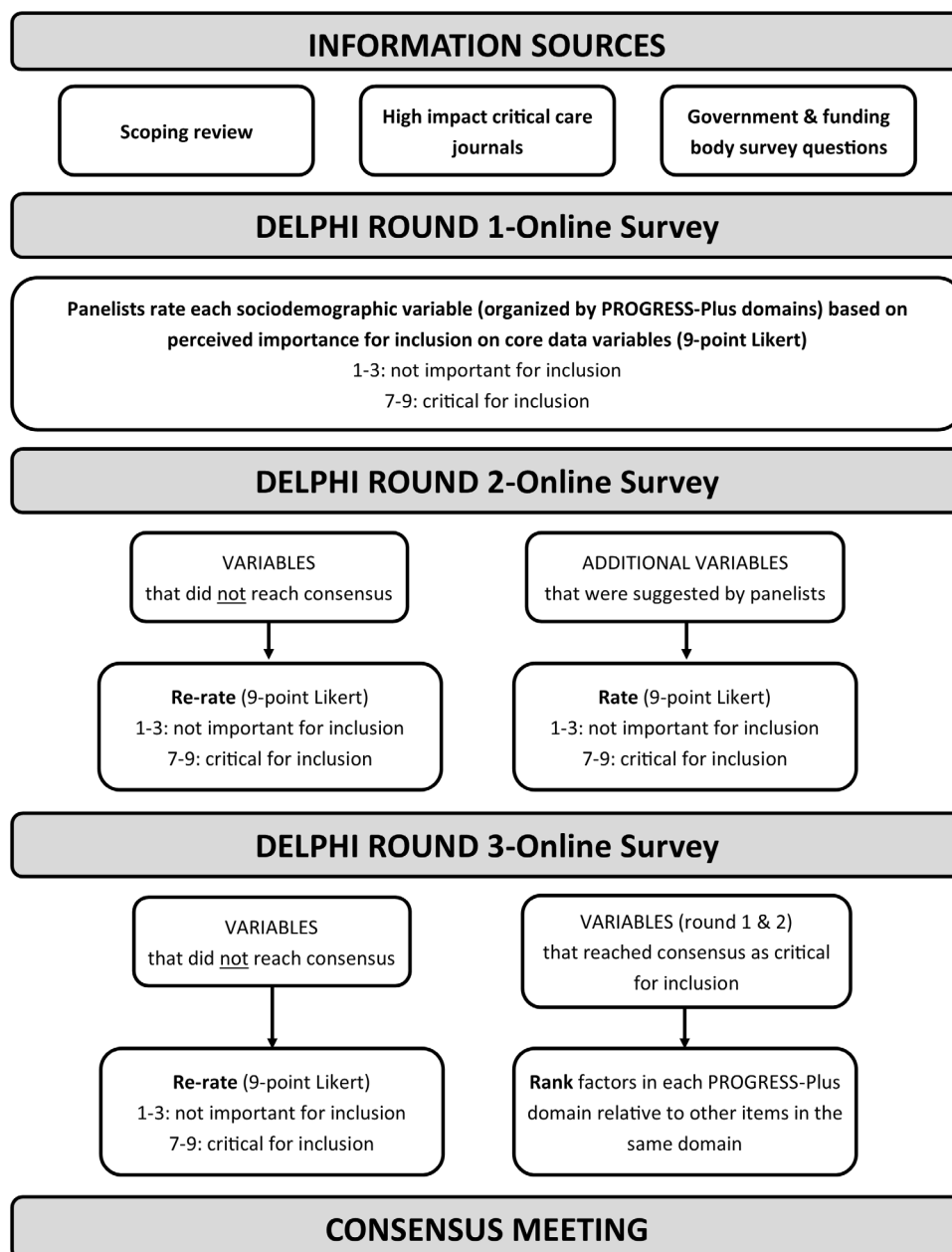


Figure 1 Description of the methods used to generate a set of core data variables for collection of sociodemographic measures in adult critical care trials. We will conduct a scoping review to generate an initial list of sociodemographic variables relevant to adult critical care research. This will be followed by three rounds of the modified Delphi consensus process to determine a core set of sociodemographic variables. This includes steps to rate (based on importance of individual variables) and rank (order or importance relative to other items in the same domain). All rounds will include panellists who are past intensive care unit (ICU) patients and family members, critical care medicine researchers, clinicians and research co-ordinators. Our methodology integrates knowledge translation by involving a diverse panel including past ICU patients and family members, critical care medicine researchers, clinicians and research co-ordinators. PROGRESS-Plus means social variables that influence health outcomes: Place of residence, Race/ethnicity/culture/language, Occupation, Gender identity, Religion, Education, Socioeconomic status and Social capital. 'Plus' includes three additional categories: (1) personal characteristics associated with discrimination (eg, age, frailty, disability); (2) features of relationships (eg, relationships that impact an individual's ability to assert their autonomy and self-manage such as social capital (eg, marital status, community networks, professional networks)); and (3) time-dependent relationships (eg, times of transitions where an individual may face increased risks for poor health management such as discharge from hospital).

ethnicity, visible minority, language, province of residence, role, duration of clinical and/or research experience, involvement in critical care research) to describe the panellists. We will then ask each panellist to rate each sociodemographic

variable (based on perceived importance for inclusion in the CoDaV) on a 9-point Likert scale (wherein 1–3: not important for inclusion; 4–6: important but not critical; 7–9: critical for inclusion). To avoid presentation bias, we

will randomise the sequence of presentation of the sociodemographic domains for each panellist. There will also be an opportunity for panellists to suggest additional sociodemographic variables or make comments using a free-text box after each domain. We will send three completion reminders at 1-week intervals.

We will define consensus for any sociodemographic factor a priori as a median score of 1–3 (not important for inclusion), 4–6 (important but not critical for inclusion) or 7–9 (critical for inclusion). Sociodemographic variables that are deemed not important for inclusion (ie, median score of 1–3) will be removed. Additional measures suggested during round 1 will be independently reviewed and coded by two study team members to ensure they represent new variables; any disagreements will be reviewed by a third study team member. The steering group will review and approve any additional variables and ensure the wording will be understandable by all panellists. We will email each panellist with a summary of the aggregated responses from all knowledge user groups 1 week prior to sending the round 2 survey.

During round 2, panellists will rate sociodemographic variables that did not meet consensus during round 1 and any new measures identified from round 1 on a scale from 1 to 9 (1–3: not important for inclusion; 4–6: important but not critical; 7–9: critical for inclusion). As with round 1, we will send three completion reminders at 1-week intervals. If there is substantial attrition (ie, loss of more than 30% of participants from a knowledge user group), we will recruit additional knowledge users for round 2. As with round 1, we will email each panellist with a summary of aggregated round 2 responses from all knowledge user groups 1 week prior to sending the round 3 survey.

Round 3 will be conducted for items that did not reach consensus from round 2. In addition, panellists will be asked to rank (based on order of importance relative to other items in the same PROGRESS-Plus domain) the items that reached consensus as critical for inclusion (ie, median score of 7–9 from rounds 1 and 2). Given that each PROGRESS-Plus domains will have an unequal number of items, items will be assessed to be a priority item if the item's mean ranking was ≥ 1 SD above the domain's mean ranking. For example, if a domain has a mean of 20.0 and a SD of 2.2, items with a mean score greater than 22.2 will be considered priority items.

Maximising panel member participation

To minimise attrition, we will use strategies reported to be effective in related studies,^{25 26} which include personalised invitations, collection of robust contact information (<http://www.improvelto.com/participant-contact-information-sheet>), regular reminders about survey completion (reminder emails, followed by telephone calls and text messages), summary of results (between Delphi rounds) and a unique identifier for each participant to monitor survey completion.

Consensus meeting

Following completion of the modified Delphi, we will invite representatives from each knowledge user group from the Delphi panellists, members from each of the key critical care organisations in Canada (CCCTG, CCCS, CSRT, CCCRCG), representatives from a research ethics board, representatives from the Canadian Institutes of Health Research and editors from high impact Canadian medical journals (eg, *CMAJ*, *Canadian Journal of Anesthesia*) to hybrid (ie, in-person or virtual) consensus meeting. We will recruit a total of 40 panellists, ensuring they represent a diverse group of individuals and include panellists with lived experience or a strong equity, diversity, inclusion and indigeneity lens. The purpose of the consensus meeting is to: (1) reach consensus on the core sociodemographic measures set; (2) determine how each sociodemographic variable in the CoDaV should be measured (eg, level of granularity); and (3) discuss dissemination of the CoDaV, which includes accompanying guidance on *how* to use the CoDaV (to prevent aforementioned unintended consequences). Research team members with participant-facing roles in this meeting (eg, facilitating breakout sessions) will have completed trauma-informed care training per Substance Abuse and Mental Health Services Administration's trauma informed approach.^{27 28} A report from this meeting will be written and published.

Patient and public involvement

Past ICU patients were involved in the design, conduct, reporting and dissemination plans of our research.

ETHICS AND DISSEMINATION

The current study protocol has received approval from the University of Calgary conjoint health research ethics board (REB22-1648). Participants will be recruited through professional groups, societies and organisations (CCCS, CCCTG, CCCRCG, CACCN, CSRT) and through social media posts (eg, Twitter). Participants will contact study team members in response to recruitment emails from professional societies and social media. Each participant will receive an information sheet on the objective of the study and expected time commitments and an informed consent form. Participation in Delphi surveys or the consensus meeting will imply consent to participate.

We will disseminate our findings through peer-reviewed and open access publications and presentations at national conferences. We will also create an infographic and lay summary and disseminate the CoDaV and its accompanying guidance on its use to key organisations for distribution among their networks and through social media posts (eg, X/Twitter, Reddit). We will engage with journal editors and funding bodies to promote awareness of the CoDaV.

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Contributors KDK, FS, AH, SME and KF planned and designed the study. JCM, KEAB, SK, CM, SMu, KO'H and KR provided advice and guidance. KDK and FS drafted the manuscript with all authors reviewing and subsequently reviewing the final draft. KF is the guarantor.

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