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Complete List of Authors:	Krewulak, Karla; University of Calgary Cumming School of Medicine, Critical Care Medicine Sheikh, Fatima; McMaster University, Health Research Methods, Evidence, and Impact Heirali, Alya; University of Calgary, Department of Critical Care Medicine Marshall, John; University of Toronto, Department of Surgery Burns, Karen; University of Toronto, Interdepartmental Division of Critical Care Medicine; Unity Health Toronto, Department of Critical Care Medicine Kupsch, Scotty; University of Calgary Cumming School of Medicine, Critical Care Medicine Maratta, Christina; University of Toronto, Department of Paediatrics Murthy, Srinivas; University of British Columbia, Paediatrics O'Hearn, Katie; Children's Hospital of Eastern Ontario Research Institute, Research Russell, Kristine; University of Calgary Cumming School of Medicine, Critical Care Medicine Mehta, Sangeeta; University of Toronto Fiest, Kirsten; University of Calgary, Department of Critical Care Medicine; University of Calgary, Department of Community Health Sciences
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Core SocioDemographic data variables in ICU Trials (CoDe-IT): A protocol for generating core data variables using a Delphi consensus process

Karla D Krewulak[1*], Fatima Sheikh[2*], Alya Heirali [1], John C Marshall[3], Karen EA Burns[4,5], Scotty Kupsch[1], Christina Maratta[6], Srinivas Murthy[7], Katie O'Hearn[8], Kristine Russell[1], Sangeeta Mehta[9,10], Kirsten M Fiest[1,11,12], Canadian Critical Care Trials Group

1. Department of Critical Care Medicine, Alberta Health Services & University of Calgary, Calgary, AB, Canada
2. Department of Health Research Methods, Evidence and Impact, McMaster University, Hamilton, ON, Canada
3. Department of Surgery, University of Toronto, Toronto, ON, Canada
4. Li Ka Shing Knowledge Institute, St. Micheal's Hospital, Toronto, ON, Canada
5. Interdepartmental Division of Critical Care, University of Toronto, Toronto, ON, Canada
6. Inter-Departmental Division of Critical Care Medicine, Department of Paediatrics, and Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, ON, Canada
7. Division of Critical Care, Department of Pediatrics, Faculty of Medicine, University of British Columbia, Vancouver, BC, Canada
8. Children's Hospital of Eastern Ontario Research Institute, Ottawa, ON, Canada
9. Department of Medicine, Sinai Health System, Toronto, ON, Canada
10. Interdepartmental Division of Critical Care Medicine, University of Toronto, Toronto, ON, Canada.
11. Department of Community Health Sciences & O'Brien Institute for Public Health, University of Calgary, Calgary, AB, Canada
12. Department of Psychiatry & Hotchkiss Brain Institute, University of Calgary, Calgary, AB, Canada

*Co first authors

Corresponding author: Dr. Kirsten Fiest

Department of Critical Care Medicine

University of Calgary

Calgary, AB, Canada

kmfiest@ucalgary.ca

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ABSTRACT:

Introduction: Sociodemographic variables influence health outcomes, either directly (i.e., gender identity) or indirectly (e.g., structural/systemic racism based on ethno-racial 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 (SDoH) 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 one of the Delphi processes. We will engage relevant knowledge users (previous ICU patients and family members, critical care researchers, critical care clinicians and research coordinators) to participate in the 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 (e.g., level of granularity), and how to disseminate the CoDaV for use in critical care studies.

Ethics and dissemination: The University of Calgary Conjoint Research Ethics Board has approved this study protocol (REB22-1648).

Open Science Framework registration number: https://osf.io/6da5m/

Strengths and limitations of this study:

- There are currently no standard sets of sociodemographic variables to ensure robust data collection and representation of social determinants of health in clinical trials involving critically ill adults
- We engaged a diverse group of knowledge users from study inception
- Patient and family partners with lived 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 generalizable to other contexts outside of the intensive care unit or outside of Canada

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. Marginalized groups in critical care medicine have worse health outcomes (3, 4). Moreover, insufficient recruitment and retention of marginalized populations in clinical trials (5-8) limits 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 marginalized populations in clinical trials, as well as robust and standardized 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 randomized 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 for delirium prevention and management (10), and for survivors of acute respiratory distress syndrome (11), the 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- and knowledge-user-informed standardized 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 is comprised of members reflecting diversity of age, gender identity, race, profession, etc., including members of the Canadian Critical Care Trials Group (CCCTG) Equity, Diversity, Indigeneity, and Inclusion (EDII) and Patient and Family Partnership committees.

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 (i.e., for any study design)
4. Context: Primarily for adoption in Canadian critical care research and clinical trials evaluating the impact of social determinants of health. This includes, but is not restricted to, randomized controlled trials, observational cohort studies, etc.

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 coordinators. 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 organizations (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. Past 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 (e.g., race, gender identity, economic strata). This will include recruiting from the patient partners who are part of patient and family-centered care or advisory committees or are engaged with research programs 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 program. A limitation of existing patient and family partnerships is a lack of diversity. 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 (e.g., 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; 4) build trusting partnerships with community organizations 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 patient- and/or family-important sociodemographic variables. 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 (e.g., 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 organizations 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 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 (i.e., physicians, registered nurses, registered respiratory therapists), and allied healthcare professionals (e.g., physical therapists, occupational therapists, speech and language pathologists, social workers) who have a primary role in a Canadian adult ICU and a minimum of two years experience post their first clinical degree. We will ensure representations from community and academic centers. Clinicians will be recruited from national professional organizations relevant to critical care (e.g., 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 Coordinators: Research coordinators will include research professionals responsible for conducting clinical trials in a Canadian ICU (e.g., research assistants, clinical research coordinators) and have at least two years of work experience in critical care. Research Coordinators will be recruited through the Canadian Critical Care Research Coordinators Group (CCCRCG) and through snowball sampling from CCCTG-sponsored trials. Research coordinators are important to include because they are recruiting critically ill adult populations for participation in studies and recognize the barriers and facilitators to engaging minoritized participants. This often includes collecting relevant sociodemographic data for ICU studies.

Information sources

A list of possible sociodemographic measures will be generated from four sources: 1) a published review of PubMed for critical care randomized trials (2010 to 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 journals) 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, organizations, CCCTG pediatric group, etc. (e.g., universities, funding bodies) and select international organizations (e.g., National Institutes of Health [NIH], Athena Scientific Women's Academic Network); 5) variables mandated by high impact journals (e.g., Canadian Medical Association Journal [CMAJ] and NEJM) (14, 15), and 6) the Canadian Insititute for Health Information "Guidance on the Use of Standards for Race-based and Indigenous Identity

Data")(16). These will establish an initial comprehensive list of sociodemographic variables for round 1 of the 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 (PRISMA-ScR)(18)(**Supplementary Table 1**). We will search MEDLINE, EMBASE, and CINAHL for MeSH terms related to the setting (ICU) and region (i.e., Canadian provinces and territories) from January 2012. The search strategy is adapted from a related study conducted by CCCTG members (13)(**Table 1**).

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 2. (ICU* or ITU* or GICU* or CCU*).mp 3. ((critical* or severe or catastrophic* or acute*) adj2 (ill* or sick* or ail*)).mp 4. ((critical* or severe or catastrophic* or acute*) adj2 (ill* or sick* or ail*)).mp 5. Or/1-4	6. Exp Canada/ 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$v$t or territoires du nord ouest or northwest territories or nwt or yukon or ontario).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 9. Or/6-8 10. 5 and 9 11. limit 10 to yr="2012 -Current"

The results of the search will be combined and deduplicated in Covidence systematic review software (Veritas Health Innovation, Melbourne, VIC, 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 (e.g., randomized controlled trials, prospective or retrospective cohort studies, etc., where social determinants of health 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 (e.g., corresponding author is Canadian); and 5) Reports participant demographics. Complete inclusion/exclusion criteria are included in **Table 2**.

Table 2. Eligibility criteria

Inclusion Criteria	Exclusion Criteria
1. Study Design: Any original, published study including RCTs and quasi RCTs, observational cohort studies (prospective/restrospective), 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 (e.g., corresponding author is Canadian). 5. Outcome of Interest: Study reports participant sociodemographic information (e.g., age, sex, gender identity, race/ethnicity, educational attainment, employment etc.).	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 enroll 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 sociodemographic information.

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. The "Plus" includes three additional categories: 1) personal characteristics associated with discrimination (e.g., age, frailty, disability); 2) features of relationships (e.g., relationships that impact an individual's ability to assert their autonomy and self-manage such as social capital (e.g., marital status, community networks, professional networks); and 3) time-dependent relationships (e.g., 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 Delphi consensus process will be informed by the RAND-UCLA appropriateness method (21) and reported according to the Conducting and Reporting Delphi Studies reporting guidelines (22). The Delphi consensus survey is a preferred method for CoDaV development because it's electronic (i.e., panelists from across Canada can participate) and will allow participants to provide their anonymous views without influence from other panelists (12).

We will use an online survey tool (Qualtrics, Provo, UT) to administer the survey. All surveys will be developed and pilot-tested with eight individuals (two from each knowledge user group) prior to commencing the formal 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 (i.e., pronouns, age, sex, gender identity, race and ethnicity, visible minority, language, province of residence, role, duration of clinical and/or research experience, involvement in critical care research) to describe the panelists. We will then ask each panelist 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 randomize the sequence of presentation of the sociodemographic domains for each panelist. There will also be an opportunity for panelists 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 (i.e., 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

measures and ensure the wording will be understandable by all panelists. We will email each panelist with a summary of the aggregated responses from all knowledge user groups one week prior to sending the round 2 survey.

During round 2, panelists 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 (i.e., loss of more than 30% of a knowledge user group), we will recruit additional knowledge users for round 2. As with round 1, we will email each panelist with a summary of aggregated round 2 responses from all knowledge user groups one 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, panelists 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 (i.e., 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 equal to or greater than one standard deviation above the domain's mean ranking. For example, if a domain has a mean of 20.0 and a standard deviation of 2.2, items with a mean score greater than 22.2 will be considered priority items.

Maximizing panel member participation

To minimize attrition, we will use strategies reported to be effective in related studies (25, 26), which include personalized invitations, collection of robust contact information (http://www.improvelto.com/participant-contact-information-sheet), regular reminders about survey

completion (reminder e-mails, 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 Delphi, we will invite representatives from each knowledge user group from the Delphi panelists, members from each of the key critical care organizations 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 (e.g., CMAJ, Canadian Journal of Anesthesia) to hybrid (i.e., in-person or virtual) consensus meeting. We will recruit a total of 40 panelists, ensuring they represent a diverse group of individuals and include panelists 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 (e.g., 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 (e.g., facilitating break out sessions) will have completed trauma-informed care training per Substance Abuse and Mental Health Services Administration's (SAMHSA'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 organizations (CCCS, CCCTG, CCCRCG, CACCN, CSRT) and through social media posts (e.g., 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 organizations for distribution among their networks and through social media posts (e.g., X/Twitter, Reddit). We will engage with journal editors and funding bodies to promote awareness of the CoDaV.

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Competing interests: None declared.

Author Contributions: KK, FS, AH, SM, and KF planned and designed the study. JC, KB, SK, CM, SM, KO, and KR provided advice and guidance. KK and FS drafted the manuscript with all authors reviewing and subsequently reviewing the final draft.

Data statement: Data from this study will be made available upon a reasonable request to the corresponding author.

Patient and public involvement: Patient and family partners with experience with critical illness and the ICU environment were involved in the design of this research.

Figure legend:

Figure 1. Description of the methods used to generate a set of core data variables (CoDaV) 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 panelists who are past ICU patients and family members, critical care medicine researchers, clinicians, and research coordinators.

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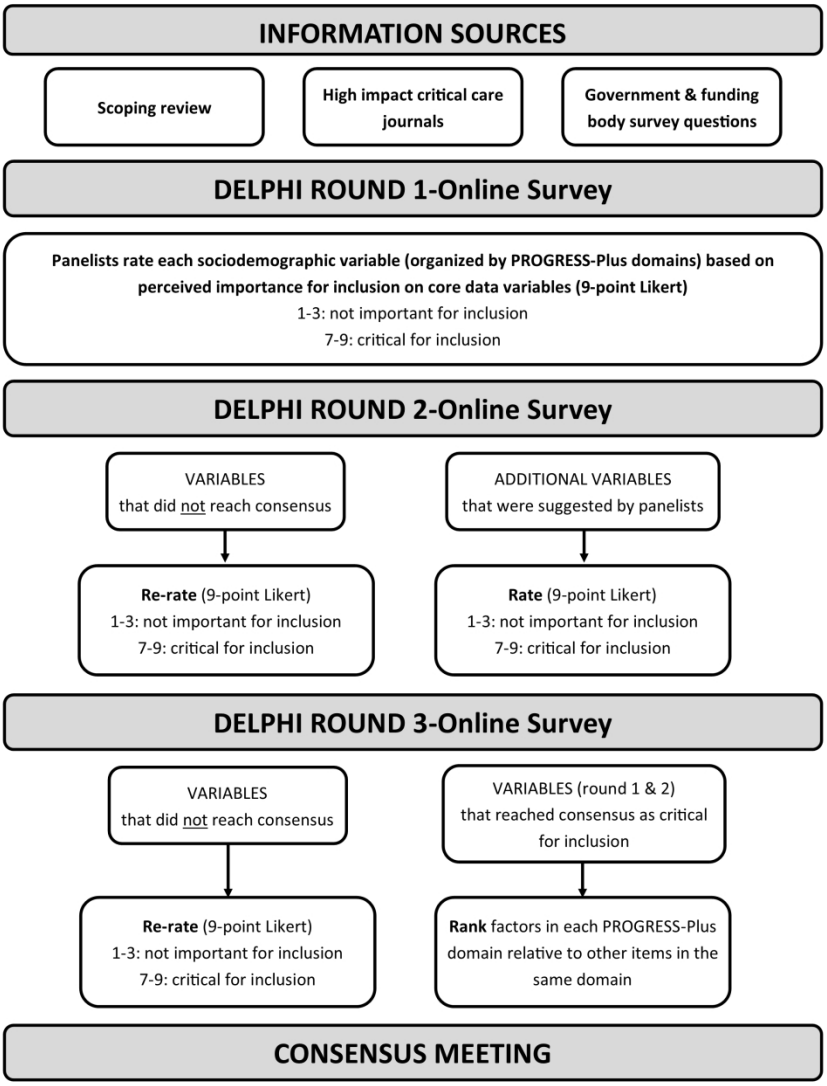

Description of the methods used to generate a set of core data variables (CoDaV) for collection of sociodemographic measures in adult critical care trials. We will conduct a scoping review to generate an initial list of sociodemographic variables relevant to adult critical care research. This will be 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 panelists who are past ICU patients and family members, critical care medicine researchers, clinicians, and research coordinators.

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Supplementary Table 1. Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	5
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	6
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	6
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	6
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	9
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	10, Table 1
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	10-11, Table 2
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	11-12
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	11-12
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	12
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	12

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	NA
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	NA
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	NA
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	NA
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	NA
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	NA
Limitations	20	Discuss the limitations of the scoping review process.	4
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	NA
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	16

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

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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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Complete List of Authors:	Krewulak, Karla; University of Calgary Cumming School of Medicine, Critical Care Medicine Sheikh, Fatima; McMaster University, Health Research Methods, Evidence, and Impact Heirali, Alya; University of Calgary, Department of Critical Care Medicine Marshall, John; University of Toronto, Department of Surgery Burns, Karen; University of Toronto, Interdepartmental Division of Critical Care Medicine; Unity Health Toronto, Department of Critical Care Medicine Kupsch, Scotty; University of Calgary Cumming School of Medicine, Critical Care Medicine Maratta, Christina; McGill University, Department of Pediatrics Murthy, Srinivas; University of British Columbia, Paediatrics O'Hearn, Katie; Children's Hospital of Eastern Ontario Research Institute, Research Russell, Kristine; University of Calgary Cumming School of Medicine, Critical Care Medicine Mehta, Sangeeta; University of Toronto Fiest, Kirsten; University of Calgary, Department of Critical Care Medicine; University of Calgary, Department of Community Health Sciences
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Core SocioDemographic data variables in ICU Trials (CoDe-IT): A protocol for generating core data variables using a Delphi consensus process

Karla D Krewulak[1*], Fatima Sheikh[2*], Alya Heirali [1], John C Marshall[3], Karen EA Burns[4,5], Scotty Kupsch[1], Christina Maratta[6,7], Srinivas Murthy[8], Katie O'Hearn[9], Kristine Russell[1], Sangeeta Mehta[10,11], Kirsten M Fiest[1,12,13]

1. Department of Critical Care Medicine, Alberta Health Services & University of Calgary, Calgary, AB, Canada
2. Department of Health Research Methods, Evidence and Impact, McMaster University, Hamilton, ON, Canada
3. Department of Surgery, University of Toronto, Toronto, ON, Canada
4. Li Ka Shing Knowledge Institute, St. Micheal's Hospital, Toronto, ON, Canada
5. Interdepartmental Division of Critical Care, University of Toronto, Toronto, ON, Canada
6. Division of Pediatric Critical Care, McGill University Health Centre, Montreal, QC, Canada
7. Department of Pediatrics, McGill University, Montreal, QC, Canada
8. Division of Critical Care, Department of Pediatrics, Faculty of Medicine, University of British Columbia, Vancouver, BC, Canada
9. Children's Hospital of Eastern Ontario Research Institute, Ottawa, ON, Canada
10. Department of Medicine, Sinai Health System, Toronto, ON, Canada
11. Interdepartmental Division of Critical Care Medicine, University of Toronto, Toronto, ON, Canada.
12. Department of Community Health Sciences & O'Brien Institute for Public Health, University of Calgary, Calgary, AB, Canada
13. Department of Psychiatry & Hotchkiss Brain Institute, University of Calgary, Calgary, AB, Canada

*Co first authors

Corresponding author: Dr. Kirsten Fiest

Department of Critical Care Medicine

University of Calgary

Calgary, AB, Canada

kmfiest@ucalgary.ca

Keywords: intensive care; clinical trials; social determinants of health

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ABSTRACT:

Introduction: Sociodemographic variables influence health outcomes, either directly (i.e., gender identity) or indirectly (e.g., structural/systemic racism based on ethno-racial 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 (SDoH) 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 one 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 coordinators) 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 (e.g., level of granularity), and how to disseminate the CoDaV for use in critical care studies.

Ethics and dissemination: The University of Calgary Conjoint Research Ethics Board has approved this study protocol (REB22-1648).

Open Science Framework registration number: https://osf.io/6da5m/

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 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 generalizable to other contexts outside of the intensive care unit or outside of Canada

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. Marginalized groups in critical care medicine have worse health outcomes (3, 4). Moreover, insufficient recruitment and retention of marginalized populations in clinical trials (5-8) limits 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 marginalized populations in clinical trials, as well as robust and standardized 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 randomized 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 for delirium prevention and management (10), 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- and knowledge-user-informed standardized 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 is comprised of members reflecting diversity of age, gender identity, race, and profession (past ICU patients and family members, critical care medicine researchers, clinicians, and research coordinators), including members of the Canadian Critical Care Trials Group (CCCTG) Equity, Diversity, and Inclusion (EDI) and Patient and Family Partnership committees.

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 (i.e., for any study design)
4. Context: Primarily for adoption in Canadian critical care research and clinical trials evaluating the impact of social determinants of health. This includes, but is not restricted to, randomized 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 coordinators. 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 organizations (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. Past 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 (e.g., race, gender identity, economic strata). This will include, but not be limited to, recruiting from the patient partners who are part of patient and family-centered care or advisory committees or are engaged with research programs 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 program. 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 (e.g., 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; 4) build trusting partnerships with community organizations 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 patient- and/or family-important sociodemographic variables. 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 (e.g., 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 organizations 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 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 (i.e., physicians, registered nurses, registered respiratory therapists), and allied healthcare professionals (e.g., physical therapists, occupational therapists, speech and language pathologists, social workers) who have a primary role in a Canadian adult ICU and a minimum of two years experience post their first clinical degree. We will ensure representations from community and academic centers. Clinicians will be recruited from national professional organizations relevant to critical care (e.g., 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 Coordinators: Research coordinators will include research professionals responsible for conducting clinical trials in a Canadian ICU (e.g., research assistants, clinical research coordinators) and have at least two years of work experience in critical care. Research Coordinators will be recruited through the Canadian Critical Care Research Coordinators Group (CCCRCG) and through snowball sampling from CCCTG-sponsored trials. Research coordinators are important to include because they are recruiting critically ill adult populations for participation in studies and recognize the barriers and facilitators to engaging minoritized participants. This often includes collecting relevant sociodemographic data for ICU studies.

Information sources

A list of possible sociodemographic measures will be generated from four sources: 1) a published review of PubMed for critical care randomized trials (2010 to 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 journals) 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, organizations, CCCTG pediatric group (e.g., universities, funding bodies) and select international organizations (e.g., National Institutes of Health [NIH], Athena Scientific Women's Academic Network); 5) variables mandated by high impact journals

(e.g., Canadian Medical Association Journal [CMAJ] and NEJM) (14, 15), and 6) the Canadian Insititute for Health Information "Guidance on the Use of Standards for Race-based and Indigenous Identity Data")(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 (PRISMA-ScR)(18)(**Supplementary Table 1**). We will search MEDLINE, EMBASE, and CINAHL for MeSH terms related to the setting (ICU) and region (i.e., 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 search strategy is adapted from a related study conducted by CCCTG members (13)(**Table 1**). The full search strategies are available in Supplementary Tables 2-4.

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 2. (ICU* or ITU* or GICU* or CCU*).mp 3. ((critical* or severe or catastrophic* or acute*) adj2 (ill* or sick* or ail*)).mp 4. ((critical* or severe or catastrophic* or acute*) adj2 (ill* or sick* or ail*)).mp 5. Or/1-4	6. Exp Canada/ 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$v$t or territoires du nord ouest or northwest territories or nwt or yukon or ontario).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 9. Or/6-8

	10. 5 and 9 11. limit 10 to yr="2012 -Current"

The results of the search will be combined and deduplicated in Covidence systematic review software (Veritas Health Innovation, Melbourne, VIC, 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 (e.g., randomized controlled trials, prospective or retrospective cohort studies, where social determinants of health 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 (e.g., corresponding author is Canadian); and 5) Reports participant demographics. Complete inclusion/exclusion criteria are included in **Table 2**.

Table 2. Eligibility criteria

Inclusion Criteria	**Exclusion Criteria**
1. Study Design: Any original, published study including RCTs and quasi RCTs, observational cohort studies (prospective/restrospective), 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 (e.g., corresponding author is Canadian). 5. Outcome of Interest: Study reports participant sociodemographic information	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 enroll 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 sociodemographic information.

(e.g., age, sex, gender identity, race/ethnicity, educational attainment, employment etc.).	

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. The "Plus" includes three additional categories: 1) personal characteristics associated with discrimination (e.g., age, frailty, disability); 2) features of relationships (e.g., relationships that impact an individual's ability to assert their autonomy and self-manage such as social capital (e.g., marital status, community networks, professional networks); and 3) time-dependent relationships (e.g., 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-

UCLA appropriateness method (21) and reported according to the Conducting and Reporting Studies reporting guidelines (22). The modified Delphi consensus survey is a preferred method for CoDaV development because it's electronic (i.e., panelists from across Canada can participate) and will allow participants to provide their anonymous views without influence from other panelists (12).

We will use an online survey tool (Qualtrics, Provo, UT) to administer the survey. All surveys and participant-facing materials (i.e., 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 (i.e., pronouns, age, sex, gender identity, race and ethnicity, visible minority, language, province of residence, role, duration of clinical and/or research experience, involvement in critical care research) to describe the panelists. We will then ask each panelist 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 randomize the sequence of presentation of the sociodemographic domains for each panelist. There will also be an opportunity for panelists 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 (i.e., 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 measures and ensure the wording will be understandable by all panelists. We will email each panelist with a summary of the aggregated responses from all knowledge user groups one week prior to sending the round 2 survey.

During round 2, panelists 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 (i.e., 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 panelist with a summary of aggregated round 2 responses from all knowledge user groups one 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, panelists 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 (i.e., 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 equal to or greater than one standard

deviation above the domain's mean ranking. For example, if a domain has a mean of 20.0 and a standard deviation of 2.2, items with a mean score greater than 22.2 will be considered priority items.

Maximizing panel member participation

To minimize attrition, we will use strategies reported to be effective in related studies (25, 26), which include personalized invitations, collection of robust contact information (http://www.improvelto.com/participant-contact-information-sheet), regular reminders about survey completion (reminder e-mails, 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 panelists, members from each of the key critical care organizations 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 (e.g., CMAJ, Canadian Journal of Anesthesia) to hybrid (i.e., in-person or virtual) consensus meeting. We will recruit a total of 40 panelists, ensuring they represent a diverse group of individuals and include panelists 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 (e.g., 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 (e.g., facilitating break out sessions) will have completed trauma-

informed care training per Substance Abuse and Mental Health Services Administration's (SAMHSA'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 organizations (CCCS, CCCTG, CCCRCG, CACCN, CSRT) and through social media posts (e.g., 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 organizations for distribution among their networks and through social media posts (e.g., X/Twitter, Reddit). We will engage with journal editors and funding bodies to promote awareness of the CoDaV.

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Competing interests: None declared.

Author Contributions: KK, FS, AH, SMehta, and KF planned and designed the study. JM, KB, SK, CM, SMurthy, KO, and KR provided advice and guidance. KK and FS drafted the manuscript with all authors reviewing and subsequently approving the final draft. Kirsten Fiest is the guarantor.

Data statement: Data from this study will be made available upon a reasonable request to the corresponding author.

Figure legend:

Figure 1. Description of the methods used to generate a set of core data variables (CoDaV) 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 panelists who are past ICU patients and family members, critical care medicine researchers, clinicians, and research coordinators. Our methodology integrates knowledge translation by involving a diverse panel including past ICU patients and family members, critical care medicine researchers, clinicians, and research coordinators.

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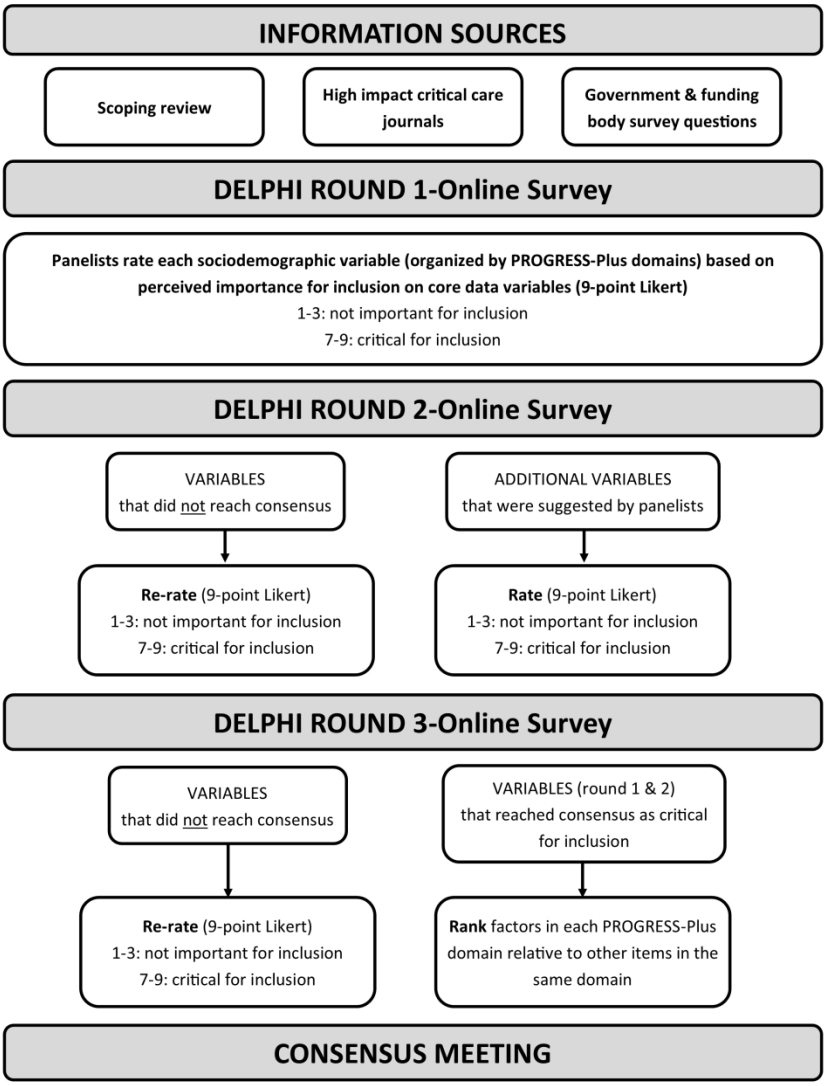

Description of the methods used to generate a set of core data variables (CoDaV) for collection of sociodemographic measures in adult critical care trials. We will conduct a scoping review to generate an initial list of sociodemographic variables relevant to adult critical care research. This will be 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 panelists who are past ICU patients and family members, critical care medicine researchers, clinicians, and research coordinators.

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ONLINE SUPPLEMENT TO:

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

Table of Contents

Supplementary Table 1. Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	5
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	6
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	6
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	6
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	9
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	10, Table 1
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	10-11, Table 2
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	11-12

Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	11-12
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	12
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	12
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	NA
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	NA
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	NA
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	NA
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	NA
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	NA
Limitations	20	Discuss the limitations of the scoping review process.	4
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	NA
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	16

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.
§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

Supplementary Table 2. MEDLINE search strategy

Study setting	Study region
1. Critical care/ or Critical Illness/ or Intensive care/ or Intensive care units/ or Intensive care units, pediatric/ 2. ((intensive or critical or acute) adj2 (care* or therap*)).tw,kf 3. (ICU* or GICU* or CCU* or PICU* or PCCU*).tw,kf 4. ((critical* or severe or catastrophic* or acute*) adj2 (ill* or sick* or ail*)).tw,kf 5. Or/1-4	6. exp canada/ 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$v$t or territoires du nord ouest or northwest territories or nwt or yukon or ontario).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).tw,kf. 9. ("Children's Hospital of Winnipeg" or Janeway Child Health Centre or IWK or "McMaster Children's Hospital" or "Children's Hospital at London Health" or "Children's Hospital of Eastern Ontario" or CHEO or Holland Bloorview Kids or Hospital for Sick Children or Hotel Dieu Hospital Child Development Centre or Centre de readaptation Marie Enfant or Sainte-Justine or "Montreal Children's Hospital" or Centre Mere-Enfant or "Jim Pattison Children's Hospital").mp. 10. Or/6-8 11. 5 and 9 12. limit 11 to yr="2012 -Current"

Supplementary Table 3. EMBASE search strategy

Study setting	Study region
1. intensive care/ or critical illness/ or intensive care unit/ or pediatric intensive care unit/ 2. ((intensive or critical or acute) adj2 (care* or therap*)).mp 3. (ICU* or GICU* or CCU* or PICU* or PCCU*).mp 4. ((critical* or severe or catastrophic* or acute*) adj2 (ill* or sick* or ail*)).mp 5. Or/1-4	6. exp canada/ 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$v$t or territoires du nord ouest or northwest territories or nwt or yukon or ontario).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. 9. ("Children's Hospital of Winnipeg" or Janeway Child Health Centre or IWK or "McMaster Children's Hospital" or "Children's Hospital at London Health" or "Children's Hospital of Eastern Ontario" or CHEO or Holland Bloorview Kids or Hospital for Sick Children or Hotel Dieu Hospital Child Development Centre or Centre de readaptation Marie Enfant or Sainte-Justine or "Montreal Children's Hospital" or Centre Mere-Enfant or "Jim Pattison Children's Hospital").mp. 10. Or/6-8 11. 5 and 9 12. limit 10 to yr="2012 -Current"

Supplementary Table 4. CINAHL search strategy

Search ID #	Search terms
S1	MH critical care
S2	MH intensive care units+
S3	critical care
S4	intensive care
S5	ICU
S6	critical* ill*
S7	MH Canada+
S8	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
S9	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#v#t or territoires du nord ouest or northwest territories or nwt or yukon or ontario
S10	S1 or S2 or S3 or S4 or S5 or S6
S11	S7 or S8 or S9
S12	S10 and S11 (**Limiters** - Publication Date: 20120101-20230231)