PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Core SocioDemographic data variables in ICU Trials (CoDe-IT): A protocol for generating core data variables using a Delphi consensus process
AUTHORS	Krewulak, Karla; Sheikh, Fatima; Heirali, Alya; Marshall, John; Burns, Karen; Kupsch, Scotty; Maratta, Christina; Murthy, Srinivas; O'Hearn, Katie; Russell, Kristine; Mehta, Sangeeta; Fiest, Kirsten

VERSION 1 – REVIEW

REVIEWER	Poulsen, Lone Musaeus Zealand University Hospital Koge Anesthesiology
REVIEW RETURNED	11-Feb-2024

GENERAL COMMENTS	A very thorough and well-written protocol. A have no further comments

REVIEWER	Kjær, Maj-Brit University of Copenhagen
REVIEW RETURNED	08-Mar-2024

GENERAL COMMENTS	Dear authors, Your planned study is of great importance. I have a few comments to consider and elaborate. 1. Where do you intend to involve patient and family members in the process? Please provide detailed explanations of the planned engagement. It might be beneficial to incorporate this information into your figure illustrating the process. 2. Are the knowledge users engaged in the study? Have the letters or the survey undergone any pilot testing? 3. Have you considered extending the study to other countries than Canada, given that the survey has already been translated into different languages? 4. Are you utilising the Modified Delphi technique or Delphi consensus process? Please maintain consistency in your choice. 5. When listing items such as inclusion criteria and using “etc.”, where can the reader find the complete list? I would as a reader appreciate seeing the full details, especially when this is the protocol. 6. When is a variable “deemed important for inclusion”? Please provide elaboration. Is it when more than 70% of respondents find

	the variable critical for inclusion as suggested by the COMET Handbook? 7. Regarding handling missing data (page 14, line 19), if less than 30% is missing, is it then restricted to complete cases only? Or do you consider using 'the last observation carried forward' if one is missing in the second round? Kindly consider and explicitly state your approach.

VERSION 1 – AUTHOR RESPONSE

REVIEWER 1
Comments to the Author:
A very thorough and well-written protocol. A have no further comments
Thank you, Dr. Poulsen, for taking the time to review our protocol and for the kind comment!

REVIEWER 2
Where do you intend to involve patient and family members in the process? Please provide detailed explanations of the planned engagement. It might be beneficial to incorporate this information into your figure illustrating the process.
Patient and Family partners were involved in the design of this study from inception and will be included in the panel, as one of four knowledge-user groups (pg. 6). On page 7, under sub-heading "Past ICU patients and family members" we outline how patient and family partners with lived ICU experience, specifically from equity-deserving groups, will be recruited to participate in the panel.

We have revised the caption for Figure 1 to explicitly state the involvement of patient and family partners throughout the study. This includes the addition of the following statement: "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."
We've also added details of our steering committee members, which can be seen on pg. 6: "Our study steering committee is comprised of members reflecting diversity of age, gender identity, ethnicity, 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."

Are the knowledge users engaged in the study? Have the letters or the survey undergone any pilot testing?
We have identified four groups of knowledge users critical to this study: 1) past ICU patients and family members; 2) critical care researchers; 3) critical care clinicians; and 4) research coordinators. Our study team, as reflected by the authorship list, is diverse and includes at least one person from each of the four knowledge user groups.

All surveys and survey letters will be pilot tested with eight individuals (two from each knowledge user group) to assess flow, salience, acceptability, and administrative ease. Information from the pilot test will be used to improve the surveys prior to dissemination (pg. 13). We have noted the inclusion of "participant-facing materials (emails, informed consent forms, social media materials) as part of the pilot testing process".

Have you considered extending the study to other countries than Canada, given that the survey has already been translated into different languages?
Thank you for noting this consideration. While this was flagged early in the conceptualization of this study, we decided to restrict to the Canadian context because the sociodemographic variables and response categories can vary across countries and would be challenging to harmonize. The additional

considerations necessary to extend this work beyond the borders of Canada are beyond the scope of this study.

Are you utilising the Modified Delphi technique or Delphi consensus process? Please maintain consistency in your choice.
Thank you for flagging this. We will be using the modified Delphi technique and have revised our protocol to ensure this is consistent throughout.

When listing items such as inclusion criteria and using “etc.”, where can the reader find the complete list? I would as a reader appreciate seeing the full details, especially when this is the protocol.
Thank you for this comment. We reviewed the use of “etc.” and removed it, where appropriate, to remove ambiguity. The full list of eligibility criteria can be found in Table 2.

When is a variable “deemed important for inclusion”? Please provide elaboration. Is it when more than 70% of respondents find the variable critical for inclusion as suggested by the COMET Handbook?
We deem any variable important for inclusion if the median score for the item is 7-9. This is described on pgs. 13-14: “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. “

Regarding handling missing data (page 14, line 19), if less than 30% is missing, is it then restricted to complete cases only? Or do you consider using ‘the last observation carried forward’ if one is missing in the second round? Kindly consider and explicitly state your approach.
Thank you for this important comment. In our protocol, we note that we would recruit additional participants if there is loss of more than 30% of **participants** in a particular knowledge user group. We have clarified in our protocol that the loss of 30% is specific to participants and not to the data itself.

VERSION 2 – REVIEW

REVIEWER	Kjær, Maj-Brit University of Copenhagen
REVIEW RETURNED	03-Jun-2024

GENERAL COMMENTS	Thank you for the sufficent replies and revision of the protocol. No further comments.

VERSION 2 – AUTHOR RESPONSE