

RESEARCH ARTICLE OPEN ACCESS

Developing a Core Outcome Measurement Set for Adult ICU Patients, the CoreMS-ICU—A Protocol

Maj-Brit Nørregaard Kjær^{1,2}  | Camilla Rahbek Lysholm Bruun¹  | Camilla Bekker Mortensen³  | Anna Schandl^{4,5}  | Kimberley Haines^{6,7}  | Kristin Hofso^{2,8,9}  | Fredrike Blokzijl¹⁰  | Anders Granholm^{1,2,11}  | Morten Hylander Møller^{1,2,12}  | Aske Tøgersen¹  | Bodil Steen Rasmussen^{2,13}  | Lone Musaeus Poulsen^{2,3}  | Thomas Strøm^{2,14}  | Eva Laerkner¹⁴  | Anne Craveiro Brøchner^{2,15}  | Trine Haberlandt¹⁵ | Anne-Marie Gellert Bunzel¹³  | Louise Stenbryggen Herløv³  | Anna Holm¹⁶  | Praleene Sivapalan¹  | Stine Estrup¹  | Maria Cronhjort^{2,17}  | Jon Henrik Laake^{2,18}  | Carmen Andrea Pfortmueller^{2,19}  | Marlies Ostermann^{2,20}  | Jade M. Cole²¹  | Matt P. Wise^{2,21}  | Anna Wludarczyk²² | Wojciech Szczeklik^{2,22} | Tomas Jovaiša²³ | Maurizio Cecconi^{24,25}  | Martin Ingi Sigurdsson^{2,26,27}  | Marek Nalos^{2,28}  | Johanna Hästbacka^{2,29}  | Marja Mäkinen³⁰  | Jacob Dye^{31,32,33}  | Naomi Hammond^{31,34}  | Edward Litton^{35,36} | Frederik Keus¹⁰  | Sheila Nainan Myatra³⁷  | Bharath Kumar Tirupakuzhi Vijayaraghavan^{38,39}  | Kavita Yadav^{39,40} | Balasubramanian Venkatesh^{31,41}  | Ingrid Egerod^{1,12}  | Rikke Faabo Larsen^{1,2}  | Dale M. Needham⁴²  | Louise Rose⁴³  | Bronwen Connolly⁴⁴ | Claudia Spies⁴⁵ | Carol Hodgson^{7,31,46,47} | Daniel Munblit⁴⁸  | Sarah Gorst⁴⁹ | Anders Perner^{1,2,12}  | Marie O. Collet^{1,2,12} 

Correspondence: Maj-Brit Nørregaard Kjær (maj-brit.noerregaard.kjaer@regionh.dk)

Received: 14 May 2026 | **Revised:** 31 May 2026 | **Accepted:** 4 June 2026

Keywords: clinical research | core outcome measurement set | patient-centred outcomes | stakeholder involvement

ABSTRACT

Background: Core outcome measurement sets (COMS) enhance the consistency and comparability of outcome reporting in clinical research. However, their effectiveness depends on the selection of valid, reliable, and feasible measurement instruments. Core outcome sets (COS) and COMS have been developed for specific intensive care unit (ICU) patient subgroups. The aim of this study is to establish a standardised approach to outcome measurement and operationalisation for adults acutely admitted to the ICU who are participating in clinical trials and other clinical research.

Methods: This protocol describes the development of a COMS for adults acutely admitted to the ICU, the CoreMS-ICU, consisting of six core outcomes: survival, free of life support, free of delirium, out of hospital, health-related quality of life, and cognitive function. We will follow the Consensus-based Standards for the Selection of Health Measurement Instruments guideline and report according to the Core Outcome Set—STandardised Protocol Items guideline. The development of the CoreMS-ICU will follow five predefined steps: (1) conceptual considerations for the six core outcomes; (2) systematic searches for outcome measurement instruments, including consideration of existing COMS; (3) quality assessment of relevant outcome measurement instruments; (4) consensus-based selection of outcome measurement instruments; and (5) recommendations and guidance on how to operationalise and report the measurement of the six core outcomes. We will involve research panels consisting of key stakeholders: patients, family members, healthcare professionals, and researchers in steps 1 and 4.

Conclusions: We aim to develop a COMS for adults acutely admitted to ICU patients to facilitate the consistent use of outcomes in trials and enhance the translation of research findings into clinical practice.

For affiliations refer to page 7.

This is an open access article under the terms of the [Creative Commons Attribution-NonCommercial-NoDerivs](https://creativecommons.org/licenses/by-nc-nd/4.0/) License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2026 The Author(s). *Acta Anaesthesiologica Scandinavica* published by John Wiley & Sons Ltd on behalf of Acta Anaesthesiologica Scandinavica Foundation.

1 | Introduction

Variation in outcome selection, definitions, and the associated measurement parameters and measurement instruments across clinical research of intensive care unit patients hinders comparisons and synthesis of evidence [1–4]. A more standardised approach to outcome selection, measurement, and reporting is needed.

Core outcome sets (COS) are minimum sets of outcomes to be reported in a particular clinical field [5]. Generation of COS focusing on patient-important outcomes should include participation of patients and other relevant stakeholders in the development [6]. Involving these stakeholders in both a COS and its corresponding core outcome measurement set (COMS) helps ensure that outcomes and measurements are meaningful and relevant.

Identifying COMS also improves the feasibility and consistency across studies [7–10]. A COMS is defined as a standardised minimum set of outcomes and their corresponding measurement instruments for specific populations and interventions [11]. The consistent use of COMS instruments is essential for improving the quality, relevance, and comparability of evidence that informs clinical practice [2, 3].

COMS have been developed for subsets of the intensive care unit (ICU) population, such as acute respiratory failure survivorship [12], delirium [13], extracorporeal membrane oxygenation (ECMO) [14], mechanical ventilation [15], and COVID-19 [16], but not for adults acutely admitted to the ICU who do not fall within these specific subgroups.

We previously developed a COS for the adult ICU population referring to adults acutely admitted to the ICU. This process involved extensive international collaboration across 14 countries and included patients and family members with lived ICU experience, clinicians representing professions involved in ICU care, and researchers. The group reached consensus on six core outcomes, the ‘Core-6’: survival, free of life support, free of delirium, out of hospital, health-related quality of life, and cognitive function [17].

The next step in this methodological process is to reach consensus among stakeholders on how and when these outcomes should be measured. This requires the development of a COMS with continued stakeholder involvement. This protocol outlines the process for identifying, evaluating, implementing, and recommending outcome measurement instruments and parameters for each of the six core outcomes identified as important for research in adults acutely admitted to the ICU.

2 | Methods

We will develop CoreMS-ICU, a COMS for the existing COS, Core-6, for adults acutely admitted to the ICU: survival, free of life support, free of delirium, out of hospital, health-related quality of life, and cognitive function. We will follow the Consensus-based Standards for the selection of health Measurement INstruments (COSMIN) guideline [18], and the recommendations outlined by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative’s Handbook 1.0 on selecting outcome measurement instruments (OMIs) [5].

We will report this protocol in accordance with the Core Outcome Set—STandardised Protocol Items (COS-STAP) guideline [19], and a modified version of the COSMIN guideline (checklist in the supplementary file) [20]. This protocol has been registered in the COMET database (<https://www.comet-initiative.org/Studies/Details/3668>).

2.1 | Scope

This COMS is intended for use with clinical research for adults acutely admitted to the ICU. The COMS for the Core-6—CoreMS-ICU—is primarily intended to be used in randomised clinical trials but will also be suitable for other ICU clinical research when the Core-6 is relevant.

2.2 | Stakeholders

We will recruit key stakeholders, including patients and family members with lived ICU experience, health care professionals (HCP) (e.g., nurses, doctors, physiotherapists, occupational therapists, and psychologists), and researchers with ICU experience, organised into *research panels* established in participating countries. All countries represented in the development of Core-6 (listed in the [Supporting Information](#)) will be invited to participate in the COMS process outlined in a modified involvement matrix (Table S1) [17]. We will provide a detailed account of key stakeholder participation in research panels, including the number of participants from each stakeholder group, their country of representation, and which steps of the process they contributed to.

We plan for the research panels to be involved in Steps 1 and 4 as illustrated in Figure 1, with stakeholder roles and contributions described in detail in the involvement matrix (Table S1 in the [Supporting Information](#)). The research panels’ perspectives are especially important to reflect on the feasibility and how best to operationalise and measure the two patient-reported outcomes: health-related quality of life and cognitive function as this affects them directly. The other core outcomes are likely to be obtained from medical records.

We have established an expert panel including COS and COMS experts, trialists, methodologists, and if needed in the process we will invite psychometric/clinometric specialists and maybe other stakeholders with other relevant expertise for the process. The expert panel is a part of the Steering Committee but is consulted before entering a new Step in the process.

All areas of expertise represented within the Steering Committee will contribute to an additional Step 5. This step extends the four-step COSMIN guideline by providing methodological guidance on the analysis of the Core-6 in future studies, thereby promoting consistent handling of outcomes.

2.3 | Overview and Structural Framework

We will develop the CoreMS-ICU by following the COSMIN steps illustrated in Figure 1:

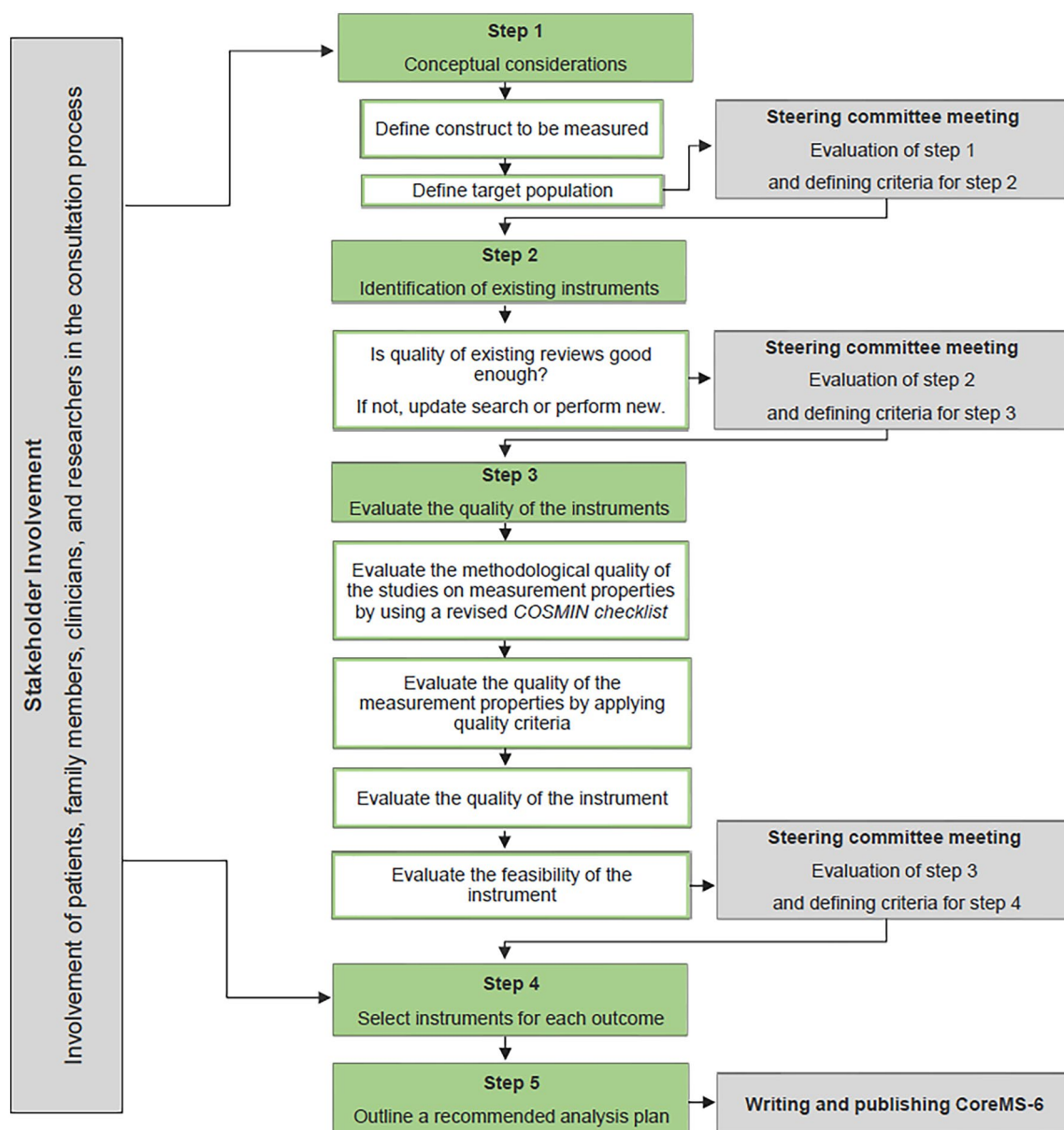


FIGURE 1 | Conceptual Framework for the development of COMS-ICU. OMI = Outcome Measurement Instrument, COSMIN = Consensus-based Standards for the selection of health Measurement Instruments. Step 1. Identifying conceptual considerations for the CORE-6. The research panels will provide feedback on the definitions, aiming for consensus on the final versions before moving to Step 2. Step 2. Systematic searching for existing outcome measurement instruments (OMIs) based on the conceptual considerations and compilation of a list for review in Step 3. Step 3. Quality assessment of the identified OMIs focused on feasibility, comprehensibility and acceptability of the instruments and outlining which OMIs should be considered for consensus in Step 4. The certainty of evidence for the OMI will be assessed using COSMINs approach, 22 which is adapted and based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. 29 If there is at least moderate certainty of evidence for an OMI, it can be forwarded to Step 4. Outcomes will not be left without recommendations; the best available alternative will be used to make the CORE-6 operationalisable. Step 4. To reach consensus on OMIs for the CORE-6, the research panels will contribute their perspectives to strengthen the considerations behind the final decision and to ensure that the COMS reflects stakeholder priorities and clinical applicability. The developed COMS-ICU will then proceed to Step 5. Step 5. In this step we will provide recommendations on methodological issues, such as how to handle non-survivors when analysing the selected measurements. This aims to ensure consistent analysis and reporting of results.

- **Step 1:** Conceptual considerations of the outcomes
- **Step 2:** Identification of existing outcome measurement instruments
- **Step 3:** Evaluation of the quality and psychometric properties of instruments
- **Step 4:** Consensus-based selection of instruments for each outcome (including time point for assessment of each outcome)
- **Step 5:** Development of recommendations for analysis. Step 5 is an additional step to ensure consistent guidance on how to operationalise the OMIs.

The COSMIN steps are briefly described below. For a detailed description, see [Supporting Information](#).

2.3.1 | Step 1: Conceptual Considerations of the Outcomes

We will conduct a structured conceptual review for each Core-6 outcome, informed by targeted literature searches ([Supporting Information](#)), existing COS and COMS (Table S2 in the [Supporting Information](#)) and expert input. We will develop preliminary construct definitions through discussion in the research panels (Table 1). The Steering Committee ([Supporting Information](#)), comprising researchers, HCP, and a patient

TABLE 1 | Mock table for conceptual considerations and the final definition on the core outcomes.

Outcome	Definition	Conceptual considerations
Survival		
Free of life support		
Free of delirium		
Out of hospital		
Health-related quality of life		
Cognitive function		

representative, many of whom participated in the development of the Core-6, will formally approve the final definitions by consensus before we proceed to instrument identification.

2.3.2 | Step 2: Identification of Existing Outcome Measurement Instruments

We will first identify existing COS and COMS (Table S2 in the [Supporting Information](#)) and subsequently identify candidate OMIs informed by the agreed construct definitions. We will search for systematic reviews from the COSMIN database and use a tiered search strategy in MEDLINE. The MEDLINE search will be designed and conducted using the COSMIN-recommended filters for the *precise* identification of studies on measurement properties [21], and the full final search strategy will be reported. Eligibility will be restricted to instruments applicable to our target population, defined as instruments that are feasible, valid, and relevant for use in adults acutely admitted to the ICU, including considerations of clinical context, patient condition, and timing of assessment. The search results and inclusion of OMIs will be outlined in a flow diagram (Figure 2).

2.3.3 | Step 3: Evaluation of the Quality and Psychometric Property of Instruments

We will appraise identified OMIs for methodological quality, psychometric properties (Table S3 in the [Supporting](#)

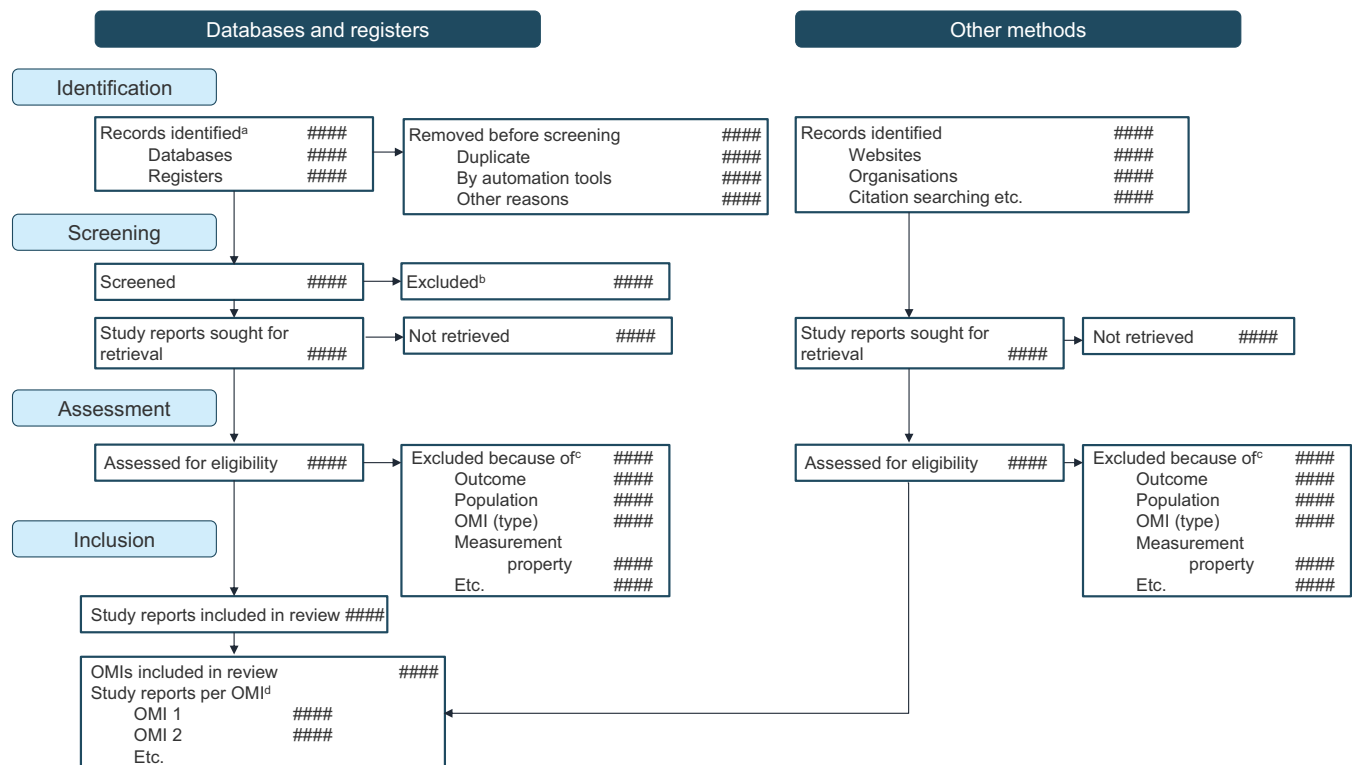


FIGURE 2 | Flow diagram for search results. ^aConsider, if feasible to do so, reporting the number of records identified from each database or register (rather than the total number across all databases/registers). ^bIf automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools. ^cReasons of exclusion will be added as applicable. ^dWill be replaced by the outcome measurement instrument (OMI) name or acronym.

2.3.5 | Step 5: Development of Recommendations for Analysis

In collaboration with experts from the COMS Steering Committee and engaged researchers, we will develop pragmatic guidance and methodological recommendations for each outcome measurement instrument (OMI) included in the CoreMS-ICU. These will cover outcome definitions, timing of assessment, summary effect measures, competing/intercurrent event handling (including handling of deceased patients) [25], cut-off value determination (if any), statistical analysis approaches, and missing data handling strategies, in accordance with the selected outcome measurement instruments (OMIs).

2.4 | Dissemination and Implementation

We will implement targeted dissemination strategies tailored to healthcare professionals, researchers, administrators, and policymakers. For each core outcome, we will present its clinical relevance and recommend a measurement instrument, accompanied by methodological guidance to support implementation and use in future research, particularly in clinical trials. Dissemination and implementation are integral to promoting consistent adoption of the CoreMS-ICU and facilitating the translation of research findings into intensive care practice.

Our dissemination strategy includes peer-reviewed publications, presentations at international conferences, workshops, webinars, and tailored communication materials co-developed with stakeholders. We will further disseminate findings through established research networks via email, newsletters, and social media platforms as wanted [26]. Awareness of CoreMS-ICU is already being established through the involvement of a broad group of collaborators and will be strengthened through these coordinated activities. We will also evaluate how key stakeholders engage with and learn about CoreMS-ICU to optimise uptake and application in clinical research.

Research panels will be actively involved in dissemination and implementation to ensure inclusion of diverse perspectives and to support communication tailored to non-specialist audiences.

Research panels will be acknowledged by name, subject to their consent, in the peer-reviewed publication reporting the CoreMS-ICU results.

2.5 | Ethics

All participants involved in the research panels do so voluntarily and may opt to leave the panel at their discretion without any explanation or obligations. Although meetings will be confidential, minutes will be documented, including the composition of the panel (patients, family members, clinicians, or researchers) without collecting other demographic details. If the meeting is to be recorded, research panel members must provide their consent prior to the recording. All participating countries must comply with national and international ethical obligations.

For the protocol no written consent has been obtained from the patients as there is no patient-identifiable data included.

3 | Discussion

This protocol describes a rigorous and transparent approach to developing the CoreMS-ICU, a COMS for adults acutely admitted to the ICU, including how it could be operationalised for adult ICU patients [17]. We will establish conceptual clarity for each core outcome and identify OMIs with acceptable psychometric properties.

The described approach will promote the consistent use of standardised outcome measurement instruments across studies, thereby improving comparability and facilitating aggregation of results. This consistency enables more coherent interpretation of findings and strengthens the cumulative value of research within the field. In turn, this may increase confidence in the certainty of evidence and enhance its clinical relevance. Importantly, the use of aligned measurement approaches may strengthen the validity and interpretability of both patient-reported outcomes and patient-important outcomes that are not directly reported by patients, such as survival and freedom from life-support modalities. By integrating evidence on methodological quality, measurement properties, and feasibility, the resulting recommendations will support practical and consistent implementation of the COMS-ICU in clinical research and decision-making [7].

3.1 | Strengths and Limitations

As a strength, we have included experienced researchers in the development of COMS, including methodological experts as part of our steering committee. They will take part in the development process, ensuring methodological rigor and reducing the risk of overlooking important considerations. A key strength of this study is the continued involvement of stakeholders through international research panels at predefined stages, as well as the inclusion of a patient perspective through a co-author (J.D.) with lived ICU experience. This approach ensures that the selected outcomes and measurement strategies are relevant, acceptable, and meaningful to both end-users and patients.

The proposed study builds on the previously published Core-6 COS, which has recognised limitations. As reported, the external representativeness of the COS may be limited, given that the Delphi consensus process was initially conducted in Denmark and later included participants from 13 additional countries [17]. However, perspectives from a lower-middle-income country were included, which may enhance the broader applicability of the findings. The extended collaboration in this COMS may further support the inclusion of additional countries, thereby strengthening the diversity of perspectives in the process. Despite including a diverse group of global experts to achieve consensus, there is a possibility that the views of this small group may not be representative of the global ICU community. Finally, the identity of the experts will not be anonymised during the consensus process, which may be a potential for bias or group pressure.

There is a risk that we will not identify any suitable OMIs for one or more outcomes. Identifying no suitable OMI for one or more of the Core-6 outcomes would itself constitute an important finding as it would highlight gaps in current measurement approaches and a need to do either more psychometric work in the ICU population [27], develop new instruments, or modify instruments for the ICU population. Nevertheless, we will avoid leaving any core outcomes without guidance; instead, we will recommend the best available alternative to ensure that the Core-6 are operationalisable and can be used in future research. Importantly, this approach facilitates implementation across diverse economic settings, including low-, middle-, and high-income countries.

3.2 | Conclusion

We aim to develop a COMS for clinical trials focused on adults acutely admitted to the ICU (CoreMS-ICU) to strengthen the quality, consistency, and comparability of clinical evidence. Through methodologically rigorous processes and inclusive stakeholder involvement by integrating clinical expertise, research experience, and lived perspectives, this CoreMS-ICU will ensure valid and meaningful measurement of patient-important outcomes.

Author Contributions

Conceptualisation: Maj-Brit Nørregaard Kjær, Camilla Rahbek Lysholm Bruun, Camilla Bekker Mortensen, Anna Schandl, Kimberley Haines, Kristin Hofso, Fredrike Blokzijl, Anders Granholm, Morten Hylander Møller, Marie O. Collet. Methodology: Maj-Brit Nørregaard Kjær, Anders Granholm, Morten Hylander Møller, Dale M. Needham, Louise Rose, Bronwen Connolly, Claudia Spies, Carol Hodgson, Daniel Munblit, Sarah Gorst, and Marie O. Collet. Project administration: Maj-Brit Nørregaard Kjær. Supervision: Anders Granholm, Morten Hylander Møller, Anders Perner, and Marie O. Collet. Visualization: Maj-Brit Nørregaard Kjær, Camilla Rahbek Lysholm Bruun, Marie O. Collet. Writing (original draft): Maj-Brit Nørregaard Kjær. Writing (review and editing): All authors.

Funding

The development of this core outcomes measurement set is as part of the *Intensive Care Platform Trial (INCEPT)* research programme (www.incept.dk), which is funded by grants from Research Council of the Copenhagen University Hospital—Rigshospitalet, Sygeforsikringen 'danmark' (2020-0320), The Novo Nordisk foundation (NNF23OC0085106), and Danmarks Frie Forskningsfond (10.46540/3165-00057B), and supported by Grosserer Jakob Ehrenreich og Hustru Grete Ehrenreichs Fond, Savværksejer Jeppe Juhl og Hustru Ovita Juhls Mindelegat, and Dagmar Marshalls Fond.

Affiliations

¹Department of Intensive Care, Copenhagen University Hospital – Rigshospitalet, Copenhagen, Denmark | ²Collaboration for Research in Intensive Care (CRIC), Copenhagen, Denmark | ³Department of Anaesthesiology, Zealand University Hospital, Roskilde, Denmark | ⁴Department of Clinical Science and Education, Södersjukhuset, Karolinska Institutet, Stockholm, Sweden | ⁵Department of Perioperative and Intensive Care, Södersjukhuset, Stockholm, Sweden | ⁶Department of Physiotherapy, Western Health, Footscray, Australia | ⁷Department of Critical Care, Melbourne Medical School, The University of Melbourne, Melbourne, Australia | ⁸Department of Postoperative and Intensive Care Nursing, Division of Emergencies and Critical Care, Oslo University

Hospital, Oslo, Norway | ⁹Lovisenberg Diaconal University College, Oslo, Norway | ¹⁰Department of Critical Care, University Medical Center Groningen, University of Groningen, Groningen, the Netherlands | ¹¹Section of Biostatistics, Department of Public Health, University of Copenhagen, Copenhagen, Denmark | ¹²Department of Clinical Medicine, Faculty of Health and Medical Science, University of Copenhagen, Copenhagen, Denmark | ¹³Department of Anaesthesia and Intensive Care, Aalborg University Hospital, Aalborg, Denmark | ¹⁴Department of Anaesthesiology and Intensive Care, Odense University Hospital, Odense, Denmark | ¹⁵Department of Anaesthesia and Intensive Care, Lillebælt Hospital, Kolding, Denmark | ¹⁶Department of Intensive Care, Aarhus University Hospital, Aarhus, Denmark | ¹⁷Department of Clinical Sciences, Danderyd Hospital, Karolinska Institutet, Stockholm, Sweden | ¹⁸Department of Anaesthesiology and Intensive Care Medicine and Department of Research and Development, Division of Emergencies and Critical Care, Rikshospitalet, Oslo University Hospital, Oslo, Norway | ¹⁹Department of Intensive Care Medicine, Inselspital, University Hospital Bern, Bern, Switzerland | ²⁰Department of Intensive Care, Guy's and St Thomas' Hospital, London, UK | ²¹Adult Critical Care, University Hospital of Wales, Cardiff, UK | ²²Jagiellonian University Medical College - Centre for Intensive Care and Perioperative Medicine, Kraków, Poland | ²³Faculty of Medicine, Clinic of Anaesthesiology and Intensive Care, Vilnius University, Vilnius, Lithuania | ²⁴Department of Biomedical Sciences, Humanitas University, Milan, Italy | ²⁵Department of Anaesthesiology and Intensive Care, IRCCS Humanitas Research Hospital, Milan, Italy | ²⁶Faculty of Medicine, University of Iceland, Reykjavik, Iceland | ²⁷Landsþítali – The National University Hospital of Reykjavik, Reykjavik, Iceland | ²⁸Medical Intensive Care Unit, 1st Department of Internal Medicine, Charles University, Faculty of Medicine, Teaching Hospital and Biomedical Center in Pilsen, Pilsen, Czech Republic | ²⁹Tampere University Hospital, Wellbeing Services County of Pirkanmaa and Tampere University, Faculty of Medicine and Health Technology, Tampere, Finland | ³⁰Department of Emergency Medicine and Services, Helsinki University and Helsinki University Hospital, Helsinki, Finland | ³¹The George Institute for Global Health, University of New South Wales, Sydney, Australia | ³²Collaborative Evaluation and Research Centre, Federation University, Gippsland Campus, Churchill, Australia | ³³Lived Experienced Expert – Patient, Sydney, Australia | ³⁴Malcolm Fisher Department of Intensive Care, Royal North Shore Hospital, Northern Sydney Local Health District, Sydney, Australia | ³⁵Intensive Care Unit, Fiona Stanley Hospital, Robin Warren Drive, Murdoch, Western Australia, Australia | ³⁶School of Medicine, University of Western Australia, Crawley, Western Australia, Australia | ³⁷Department of Anaesthesiology, Critical Care and Pain, Tata Memorial Hospital, Homi Bhabha National Institute, Mumbai, India | ³⁸Apollo Hospitals, Chennai, India | ³⁹The George Institute for Global Health, New Delhi, India | ⁴⁰Prasanna School of Public Health, Manipal Academy of Medical Sciences, Manipal, India | ⁴¹Department of Intensive Care, Gold Coast University Hospital, Southport, Australia | ⁴²Division of Pulmonary & Critical Care Medicine, and Department of Physical Medicine & Rehabilitation, School of Medicine, and School of Nursing, Johns Hopkins University, Baltimore, Maryland, USA | ⁴³Faculty of Nursing, Midwifery & Palliative Care, King's College London, London, UK | ⁴⁴Queen's University Belfast, Belfast, UK | ⁴⁵Department of Anaesthesiology and Intensive Care Medicine, Charité – Universitätsmedizin Berlin, Berlin, Germany | ⁴⁶Australian and New Zealand Intensive Care Research Centre, Monash University, Melbourne, Australia | ⁴⁷The Alfred Hospital, Intensive Care Unit and Physiotherapy Department, Melbourne, Australia | ⁴⁸King's College London, London, UK | ⁴⁹Department of Health Data Science, University of Liverpool, Liverpool, UK

Conflicts of Interest

M.O. received research funding from Baxter and Biomerieux (paid to institution).

The Department of Intensive Care at Rigshospitalet (M.N.K., C.R.L.B., A.G., M.H.M., A.T., P.S., I.E., A.P., M.O.C.) receives funding from The Novo Nordisk Foundation.

Data Availability Statement

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

References

1. A. Granholm, C. T. Anthon, M.-B. N. Kjær, et al., "Patient-Important Outcomes Other Than Mortality in Contemporary ICU Trials: A Scoping Review," *Critical Care Medicine* 50 (2022): e759–e771.
2. M. L. Behal, A. H. Flannery, and T. A. Miano, "The Times Are Changing: A Primer on Novel Clinical Trial Designs and Endpoints in Critical Care Research," *American Journal of Health-System Pharmacy* 81, no. 18 (2024): 890–902.
3. P. R. Williamson, R. d. Á. Oliveira, M. Clarke, et al., "Assessing the Relevance and Uptake of Core Outcome Sets (An Agreed Minimum Collection of Outcomes to Measure in Research Studies) in Cochrane Systematic Reviews: A Review," *BMJ Open* 10 (2020): e036562.
4. P. R. Williamson, D. G. Altman, J. M. Blazeby, et al., "Developing Core Outcome Sets for Clinical Trials: Issues to Consider," *Trials* 13 (2012): 132.
5. P. R. Williamson, D. G. Altman, H. Bagley, et al., "The COMET Handbook: Version 1.0," *Trials* 18 (2017): 280.
6. A. Kearney, P. R. Williamson, and S. Dodd, "A Review of Core Outcome Sets (COS) Developed for Different Settings Finds There Is a Subset of Outcomes Relevant for Both Research and Routine Care," *Journal of Clinical Epidemiology* 173 (2024): 111440.
7. C. A. C. Prinsen, S. Vohra, M. R. Rose, et al., "How to Select Outcome Measurement Instruments for Outcomes Included in a "Core Outcome Set" – A Practical Guideline," *Trials* 17 (2016): 449.
8. A. Granholm, W. Alhazzani, L. P. G. Derde, et al., "Randomised Clinical Trials in Critical Care: Past, Present and Future," *Intensive Care Medicine* 48 (2022): 164–178.
9. M. H. Møller, "Patient-Important Outcomes and Core Outcome Sets: Increased Attention Needed!," *BJA: British Journal of Anaesthesia* 122 (2019): 408.
10. S. L. Gorst, D. C. Bouhassira, and A. E. Turnbull, "Developing Core Outcome (Measurement) Sets for Critical Care Research Using the Modified Delphi Method: A Narrative Review," *CHEST Critical Care* 3, no. 1 (2025): 100128, <https://doi.org/10.1016/j.chstcc.2025.100128>.
11. V. D. Dinglas, S. P. S. Cherukuri, and D. M. Needham, "Core Outcomes Sets for Studies Evaluating Critical Illness and Patient Recovery," *Current Opinion in Critical Care* 26 (2020): 489–499.
12. D. M. Needham, K. A. Sepulveda, V. D. Dinglas, et al., "Core Outcome Measures for Clinical Research in Acute Respiratory Failure Survivors: An International Modified Delphi Consensus Study," *American Journal of Respiratory and Critical Care Medicine; New York* 196 (2017): 1122–1130.
13. L. Rose, B. Blackwood, D. M. Needham, J. W. Devlin, M. Clarke, and L. D. Burry, "Measures for the Core Outcome Set for Research Evaluating Interventions to Prevent and/or Treat Delirium in Critically Ill Adults: An International Consensus Study (Del-CORs)," *Critical Care Explorations* 5 (2023): e0884.
14. C. L. Hodgson, A. J. C. Burrell, D. M. Engeler, et al., "Core Outcome Measures for Research in Critically Ill Patients Receiving Extracorporeal Membrane Oxygenation for Acute Respiratory or Cardiac Failure: An International, Multidisciplinary, Modified Delphi Consensus Study," *Critical Care Medicine* 47 (2019): 1557–1563.
15. B. Blackwood, S. Ringrow, M. Clarke, et al., "A Core Outcome Set for Critical Care Ventilation Trials," *Critical Care Medicine* 47 (2019): 1324–1331.
16. A. Tong, A. Baumgart, N. Evangelidis, et al., "Core Outcome Measures for Trials in People With Coronavirus Disease 2019: Respiratory Failure, Multiorgan Failure, Shortness of Breath, and Recovery," *Critical Care Medicine* 49 (2021): 503–516.
17. M.-B. N. Kjær, C. R. L. Bruun, A. Granholm, et al., "A Core Outcome Set for Adult General ICU Patients," *Critical Care Medicine* 53 (2025): e575–e589.
18. C. A. C. Prinsen, S. Vohra, M. R. Rose, et al., "Guideline for Selecting Outcome Measurement Instruments for Outcomes Included in a Core Outcome Set," *Cosmin* (2016), <https://www.cosmin.nl/wp-content/uploads/COSMIN-guideline-selecting-outcome-measurement-COS.pdf>.
19. J. J. Kirkham, S. Gorst, D. G. Altman, et al., "Core Outcome Set-STandardised Protocol Items: The COS-STAP Statement," *Trials* 20 (2019): 116.
20. J. J. Gagnier, J. Lai, L. B. Mokkink, and C. B. Terwee, "COSMIN Reporting Guideline for Studies on Measurement Properties of Patient-Reported Outcome Measures," *Quality of Life Research* 30 (2021): 2197–2218.
21. C. B. Terwee, S. D. M. Bot, M. R. de Boer, et al., "Quality Criteria Were Proposed for Measurement Properties of Health Status Questionnaires," *Journal of Clinical Epidemiology* 60 (2007): 34–42.
22. L. B. Mokkink, C. B. Terwee, D. L. Patrick, et al., "The COSMIN Checklist for Assessing the Methodological Quality of Studies on Measurement Properties of Health Status Measurement Instruments: An International Delphi Study," *Quality of Life Research* 19 (2010): 539–549.
23. C. a. C. Prinsen, L. B. Mokkink, L. M. Bouter, et al., "COSMIN Guideline for Systematic Reviews of Patient-Reported Outcome Measures," *Quality of Life Research* 27 (2018): 1147–1157.
24. S. S. McMillan, M. King, and M. P. Tully, "How to Use the Nominal Group and Delphi Techniques," *International Journal of Clinical Pharmacy* 38 (2016): 655–662.
25. E. Colantuoni, D. O. Scharfstein, C. Wang, et al., "Statistical Methods to Compare Functional Outcomes in Randomized Controlled Trials With High Mortality," *BMJ* 360 (2018): j5748.
26. A. Akinremi, A. E. Turnbull, C. M. Chessare, C. O. Bingham, D. M. Needham, and V. D. Dinglas, "Delphi Panelists for a Core Outcome Set Project Suggested Both New and Existing Dissemination Strategies That Were Feasibly Implemented by a Research Infrastructure Project," *Journal of Clinical Epidemiology* 114 (2019): 104–107.
27. K. A. Robinson, W. E. Davis, V. D. Dinglas, et al., "A Systematic Review Finds Limited Data on Measurement Properties of Instruments Measuring Outcomes in Adult Intensive Care Unit Survivors," *Journal of Clinical Epidemiology* 82 (2017): 37–46.
28. G. Guyatt, L. Yao, M. H. Murad, et al., "Core GRADE 6: Presenting the Evidence in Summary of Findings Tables," *BMJ* 389 (2025): e083866.

Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** Filled in version of a modified involvement matrix.¹ **Table S2:** COS and COMS in critical care overlapping with Core-6. **Table S3:** Modified COSMIN quality criteria for psychometric properties.⁷