INPLASY

Identification and evaluation of patient-reported outcome and experience measures (PROEMS) in trials of critically ill adults with sepsis: A scoping review

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 January 2024 and was last updated on 16 January 2024.

INTRODUCTION

Review question / Objective 1. In adult patients with sepsis or septic shock in ICU, what patient reported outcomes and patient experience measures (PROEMS) are reported in clinical trials?
2. What is the survivor-centricity of the PROEMS?

Background PROEMS are considered an important endpoint for evaluating patient self-reported health as well as the quality of health system performance and delivery. Critical care is not without exception, where the quality of survival, as captured by PROEMS, is an important measure of the outcome of critical care, beyond traditional metrics such as mortality. Sepsis patients are known to experience significant post-ICU impairments across the domains of physical, mental, and cognitive health. They also have high and sustained health care utilization across the spectrum of care from the ICU to community.

Understanding what PROEMS exist in studies of adults admitted to the ICU with sepsis is important to understand the current landscape and help inform the selection of high-quality PROEMS for future research. Further, in the evolving landscape of patient and family engagement in critical care research, it is also important to ascertain whether the current PROEMS being used in trials reflect key domains previously identified by sepsis survivors as important. This can be referred to as the "survivor-centricity" of these measures, which can be used to identify areas for future methodological improvement which will assess with the help of sepsis survivors.
Therefore, this systematic review aims to:
1. Identify and describe the PROEMS used in studies of critically ill adults with sepsis.
2. Determine the survivor-centricity of the PROEMS by evaluating the extent to which key domains previously identified as being important to sepsis survivors are being assessed in trials.

Rationale For the purposes of this review, we use previously published definitions of PROMS, PREMS (Williams and Thompson 2018, Australian Commission on Safety and Quality in Health Care 2018), and the concept of "survivor-centricity" (Bull et al. 2022).

1. PROMS have been defined as: "standardised, validated questionnaires with items that can be combined to represent an underlying construct such as pain, physical functioning, symptom control or psychological distress. PROMs can be generic (applicable across a variety of disease states or conditions), condition-specific (relevant to a particular population group, such as elderly people or those with mental illness) or disease specific. In general, analysis of PROMs focuses on the change in scores following a health intervention. By comparing patients' self-reported health before and after the intervention, the outcomes of the care they received can be assessed."
2. PREMS have been defined as measures: "designed to capture an individual's experience of receiving care, namely, their perception of what happened during a care encounter and how it happened" (Bull et al. 2019).
3. Survivor-centricity: we borrow this concept from an existing and similar systematic review protocol (Bull et all. 2022) - where this refers to the involvement of survivors "in defining what is relevant, comprehensive and comprehendible instrument content—to support meaningful, value-based measurement" in critical care. A prior qualitative study has identified specific health-related quality of life domains that matter most to sepsis survivors. In collaboration, with an expert panel of sepsis survivors, we evaluate the extent to which these previously identified key domains are being assessed in the included trials.

METHODS

Strategy of data synthesis We will search MEDLINE (via OVID). Embase (via Elsevier), CINAHL Plus (via EBSCO Host), PsycINFO (via OVID).
Search dates: published between 1 Jan 2000 to current.
Restrictions: published in languages other than English, paediatric patients, published prior to 2000.
Search terms will include the following domains of: critical care and sepsis survivorship, PROEMS, and measurement properties.

Eligibility criteria Population/participant inclusion and exclusion criteria:
Inclusion:
- Adult (≥18 years of age) patients, admitted to the ICU with sepsis, where they met one of the following definitions:
o Sepsis-3 criteria –suspected infection and meets two or more sequential organ failure assessment (SOFA) criteria (Venkatesh et al. 2018)
o Sepsis-1,2 criteria – suspected infection and systemic inflammatory response syndrome (SIRS) > 2
o OR where the trial endeavored to use systematic approach to identify patients with sepsis for study enrollment (e.g. presence of infection and need for vasopressor and/or ventilation).
o OR admitted to the intensive care unit for another reason, then developed sepsis or septic shock.
- NB. Where studies included both paediatric and adult patients, only studies that report results separately for adults will be included.
Exclusion:
- Pediatric (<18 years of age) patients
- Cohort with less than 2/3 intensive care patients with sepsis
- No clear definition of sepsis used to enroll patients into study
Types of studies:
Inclusion:
Clinical trials reporting the use of PROEMS
Clinical trials published from 2000 onwards
Published in English
Available in full-text
Randomised clinical trials including adult sepsis patients as the primary cohort – where sepsis is the primary cohort of interest rather than a sub-group.
Observational studies.
Exclusion:
Published before 1990
Published in languages other than English
Case report, reviews, editorials, theses, descriptive commentary, qualitative designs
Studies that do not clearly report use of PROEMS or where PROEMS are not used in adult sepsis patients admitted to the ICU.

Source of evidence screening and selection Using the program Covidence, two independent reviewers (sourced from a team of three reviewers) will screen titles and abstracts against eligibility criteria. Full-text articles will be sourced where the abstract contains insufficient information. Relevant full-text articles will be retrieved and independently reviewed by two reviewers. Discrepancies will be resolved by consensus between two reviewers but where consensus cannot be reached, a third independent reviewer will adjudicate.

Data management Will use COVIDENCE for data management as stated above and use of Excel as required.

Reporting results / Analysis of the evidence A standardised data collection form will be created, piloted, and data extracted by two independent reviewers into the form. A third reviewer will independently cross-reference extracted data. Data items will include items defined in a systematic review (Bull et al. 2022): 1. PROM/PREM name; 2. construct(s)/domain(s) captured; 3. target population and setting (e.g. in ICU, ward, post-hospital); 4. mode of administration (phone, postal, online); 5. recall period; 6. number of items; 7. response options and 8. original language.

Presentation of the results A table will be used to present the results. Data items will include items defined in a similar systematic review (Bull et al. 2022): 1. PROM/PREM name; 2. construct(s)/domain(s) captured; 3. target population and setting (e.g. in ICU, ward, post-hospital); 4. mode of administration (phone, postal, online); 5. recall period; 6. number of items; 7. response options and 8. original language.
The panel will look for the 11 key domains (1. psychological impairment; 2. control over one's life; 3. ability to walk; 4. return to normal living; 5. cognitive impairment; 6. family support; 7; coping with daily life; 8. delivery of health care; 9. fatigue; 10. physical impairment; and 11. self-perception) that sepsis survivors have identified as significant in defining their quality of life after sepsis (Konig et al. 2019).
Survivor-centricity will be evaluated by whether the PROEMS instruments reported in the sepsis trials have included the domains of interest above and will be labelled as 'Present' or 'Missing' or 'Unclear'.

Language restriction English only.

Country(ies) involved Australia, United States of America.

Other relevant information Nil.

Keywords Critical illness; intensive care; sepsis; patient reported outcomes; patient reported experiences, patient perspective.

Dissemination plans The results of the Scoping review (SR) will be presented at national and international scientific conferences/meetings. The SR will be published in a peer-reviewed journal.

Contributions of each author

Author 1 - Dasom Kim - Complete search, apply for INPLASY, draft manuscript.
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