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Use of patient-relevant outcome measures to assess the long-term effects of care bundles in the ICU: a scoping review protocol

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ABSTRACT

Introduction There is only moderate adherence to evidence-based practice in critical care. Care bundles can be used to increase adherence to best clinical practice. Components of bundle interventions, bundle implementation rates, barriers and facilitators of bundle implementation, and the effect of care bundles on short-term patient outcomes such as intensive care unit (ICU) mortality all appear to be regularly studied. However, over the last years, critical care research has turned towards long-term patient-relevant outcomes after discharge from the ICU. To our knowledge, there is no systematic overview on the long-term effect of care bundle implementation on patient-relevant outcomes. We present a protocol for a scoping review of the available literature on the effect of the implementation of care bundles in the ICU on long-term patient-relevant outcomes.

Methods and analysis This scoping review will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines and the Arksey and O'Malley framework. The recommendations of the Joanna Briggs Institute for Scoping Reviews will also be followed. A systematic literature research will be performed using electronic databases (MEDLINE, EMBASE, CINAHL, PsycINFO, Web of Science, CDSR and CENTRAL). A preliminary search has been conducted on 1 September 2021, yielding 1929 entries. The main search, data extraction and charting has not been started yet. This scoping review will provide an overview of the long-term patient-relevant outcomes that have been used to assess the implementation of care bundles in the ICU. It will be the first study to summarise the long-term impact of care bundles for critically ill patients and identify research gaps to inform future research.

Ethics and dissemination Due to the utilisation of already published primary studies, ethical approval is dispensable. Results of this work will be published in a peer-reviewed journal.

Strengths and limitations of this study

- We will search five electronic databases for relevant literature (MEDLINE, EMBASE, CINAHL, PsycINFO, Web of Science, CDSR, and CENTRAL).
- The Arksey and O'Malley framework and the rigorous methods for scoping reviews by the Joanna Briggs Institute will be applied.
- The search strategy has been peer-reviewed according to the Peer Review of Electronic Search Strategies (PRESS) guidelines.
- Although it is optional for scoping reviews, two authors will conduct a critical appraisal of individual studies.
- We will not perform an in-depth assessment of the risk of bias due to missing results across studies.

INTRODUCTION

Background

The demand for intensive care medicine has starkly increased over the past two decades[1 2] and is forecasted to further grow in the future.[3] While patients show more comorbidities and a higher severity of illness, intensive care unit (ICU) mortality rates have been continuously declining.[4 5] Parts of this decline in mortality might have been due to technological advancements and the application of an increasing body of evidence on best clinical practice. In the rapidly changing and complex environment of the ICU, intensivists face more than 100 critical care decisions per day, where the growing body of evidence should be implemented.[6] A well-established way to put evidence into practice is the development and application of clinical practice guidelines, which systematically search and assess available evidence to derive recommendations to be applied at the bedside.[7 8] They usually address a particular area of critical care, for example the management of pain, sedation and delirium in the ICU.[9–11] Despite the existence and continuous development of guidelines, adherence to best practice in the ICU has shown to be relatively low,[12] and the transfer of new evidence to the bedside has shown to be slow.[9–11]

Another way to facilitate the transfer of novel evidence to practice is the application of care bundles.[13] Care bundles comprise groups of practice measures (usually 3–5) that are applied in conjunction to improve patient outcomes.[14] Usually, they centre around a specific aspect of patient care, and the measures of the care bundle are evidence based, non-controversial and well established. Each element of a bundle is well defined and adherence can be quantified and monitored.[15] The underlying idea is that the bundle's measures have greater impact on patient outcome if applied together.[15] With multiple interacting components, a large variability between bundle interventions, and various potential outcome measures, programmes for bundle implementation are usually complex interventions.[16] Examples of care bundles in the ICU are the sepsis bundle of the Surviving Sepsis Campaign, which includes measures for early recognition and treatment of sepsis,[17] or the ABCDEF bundle, which includes measures pertaining to pain, sedation, delirium, spontaneous awakening and breathing trials, mobilisation, and family engagement.[18]

Over the last decade, a plethora of studies has emerged on the implementation of care bundles in the ICU,[19] for instance, for the ventilator bundle,[20] the central line bundle,[21] or the sepsis bundle.[22 23] These studies used a diverse set of interventions to implement the respective bundles. For example, some studies involved auditing,[23 24] feedback and reminders to ICU staff,[23] activation of a sepsis response team,[23] checklists,[21] educational posters,[21] or teaching sessions.[21] Studies were prospective observational cohort studies,[22 23] retrospective studies,[24] or before-and-after studies,[20 21 25] and were conducted in a single centre[20–22 25] or in multiple centres.[23] Even if bundles were labelled similarly (eg, sepsis resuscitation bundle), the individual bundle components varied.[19 22 23] In terms of outcomes, studies regularly assessed the adherence to the bundles,[21 22 24 25] ICU mortality,[21 23 25] hospital mortality,[22 23] ICU length of stay,[23 25] costs of patient care,[25] and/or incidence of adverse events (eg, the incidence of ventilator-associated pneumonia[21 24] or the rate of catheter-related bloodstream infections[24]).

However, survivors of critical illness frequently face functional, long-term impairments after discharge from the ICU,[26] summarised under the umbrella term post-intensive care syndrome (PICS).[27] These impairments pertain to their cognitive functions,[28] mental health (depression,[29] anxiety,[30] and post-traumatic stress disorder[31]), and mobility.[32] PICS impairs patients' health-related quality of life and can last for several years after discharge.[32] As awareness of these impairments has grown over the last two decades, critical care research has turned from clinical outcomes in acute care, such as delirium rates or ICU mortality, towards these long-term PICS-related outcomes.[33] More generally, long-term PICS-related outcomes are part of a broader research focus on long-term patient-relevant outcomes, which comprise the PICS domains as well as health-related quality of life, mortality, symptoms, adverse events and complications.[34] There is an increasing effort to identify effective treatment options for patients suffering from different aspects of PICS, and to identify risk factors and interventions during ICU treatment to prevent PICS.[33]

Literature gap

Despite the consensus on their relevance, long-term patient-relevant outcomes appear to have received little attention in research on the implementation of ICU care bundles. So far, systematic reviews have focused on the most common elements of bundle implementation interventions in the ICU,[19] assessed the behaviour change techniques used in bundle interventions,[13] assessed if bundle implementation was associated with a favourable outcome,[13] or reviewed facilitators and barriers of bundle implementation in acute care settings.[35] It is unclear if studies on care bundle interventions in the ICU have used long-term patient-relevant outcomes, including functional outcomes in the PICS domains, and if they have been used, what the effect of bundle implementation on these outcomes is. Thus, there is merit in exploring the long-term patient-relevant outcomes that have been used to evaluate the effects of care bundle implementation in the ICU.

Objectives

A scoping review is considered a suitable tool to provide a comprehensive overview of a heterogeneous field of research and identify relevant research gaps. It may serve as a reference for subsequent, systematic reviews and meta-analyses. The aim of the planned scoping review is to map published literature that assesses the effect of the implementation of care bundles in the ICU on long-term patient-relevant outcomes.

Specific objectives are:

1. To identify which long-term patient-relevant outcomes have been assessed.
2. To identify the points in time when these outcomes have been assessed.
3. To describe the care bundles, their elements, and interventions used to implement these bundles.
4. To describe potential effects of care bundles on long-term patient-relevant outcomes.
5. To identify evidence gaps to target future research.

METHODS

Protocol

This protocol was drafted using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) checklist[36] and considered the Arksey and O'Malley framework for scoping reviews.[37] The protocol was registered on Open Science Framework[38] on 12 October 2021, and important protocol amendments will be uploaded there.

Study design

A scoping review was considered the most appropriate approach to identify patient-relevant outcome measures

Table 1 Search terms of the search strategy related to the four concepts

Concept	Search terms
Intensive care	critical care; critical illness; intensive therapy; intensive therapy unit; intensive care unit; intensive care
Care bundle	bundle; patient care bundle; care bundle; bundling; bundle intervention
Patient-relevant outcome	outcome; patient outcome; patient outcome assessment; patient-related outcome; patient reported outcome measure; patient centered outcome; patient centred outcome; critical care outcome; outcome assessment, health care; treatment outcome; pics; postintensive care syndrome; post-intensive care syndrome; patient important outcome; patient-important outcome; patient relevant outcome; patient-relevant outcome; quality of life; health-related quality of life; hrqol; survival; cognition; neurocognitive; cognitive; memory; memory disorder; executive function; attention; language; physical health; mental health; mental disorder; depression; depressive disorder; anxiety; anxiety disorder; ptsd; post-traumatic stress disorder; social health; return to work; social participation; social relationships; complications; adverse events; infection; pneumonia; stroke; accidental falls; dialysis; morbidity; dementia; fatigue; chronic fatigue syndrome; dysphagia; deglutition disorder; delirium; incontinence; urinary incontinence; fecal incontinence; mortality; mobility; weakness; muscular weakness; frailty
Follow-up studies	continuity of patient care; long-term care; long-term adverse effects; long-term; follow-up; follow-up studies; discharge; patient discharge; patient transfer

that were used to assess the long-term effects of the implementation of care bundles, regardless of study design and methods. Scoping reviews are used to explore an existing body of literature and give a broad overview of its focus.[39] The framework by Arksey and O'Malley will be applied, considering the additional explanations to this framework by Levac *et al*[37 40]: (1) identifying the research question, (2) identifying relevant studies (table 1), (3) study selection (table 2), (4) charting the data (table 3) and (5) collating, summarising, and reporting the results. We will adhere to the PRISMA extension for Scoping Reviews (PRISMA-ScR) checklist.[41]

The study team consists of a resident physician in anesthesiology and critical care, who is experienced in quality improvement interventions and post-ICU follow-ups (NP); a doctoral student conducting research on post-ICU cognitive impairments (A-CK), a student research assistant conducting research on functional post-ICU impairments (ERB), a medical doctor working for the Association of the Scientific Medical Societies with extensive experience in the development of clinical practice guidelines and appraisal of systematic and scoping reviews (MN), a critical care consultant experienced in quality of care research (BW); and a professor and head of department of anesthesiology and critical care with extensive

Table 2 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
► ICU setting ► Targeting the implementation of care bundles ► Measuring patient-relevant outcomes* ► Measuring outcomes at ICU discharge or later ► English, German, or Spanish publications ► Adult human study participants ► Original research articles	► Studies involving paediatric or neonatal patients ► No measurement of patient-relevant outcomes (eg, costs or employee satisfaction) ► Publications based on expert opinion only (eg, letters or editorials) ► Secondary research (eg, reviews or meta-analyses)

*Defined as outcomes pertaining to mortality, symptoms, adverse events, complications, health-related quality of life, or the PICS domains cognition, mental health (anxiety, depression, and post-traumatic stress disorder), and physical health/mobility.
ICU, intensive care unit; PICS, post-intensive care syndrome.

Table 3 Results reported for included studies

Study characteristics	► First author ► Publication year ► Country of origin ► Design ► Setting (including number of centres and ICUs) ► Study periods ► Aim of the study
Study population	► Inclusion and exclusion criteria ► Number of participants ► Characteristics of the study population ► Admission category
Characteristics and details of the intervention and comparator	► Care bundles used ► Elements of the care bundles ► Bundle implementation strategies used* ► Comparator (eg, standard of care)
Outcomes	► Bundle adherence rates ► Outcomes assessed, including patient-relevant outcomes (eg, mortality, morbidity, post-intensive care syndrome, health-related quality of life) ► Time points of outcome measurement after ICU discharge ► Follow-up rates ► Effect of the intervention on respective outcomes

*Applying the compilation of implementation strategies of the Expert Recommendations for Implementing Change (ERIC) project.[47]

experience in post-ICU care and the implementation of quality improvement measures (CS).

Step 1: identifying the research question

Our scoping review maps the long-term patient-relevant outcomes that were used to assess the implementation of care bundles in the ICU. The research question is as follows: What long-term patient-relevant outcomes have been measured in studies on the implementation of care bundles in the ICU? Additionally, we aim to answer the following questions: At what point in time were the patient-relevant outcomes assessed? Which care bundles have been implemented in studies that assessed long-term patient-relevant outcomes and how were they implemented? What is the effect of the implementation of care bundles in the ICU on long-term patient-relevant outcomes?

There is no consensus on the definition of patient-relevant outcomes.[34] Following the most frequent findings from a scoping review by Kersting *et al*,[34] we defined patient-relevant outcomes as outcomes pertaining to mortality, symptoms, adverse events, complications, and social health (ie, social reintegration, participation, or return to work). Given the nature of functional impairments of ICU survivors, we also included the PICS domains cognition, mental health (anxiety, depression, and post-traumatic stress disorder) and physical health/mobility, as well as health-related quality of life.[27 42] Long-term assessment was defined as measurement at ICU discharge or later.

Step 2: identifying relevant studies

A systematic search for peer-reviewed literature will be performed across the following electronic bibliographic databases: PubMed (including MEDLINE), EMBASE (via Ovid), CINAHL and PsycINFO (via EBSCO host), Web of Science, the Cochrane Database of Systematic Reviews (CDSR), and the Cochrane Central Register of Controlled Trials (CENTRAL). The search strategy does not have restrictions with respect to the publication date and includes English keywords as well as medical subject headings for four concepts: (1) intensive care, (2) care bundles, (3) patient-relevant outcomes and (4) follow-up studies. Table 1 shows the search terms used for the four concepts, which were combined with the appropriate Boolean operators. The exact search query for each database is shown in online supplemental file 1. The guidelines of the Peer Review of Electronic Search Strategies (PRESS) have been applied to formulate the queries and the search strategy has been reviewed by all members of the research team as well as an additional researcher from outside the study team.[43] Identified records will be imported to EndNote (V.20.1, Clarivate, Philadelphia, USA). Duplicates will be identified and removed using EndNote's duplicate finding. In addition to the electronic search, the reference lists of relevant reviews, meta-analyses, and included studies will be screened for additional literature.

Step 3: study selection

After duplication removal, all remaining results of the literature search will be imported to the web-based program Rayyan.[44] Titles and abstracts of all studies will be screened individually by two authors, applying inclusion and exclusion criteria. We will use Rayyan's blinding option for screening. Disagreements between the authors will be solved through discussion based on consensus of the reviewers. Decisions taken during the screening will be documented and outlined in the final report. The number of identified and selected articles at each stage will be presented in a PRISMA flow diagram. For potentially matching studies, full text will be retrieved, and a detailed, second screening will be conducted. We will publish a complete list indicating which studies were excluded in the second screening and the reasons for exclusion.

Considering discussions among the research team, inclusion criteria were defined based on the PICO (participant/population, intervention, control/comparison, and outcome) framework.[45] Participants: adult patients treated in the ICU; intervention: implementation of care bundles; comparison: standard care without systematic implementation and use of care bundles; outcome: patient-relevant outcomes measured at ICU discharge or later. Only original research articles published in English, German or Spanish will be included. There will be no limitation with respect to the publication date nor with respect to the primary research study design. Records that studied paediatric or neonatal patients, records that do not measure patient-relevant outcomes after ICU discharge, or records that are only based on expert opinion (eg, letters or editorials) will be excluded (table 2).

Step 4: charting the data

The data of the selected studies will be imported to Microsoft Excel and charted independently by two authors. Discrepancies between the authors will be resolved through discussions. For charting, the Joanna Briggs Institute data extraction form will be used[46] and adapted to include the following aspects: characteristics of the study population, study period, the type of care bundle that was implemented, elements of the care bundle, bundle implementation strategies used in the intervention, bundle adherence, study outcomes (including the patient-relevant outcomes), the time points after ICU discharge when these patient-relevant outcomes were measured, follow-up rate (if applicable), and effect of the intervention on respective outcomes. To enhance the comparability of bundle implementation strategies used in interventions, we will adhere to the nomenclature of 73 implementation strategies proposed in the Expert Recommendations for Implementing Change (ERIC) project.[47] The extracted data are summarised in table 3. Data extraction forms will be piloted using a small sample of publications and approved by the authors. The

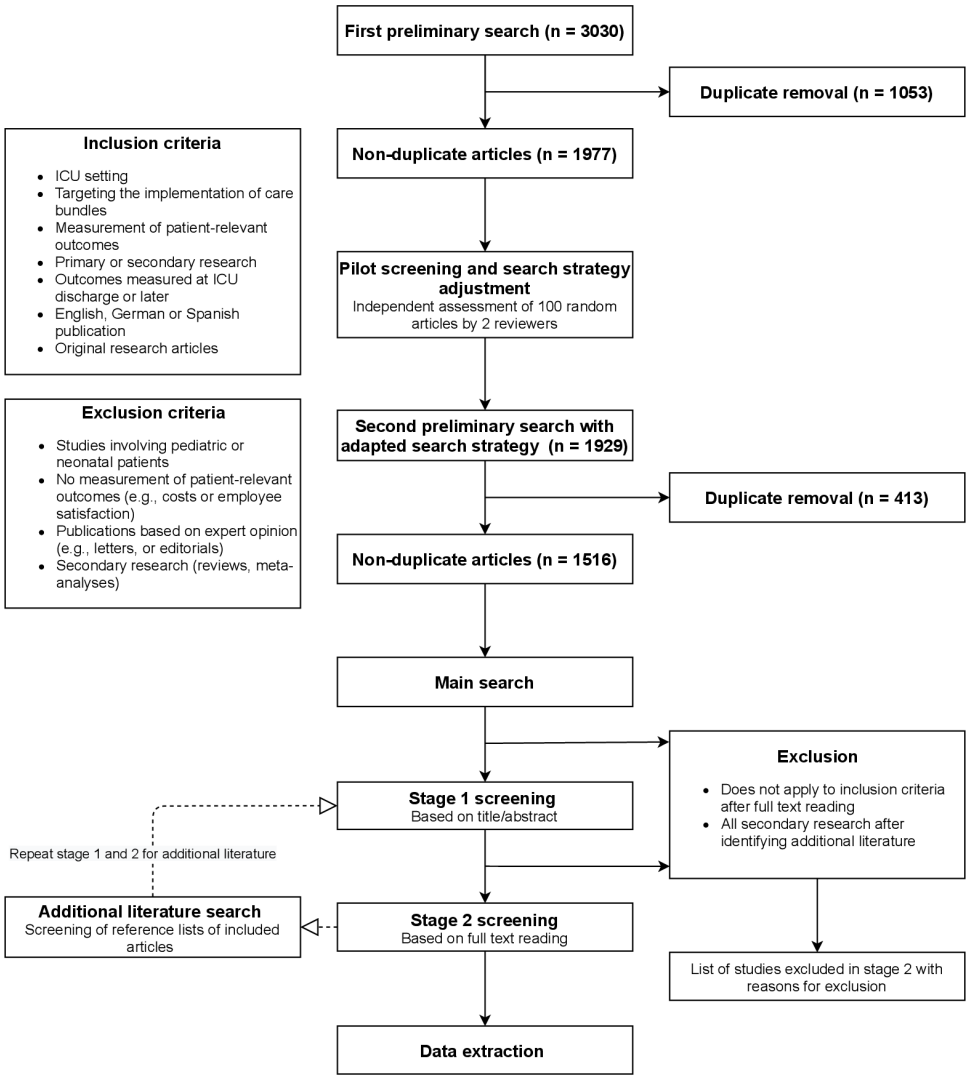

Figure 1 Search and selection process. ICU, intensive care unit.

extracted data for each study will be presented in a table accompanied by a summary.

Given the aim of a scoping review to provide an overview of existing evidence, an in-depth assessment of the risk of bias due to missing results across studies will not be conducted.[41] Nevertheless, a critical appraisal of individual studies may be used in scoping reviews if appropriate.[41] Hence, two authors will independently appraise included studies using the applicable Joanna Briggs Institute Critical Appraisal Tool.[48] Disagreements between the two authors will be resolved through discussions. As appropriate for scoping reviews, studies will not be excluded from the review based on inferior quality.

Step 5: collating, summarising and reporting the results

The results will be grouped by study population, the type of long-term patient-relevant outcome measure, the type of care bundle, and the type of bundle implementation strategy (using the nomenclature of the ERIC project[47]). Based on this grouping of our findings, we will be able to identify clusters of common themes, common patient-relevant outcomes for different care bundles, and relevant gaps in the literature. We will present our summarised results as a series of tables and graphs.

Patient and public involvement

No patients were involved in developing the research question or developing the scoping review design. For public involvement, we plan to disseminate results of the scoping review through the corresponding author's department website.

Ethics and dissemination

This scoping review will only evaluate primary studies that were already published and, thus, does not require an ethical approval. Results of this scoping review will be published in a peer-reviewed journal. In addition to dissemination via the corresponding author's department website, authors will use their social networks to disseminate results.

Preliminary search

A first preliminary literature search was conducted on 20 August 2021 to pilot the search strategy and ensure that

no other scoping review has been conducted on this topic (figure 1). The first preliminary search strategy resulted in 3030 findings across all included databases. After duplicate removal, 1977 entries remained. After import to Rayyan,[44] two reviewers (A-CK and ERB) performed a feasibility testing of title and abstract screening of 100 references to test the search strategy as well as inclusion and exclusion criteria. Disagreements were discussed until consensus was reached. Based on findings of the feasibility testing, the search strategy was refined by adding single patient-relevant outcomes as search terms to the search strategy (eg, depression, mobility, or health-related quality of life). A second preliminary literature search was performed on 1 September 2021, using the refined search strategy that is presented in online supplemental file 1. This search yielded 1929 entries with 413 duplicates. The main search, study selection, data charting, collating, summarising and reporting of the results is aimed to be completed by mid 2022.

Our preliminary searches indicated that our search strategy yields a sufficient number of entries. Hence, after screening, selecting, charting and summarising the findings, this scoping review will provide an overview on the long-term patient-relevant outcomes that have been used to assess the effect of care bundle implementation in the ICU. If our findings unveil relevant research gaps, this scoping review may guide planning of future systematic reviews and original research projects. In addition, findings from this scoping review might inform future consensus projects to define a core outcome set (COS), which is a minimum set of outcomes to be used in studies assessing the long-term effects of bundle interventions in the ICU. The Core Outcome Measures in Effectiveness Trials (COMET) initiative, for example, supports the definition of COS to harmonise, ease comparison and combine study results.[49]

This scoping review will be subject to limitations. First, the search terms to answer the research question were selected by the research team, which has expertise in critical care, quality improvement projects, care bundles, post-ICU follow-ups, and PICS-related impairments. Despite their expertise, the clinical focus of the research team might introduce a bias which will be discussed when reporting the scoping review's findings. Second, the scoping review will not apply restrictions to the type of ICU care bundles or interventions for bundle implementation and will consider a large spectrum of potential outcomes. While the heterogeneity of potential findings can be perceived as a strength, it will impose challenges on evidence synthesis and the ability to draw conclusions. Third, there is no uniform consensus on the definition of patient-relevant outcomes. For the purpose of this review, we used an inclusive definition, which was based on previous research and supplemented with outcomes that were shown to be particularly relevant in survivors of critical illness. Nevertheless, we might have excluded relevant studies a priori by using this definition.

CONCLUSIONS

This scoping review will identify and map existing studies that used long-term patient-relevant outcomes to assess the implementation of care bundles in the ICU. Our preliminary search revealed that there is sufficient literature to proceed to study selection, charting, summarising and reporting of our results. Findings of this scoping review will inform clinicians and researchers on the impact of care bundles on long-term patient-relevant outcomes and indicate research gaps for future systematic reviews and studies.

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