

Gli esiti dell'Assistenza Infermieristica in Terapia Intensiva: protocollo di ricerca di una scoping review

Nursing Sensitive Outcomes in the Intensive Care Unit: a scoping review protocol

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RIASSUNTO

Introduzione: spinti dall'attuale bisogno di costruire organizzazioni sanitarie sempre più affidabili e orientate ai bisogni dei pazienti, numerosi sforzi sono stati messi in atto per quantificare e qualificare il contributo degli infermieri in termini di Esiti Sensibili alle cure Infermieristiche (ESI) in area critica. Sebbene molti studi siano stati condotti in Terapia Intensiva (TI), gli ESI da considerare nella progettazione di nuove ricerche sono limitati e non ben definiti. In questo lavoro, abbiamo delineato un protocollo di ricerca per la conduzione di una scoping review, con l'obiettivo di mappare le caratteristiche degli studi condotti finora sugli ESI in TI, e di formulare ipotesi di ricerca futura.

Metodi e analisi: questa scoping review seguirà il metodo illustrato dal Joanna Briggs Institute e contenuto nel PRISMA Statement per scoping reviews. La ricerca della letteratura sarà condotta attraverso i seguenti database: Cochrane Database of Systematic Reviews, CINAHL, Joanna Briggs Library, MEDLINE/PubMed, Scopus, Web of Science; in aggiunta, saranno consultate anche fonti di letteratura grigia. Saranno incluse pubblicazioni: (a) con oggetto di studio gli ESI su popolazione adulta di pazienti critici ricoverati in TI, (b) in lingua inglese, (c) senza limiti temporali. Due tra gli autori valuteranno, in maniera indipendente, titoli, abstract e full-text per individuare i lavori da includere. In seguito, un file di estrazione dati sarà utilizzato per raccogliere le informazioni necessarie dagli studi selezionati. I risultati saranno riportati in forma narrativa e con il supporto di tabelle, fornendo una panoramica della letteratura esistente.

Diffusione dei risultati: la scoping review riporterà lo stato dell'arte della ricerca sugli ESI in TI. Questo lavoro costituisce il primo punto di un'agenda di ricerca volta a studiare e sviluppare gli ESI sul paziente critico in TI per monitorare sia la qualità delle cure ricevute, che la qualità di vita del paziente. I risultati di questo lavoro saranno diffusi attraverso incontri professionali e conferenze, nonché pubblicati in riviste scientifiche.

Parole chiave: Terapia Intensiva; Assistenza Infermieristica; Nursing Outcomes; Nursing Sensitive Outcomes; Scoping Review



ABSTRACT

Introduction: driven by the current need of achieving high-reliability and patient-focused organization, several efforts have been enacted to date with the purpose of identifying and qualifying nurses' contribution to Nursing Sensitive Outcomes (NSOs) in critical care. Although many studies have been conducted in Intensive Care Unit (ICU), the set of NSOs that should be considered while designing studies in the field are limited and have not been well defined to date. In this paper, we outline a scoping review protocol to map the characteristics of the studies on NSOs in ICU to inform future research in the field.

Methods and analysis: this scoping review will follow the Joanna Briggs Institute's framework and the Preferred Reporting Items for Systematic reviews and Meta-Analyses - Scoping Reviews (PRISMA-ScR) statement. A search will be conducted through the Cochrane Database of Systematic Reviews, CINAHL, Joanna Briggs Library, MEDLINE/PubMed, Scopus, Web of Science, as well as grey literature sources. We will include all studies (a) focused on NSOs in adult critically ill patients admitted and cared for in an ICU and (b) published in English language, (c) with no limit on publication time frame. Two researchers will independently screen titles, abstracts and full-text for inclusion. Then, a pre-defined data extraction tool will be used to extract information from selected studies. Results will be presented in tabular and narrative form, providing a complete overview of the existing literature.

Results dissemination: the scoping review will summarize the state of research by providing an overview of NSOs studied among patients cared for in ICU settings. This study constitutes the first step in a research agenda aimed at deepening and developing a set of NSOs reliable on critically ill patients and useful to proxy monitoring both the quality of care in hospital and the health-related quality of life of critically ill patients. The results of this study will be disseminated through professional meetings and conference presentations, as well as published in biomedical journals.

Key words: intensive care unit, nursing care, nursing outcomes, nursing sensitive outcomes, scoping review.

PROTOCOLLO DI RICERCA

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INTRODUCTION

Critically ill patients' outcomes vary extensively across intensive care units (ICUs), partly because of differences in patient characteristics (including demographics, severity of illness, admission status, and underlying comorbidities)^[1] and partly because of organisational features (including hospital and ICU sizes, closed or open ICU policies, availability of specialty ICUs, and nursing staff characteristics)^[2]. All elements of nursing care, from the *fundamentals* focusing on basic technical- and non-technical interventions (e.g., ensuring personal hygiene and comfort) to the *advanced* (e.g., managing devices), are aimed at ensuring patients' outcomes. Several studies have focused on the relation between ICU patients' outcomes and staffing, proving that mortality, complications, and length of stay (LOS) are all influenced by the quality of nursing care delivered^[3-5]. However, establishing nursing care's contribution to patients' outcomes is something more than just the estimation of a mere nurse-to-patient ratio. Maas *et al.*^[6] performed one of the first studies along this line, highlighting the relationship between nursing care variables and patient outcomes by developing and validating a list of nursing-sensitive outcomes (NSOs) as a change in the patient's or in the family caregiver's state, behaviour, or perception associated with the care received^[6]. Over the years, NSOs have been used to assess nursing practice, to examine patient safety enhancement programmes, and to measure improvements in patient care^[7].

Only five reviews focused on NSOs in the ICU setting have been produced^[8-11], likely due to the fact that multidisciplinary work is predominant in this clinical field^[12], making it difficult to identify suitable outcomes for patients associated with nursing care^[11]. The critical review of Carayon and Gurses in 2005 was the first attempt to summarise the literature on NSOs and nursing care in the ICU^[8]. By including 22 studies published from 1991 to 2003, the authors presented ICU nursing workloads at four levels (ICU, job, patient, and situation), as determined with different measures, such as nurse-to-patient ratio, the Nursing Activities Score (NAS)^[13], and self-report scales. These factors have been documented as affecting different outcomes, mainly concerning patient safety (e.g., medication administration errors, inadequate surveillance, erroneous ventilator setup, and unplanned extubation [UE]).

With the same intent, Kane *et al.*^[9] performed a systematic review and meta-analysis in 2007 that included 96 studies published between 1990 and 2006. According to the findings, a rise of one nurse per patient per day decreased the odds of respiratory failure by 60%, UEs by 51%, ICU LOS by 34%, ventilator-associated pneumonia (VAP) by 30%, cardiac arrest by 28%, ICU-related mortality by 9%, and hospital-related mortality by 4%. Two years later, one more systematic review investigated the impact of nursing staff variables (e.g., education, staffing levels) on mortality and adverse events in ICU settings^[9]; it included 15 studies published from 1990 to 2006. The authors pointed out that all primary studies included found a close relationship between nursing staffing levels and at least one outcome. Although mortality rate was the most explored dependent variable, its association with nursing staffing was established in only three out of ten statistical analyses performed. In addition, other nursing role variables on patients' adverse events emerged, such as central-line-associated bloodstream infections (CLABSIs), pneumonia, and delays in weaning from mechanical ventilation.

In 2012, McGahan *et al.*^[10] focused on the association between nursing staffing levels and mortality, infections, and pressure ulcers by systematically reviewing 19 studies published between 2002 and 2011. While a lower level of nurse staffing was associated with higher patient mortality and occurrence of infections in the majority of primary studies included, the association between nurse staffing levels and pressure ulcer development was found to be weak. Moreover, the authors were unsuccessful at identifying the exact nurse-to-patient ratio in the ICU required to optimise patients' outcomes, reporting that multiple confounders might have influenced the estimations.

The most recent systematic review on NSOs in high acuity areas was conducted in 2017, covering the period from January 2000 to November 2016^[11]. The authors examined studies highlighting patients' outcomes that were found to be associated with nurse staffing and skill-mix levels in stand-alone high acuity settings, including the ICU, step-down unit (with an intermediate level of care), high dependency unit, and emergency department (ED). Of the 35 articles included in the final analysis, all were observational in design and mainly performed in the US. Only eight NSOs

have emerged as applicable to high acuity areas: mortality and LOS (in both the specific ICU care setting and the hospital), CLABSIs, VAPs, reintubations, falls with injury, sepsis, and medication errors. However, the authors concluded that there was still the need to clarify the definitions for each of these indicators, establishing common metrics and instruments across studies; moreover, given that grey literature was excluded, a potential bias could have affected these findings.

STUDY RATIONALE

Alongside the five reviews mentioned above, which were unable to fully meet the purposes and the requirements of knowledge, no published or ongoing scoping reviews have emerged on this topic. All the above-mentioned reviews summarised studies that considered mortality and adverse effects as NSOs with predominantly quantitative approaches. Other outcomes of nursing care, such as psychological recovery^[14], sleep effectiveness^[15], pain and discomfort^[16], or oral hygiene^[17], which have also been reported as being important according to the patients' experience, have been neglected, most likely due to the complexity of the nursing discipline in the ICU and the lack of measures capable of depicting the effects of nursing care on behaviour and perceptions of critically ill patients.

Moreover, primary studies included have often been observational in design and/or of low methodological quality, making it difficult to demonstrate a clear causal relationship between nursing care and NSOs. Furthermore, with regards to the setting, while high acuity reflects a general concept that refers to the high level of care required by a patient regardless of the location^[11], the ICU is a specific physical space in which critically ill patients with life-threatening conditions are supported by advanced technology, monitored continuously, and cared for by a multidisciplinary team that is specially qualified^[12]. As a consequence, the set of NSOs that should be considered while designing studies in the field is limited and has not been well defined.

STUDY OBJECTIVES

The objective of this scoping review is to map (a) all primary studies performed in the field of NSO, thus overcoming the selection limits applied by the systematic reviews available; (b) NSOs in the ICU, thus providing a

summary of the evidence published to date and highlighting outcomes requiring further research; and (c) nursing care variables that have been associated with NSOs.

From the research point of view, this scoping review will function as a precursor of the systematic review^[18] in the case of those NSOs and/or nursing variables that will emerge as susceptible to a systematic review. Moreover, from the clinical practice point of view, findings of this work will inform (a) health care systems regarding the most suitable indicators to monitor failing in the scope of ICU nurses' responsibilities^[19], (b) the nurse managers and the clinical nurses regarding the set of NSO data that should be collected at the bedside and recorded^[7], and (c) (at both levels) structure and process care variables that should be considered as affecting the quality of nursing care. Finally, from the nursing education point of view, the findings of this scoping review will inform curriculum re-design at both the undergraduate and postgraduate (e.g., master's degree) levels regarding NSOs and associated factors in caring for critically ill patients in the ICU.

METHODS AND ANALYSIS

A scoping review design will be performed by following the framework proposed by Arksey and O'Malley^[20] in 2005, which was further developed by Levac *et al.*^[21] in 2010 and enhanced in rigor and clarity by the Joanna Briggs Institute^[22] in 2017. The following five stages will be performed: 1) identifying the research question; 2) identifying relevant studies; 3) selecting studies; 4) charting the data; and 5) collating, summarising, and reporting the results. Moreover, this protocol is conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis – Scoping Reviews (PRISMA-ScR) statement^[23].

Stage 1: Identifying the research question

The review questions are:

- What is the current state of research in the field of NSOs in the ICU?
- What are the ICU's nursing outcomes that have been conceptualised and measured to date?
- What nursing care variables have been studied as associated with NSOs?

Stage 2: Identifying relevant studies PCC framework

The search strategy will be strengthened by the inclusion criteria based on the 'Population-Concept-Context (PCC)' framework^[22].

Participants

This scoping review will map studies concerning adult (≥ 18 years old) critically ill patients admitted and cared for in an ICU.

Therefore, studies regarding the paediatric population (<18 years old) and patients receiving palliative care in the ICU will be excluded.

Concepts

The central focus of this review will be the NSOs. According to Maas *et al.*^[6], which has been subsequently universally recognised^[11], an NSO is considered as any change in a patient's health state, behaviour, and/or perception associated with nursing care interventions, as performed by nurses.

With regards to the NSOs, we will consider the classification developed by Doran^[24], who categorised nursing outcomes in (a) *clinical* (e.g., deterioration of pain and vital signs)^[25], (b) *functional* (e.g., duration of early morning stiffness, fatigue)^[26], (c) *safety* (e.g., urinary tract infection, pressure ulcers, and pneumonia)^[27], and (d) *perceptive* outcomes (e.g., patients' perceptions of nursing care received)^[28]. With regards to the nursing care variables, we will consider Irvine *et al.*'s^[29] framework, which categorises nurses' role functions as (a) *independent* (without a physician order or prescription), (b) *dependent* (medical care-related), and (c) *interdependent* (team-related). Moreover, alongside these process variables (e.g., independent, dependent interventions), emerging factors affecting NSOs will also be categorised in structural variables^[24] (e.g., the nurse-to-patient ratio) when appropriate.

Therefore, all studies that refer to any NSO for patients admitted to the ICU will be included in this scoping review. In particular, all clinical, functional, safety, and perceptive NSOs will be considered when associated with nurse's independent, dependent, and interdependent role functions. When documented, data on nurse-related structural and process variables and NSOs will also be considered.

Context

The context will include (a) general ICUs where patients from medical, surgical, and emergency departments are admitted and

cared for, and (b) specialty ICUs where specific care for select populations of critically ill patients is delivered. For the intent of this scoping review, an ICU is defined as a multidisciplinary and inter-professional environment in which patients with or at risk of developing life-threatening organ dysfunction are cared for^[12]. No country restrictions will be applied in order to scope the full amount of studies available in the field.

Types of studies

The following studies will be included: (a) primary (all methods, both quantitative and qualitative) and secondary studies as reviews and meta-analyses, (b) published in indexed journals or as grey literature, and (c) written in the English language. No limitation on the time frame of publication will be applied. The following studies will be excluded: (a) conference abstracts, book chapters, commentaries, and editorials, and (b) studies written in a language other than English according to the language background of the research team.

Search strategy

Following the Joanna Briggs Institute's guideline^[2], the search strategy will be a three-step process. First of all, a preliminary and fast search will be conducted on at least two online databases relevant to our topic (MEDLINE and Cumulative Index to Nursing and Allied Health Literature [CINAHL]), combining the terms *nursing-sensitive outcomes*, *critically ill patients*, and *intensive care unit*, with the aim of identifying other keywords and index terms to develop a full search strategy. Subsequently, multiple databases will be examined in the second step. The search strategy was designed with the assistance of a librarian; its implementation will be assisted by the same expert librarian. An example for one electronic database (MEDLINE) is outlined in **Table 1**. In the final step, researchers will scan the references of all relevant studies identified for additional sources of inclusion. In the case of reviews, the reference lists will be screened by hand, with the aim of retrieving relevant studies to add for their evaluation against the

Table 1. Literature search strategy for MEDLINE (PubMed).

1	"Outcome Assessment (Health Care)" [Mesh] OR "Patient Outcome Assessment" [Mesh] OR "Treatment Outcome" [Mesh] OR "Quality of Health Care" [Mesh] OR "Critical Care Outcomes" [Mesh] OR "Outcome Measures"
2	"Intensive Care Units" [Mesh] OR "Critical Illness" [Mesh] OR "Critical Care" [Mesh] OR "Critical Care Nursing" [Mesh] OR "Critically ill patient"
3	"Nursing" [Mesh] OR "Nursing Care" [Mesh] OR "Contribution of nursing care" OR "Nursing sensitive outcome" OR "Nurse sensitive indicator"
4	#1 AND #2 AND #3
5	(Limits: English language and adult population)

inclusion criteria. Moreover, in case of doubts regarding the study inclusion due to data not reported in the fulltext, authors will be contacted via email with at least three attempts to obtain missed information.

Information sources

Information sources to be consulted in-depth will include the MEDLINE (via PubMed), Cochrane Database of Systematic Reviews, CINAHL, Joanna Briggs Library, Web of Science, and Scopus databases. Additionally, freely accessible web search databases (e.g., Google Scholar); websites of governmental and professional organisations about ICU care, such as the European Society of Intensive Care Medicine (ESICM); and OpenGrey for unpublished studies will be hand-consulted.

Stage 3: Study selection

All identified studies will be uploaded into the bibliographic management software End-Note (Clarivate Analytics, PA, USA), and duplicates will be removed. In the first phase, study titles and abstracts will be screened and evaluated for their eligibility against the inclusion criteria by two researchers, independently. All studies considered relevant will be included; disagreements will be resolved by discussion with a third researcher. In the second level of screening, an independent full-text review will be performed by two researchers to determine if studies meet the inclusion criteria. Even in this step, in cases of disagreement, a third researcher will be involved. The reasons given for excluded articles will be summarised in the PRISMA-ScR flow diagram^[22], which will provide the flow process of a study's search and selection process. According to Arksey and O'Malley^[20], no assessment of methodological quality of the studies included will be performed.

Stage 4: Charting the data

A Microsoft Excel® spreadsheet will be

used to extract data from the included studies (**Table 2**). Data extraction will be performed independently by two researchers. The following will be extracted: (a) the study's general information (author, journal/source, publication/data collection year, and country); (b) the study's main features, such as study design, setting(s) involved (e.g., type of ICU), aims, participants' inclusion criteria, participants included, and their main characteristics; (c) a description of the reported NSOs in terms of definition, instruments, metrics and procedures, and timeframe; (d) the nursing care variables (as structure and process variables, when reported) that have been associated with NSOs; and (e) the key findings of the study. Then, a pilot test will be performed to assess the capability of the form to capture the proper information by reading and extracting at least 10% of the studies retrieved by two researchers independently, before agreeing on the findings. The final data extraction sheet will be reviewed by all authors to eliminate discrepancies and ensure consistency in the data included.

Stage 5: Collating, summarising, and reporting the results

Data presentation

Data presentation will offer:

- a) a description of the state of the research in the field (e.g., countries involved, types of ICUs, and methodologies used), thus offering a comprehensive map on how studies have been designed and performed to date;
- b) NSOs as measured in the ICU to date, reporting their definitions, measures, instruments, and timeframes^[21];
- c) independent variables related to NSOs as measured in the ICU, categorised in (a) process variables as *independent*, *dependent*, and *interdependent* role functions, and in (b) structure variables (as

nurse-to-patient ratio)^[24,29].

Moreover, tables, charts, and maps will be used to present the findings. Graphic representations will be accompanied by narrative summaries.

DISSEMINATION AND ETHICS

To the best of our knowledge, no other published works have provided a comprehensive overview of the NSOs in ICUs. This protocol for a scoping review constitutes the first step in a research agenda aimed at deepening and developing a set of NSOs reliable across the ICUs and useful for proxy monitoring the quality of care in hospital and the health-related quality of life of critically ill patients. In view of the nature of this study that collects and examines data from the available literature, the researchers do not consider any ethical risk. To facilitate knowledge sharing, the results of this study will be disseminated through professional meetings and conference presentations, as well as published in biomedical journals.

Strengths and limitations of this study

- This will be the first scoping review to identify a broad set of nursing outcomes that are specific to critically ill patients in intensive care units.
- This study will be the first to focus on structure and process nursing care variables that have been associated with nursing-sensitive outcomes.
- The search strategy is wide-ranging, including both electronic databases and grey literature, without time restrictions.
- Due to the inclusive nature of this review and the high expected methodological heterogeneity across studies, no quality assessment of studies will be performed.

Table 2. Data extraction table

Study general information			Study main characteristics				NSOs measured, instruments, metrics and procedures, and timeframe	Nursing care process variables (independent, dependent or interdependent role function) and structure variables ^[24,29] (when reported)	Key findings
First author and year of publication and data collection	Country	Journal / source	Design, Setting(s)	Aim (s)	Participants inclusion criteria	Participants: profile			

NSOs, Nursing Sensitive Outcomes.

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