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# Determinants of clinical nurses' patient safety competence: a systematic review protocol



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| Complete List of Authors: | Park, Jong-Hyuk; Seoul National University College of Nursing, patient safety research team<br>Lee, Nam-Ju; Seoul National University, Research Institute of Nursing Science<br>Han, Hanseulgi; Seoul National University College of Nursing<br>Park, Gihwan; Seoul National University College of Nursing |
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| | |

# Determinants of clinical nurses' patient safety competence: a systematic review protocol


## Abstract

### Introduction

Patient safety has become a fundamental indicator of healthcare quality. However, despite the ongoing efforts of various organisations, patient safety issues remain a problem in the healthcare system. Considering the crucial role of nurses in the healthcare process, improving patient safety competence among clinical nurses is important. In order to promote patient safety competence, it is essential to identify the relevant factors and strengthen these aspects. This protocol is for a systematic review aiming to examine and categorise the factors influencing patient safety among clinical nurses.

### Methods and analysis

This review protocol is based on the Joanna Briggs Institute (JBI) Methodology for Systematic Reviews of Effectiveness and Preferred Reporting Items for Systematic Reviews and Meta-Analyses protocols. Four electronic databases, including Ovid-MEDLINE, CINAHL, Cochrane Library, and EMBASE will be utilised for the systematic review. After consulting with a medical librarian, we designed our search terms to include medical subject headings (MeSH) terms and related terms in the titles and abstracts. Databases from January 2012 to August 2023 will be searched.

Two reviewers will independently conduct the search and extract data including the author(s), country, study design, sample size, clinical setting, clinical experience, tool used to measure patient safety competence, and factors affecting patient safety competence. The quality of the included studies will be assessed using the JBI critical appraisal tool. Because heterogeneity of the results is anticipated, the data will be narratively synthesised and divided into two categories: individual and organisational factors.

### Ethics and dissemination

Ethical review is not relevant to this study. The findings will be presented at professional conferences and published in peer-reviewed journals.

PROSPERO registration number CRD42023422486


### Strengths and limitations of this study

- The review protocol has been rigorously and systematically developed according to the JBI Methodology for Systematic Reviews of Effectiveness and Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol.

- This study is the first systematic review that categorises the factors that influence patient safety competence among clinical nurses into two main categories: individual and organisational.
- This study will rigorously select relevant articles according to the Canadian Patient Safety Institute's patient safety competence framework.
- The anticipated heterogeneity of contributing factors is expected to make it challenging to conduct a meta-analysis.
- This study will only include articles in English and exclude grey literature, which could result in potential publication bias.

## Introduction

Patient safety has become a global public health issue and a fundamental element of healthcare quality [1-3]. According to the World Health Organisation, patient safety is a framework of organised activities that creates cultures, processes, procedures, behaviours, technologies and environments in healthcare that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make errors less likely, and reduce the impact of harm when it does occur [1].

Despite its importance, patient safety issues continue to undermine the healthcare system [4-5]. Annually, an estimated 421 million patients worldwide are admitted to hospitals, while approximately 42.7 million patient safety incidents occur within the healthcare system [6]. The impact of patient safety incidents during patient care is noteworthy on a global scale, leading to over 3 million deaths annually [7]. Approximately 237 million patient safety problems occur each year in England [8] resulting in a financial burden of more than 750 million pounds [9]. Approximately 10% of healthcare expenditures are allocated to address the consequences of patient safety incidents, resulting in a considerable decrease in the global economy costing trillions of dollars annually [6, 7]. However, it has been found that a significant portion (ranging from 25% to 50% or more) of these events are preventable within the healthcare system [6, 10-11].

In all dimensions of the healthcare process, nurses are responsible for patient safety [12]. Nurses, who spend more time with patients than other healthcare professionals, play a vital role in identifying patient safety risks and ensuring high-quality care [12-14]. Through careful monitoring of patient conditions, quick identification of risks, and supervision of the healthcare process, they actively contribute to patient safety [13, 15]. In addition, nursing activities such as medication administration, infection control, and fall prevention have a direct impact on patient safety [16]. Therefore, maintaining high levels of patient safety competence among nurses is crucial for decreasing patient safety issues and enhancing the quality of patient care [13, 17].

The Quality and Safety Education for Nurses (QSEN) project identified the fundamental elements of quality and safety competence in nursing, including patient-centred care, teamwork and collaboration, evidence-based practice, quality improvement, safety, and informatics [18]. These core principles improve evidence-based standards with a systemic perspective and enhance the quality of patient care [19]. In addition, the Canadian Patient Safety Institute (CPSI) outlines crucial aspects of patient safety competence, including the ability to recognise, respond to, and disclose patient safety incidents, foster a patient safety culture, promote effective teamwork and communication, ensure safety and manage risks, promote quality improvement, and optimise both human and system factors [20].

The definition of patient safety competence encompasses the attitude, skills, and knowledge that prevent unnecessary risk and harm to patients [18, 21]. This competence helps prevent patient safety incidents and addresses latent problematic issues in the healthcare system [13, 22]. A recent study revealed that a patient safety competence can reduce preventable adverse events, including medication errors, surgical site infections, urinary tract infections, and ventilator-associated pneumonias [13].

In addition to recognising the significance of the patient safety competence of nurses, there are many aspects of patient safety competence that require further investigation and understanding [23]. First, it is important to identify the factors relevant to patient safety competence and enforce the contributing factors. A study by Huh et al. revealed that demographic factors such as age, education level, patient safety education, and experience in patient safety activities are associated with patient safety competence [16]. However, prior studies have focused primarily on the individual attributes of patient safety competence and have not emphasised the organisational factors [24]. Patient safety is a complex process within the context of a system that requires collaborative efforts from both the individual and the organisation [14,25].

Although there are limited reviews of patient safety competence instruments [26, 27], there are currently no systematic reviews of the factors that contribute to the patient safety competence of clinical nurses. A previous review by Okuyama et al. [26] conducted in 2011 explored patient safety competence across diverse healthcare professionals. However, the patient safety competence of clinical nurses may differ from other healthcare professionals. In addition, most recent instruments of patient safety competence may not have been included in that review. Mortensen et al. [27] published a scoping review of the instruments of patient safety competence in nursing. However, scoping reviews have methodological limitations that offer a general overview rather than a comprehensive in-depth analysis and they do not include a formal quality appraisal process [28]. Moreover, there is a lack of consensus on the definition of patient safety competence and its conceptual framework in that study.

This protocol aims to provide guidance for a systematic review to identify the factors affecting the patient safety competence of clinical nurses. To foster a comprehensive understanding of patient safety

competence, we will categorise those factors into two domains: individual and organisational. Moreover, this study will encompass research that has examined the core concept of patient safety competence based on the CPSI framework. This review would essentially provide a starting point for identifying the determinants of patient safety competence.

## Study objectives

The purpose of this research is to examine the factors that influence the patient safety competence of nurses. The specific research questions include: 1) what is the definition of patient safety competence, 2) what instruments for assessing patient safety competence are examined in this research, and 3) what factors affect the patient safety competence of clinical nurses?

## Methods

Before conducting this review, we thoroughly searched the International Prospective Register of Systematic Reviews, which revealed no ongoing systematic reviews of the factors influencing the patient safety competence of clinical nurses. To conduct a systematically organised review, this protocol was developed based on the Joanna Briggs Institute (JBI) Methodology for Systematic Reviews of Effectiveness. The JBI checklist, an organised tool to promote and support evidence-based practice, provides a rigorous systematic review process [29]. Some elements were updated and modified from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol [30]. We registered this systematic review with the International Prospective Register of Systematic Reviews (CRD42023422486). The systematic review started in August 2023 and included a preliminary search and pilot study selection process to screen the search results based on the eligibility criteria.

## Search strategy (PICO) and data sources

This systematic review explores the determinants of patient safety competence among clinical nurses (P-population). The study examines the impact of various factors that either enhance or impair patient safety competence (I-indicator), comparing their effects on nurses exposed to these factors to those who are not exposed (C-comparison). The primary outcome to be measured is the level of patient safety competence (O-outcome). According to the PICO statement guidelines, the search strategy was developed in consultation with a health sciences librarian. Four databases, including EMBASE, CINAHL, Ovid-Medline, and Cochrane Library will be explored from January 2012 to August 2023. The reason for selecting this period is because the MeSH term for patient safety was introduced in 2012. The specific search strategy is presented in Table 1.

Table 1. Search terms identified to screen for Ovid-Medline

| *Search Topic* | *Search Term* |
|---|---|
| #1. Competence | ("abilit*" or "skill*" or "knowledge" or "behavio*" or "perception*" or "performance*" or "attitude*" or "competence*" or "efficac*").ti,ab. OR Exp Clinical competence/ |
| #2. Patient safety | Exp patient safety/ OR "patient safety".ti,ab. |
| #3. Nurse | Exp nurses/ OR "nurs*".ti,ab. |
| #4. Time | January 2012 - August 2023 |
| #1 AND #2 AND #3 AND #4 | |

**Population**

This study will include licensed clinical nurses of all ages and genders across diverse fields. However, it will exclude nurses who are not directly involved in frontline patient care, such as chief nurses and nurse managers. Moreover, this study excludes nursing students who are not licensed or certified.

**Indicator**

This study will explore multiple influencing factors that serve as indicators of patient safety competence. The JBI quality appraisal tools employ a rigorous assessment process to evaluate the validity and reliability of indicators. A diverse and heterogeneous range of tools is expected to be employed in the study.

**Comparator**

This systematic review allows for comparisons based on exposure to the indicators. Comparisons can be made between clinical nurses who have been exposed to specific factors and those who have not. Furthermore, the study also enables comparisons across different health settings, providing valuable insights into the variations in patient safety competence within diverse healthcare environments.

**Outcome**

The primary outcome is patient safety competence, which encompasses complex patient safety principles, including the CPSI's patient safety competence. This competence includes the ability to recognize, respond to, and disclose patient safety incidents, manage safety, risks, and quality improvement, communicate effectively, foster teamwork, understand patient safety culture, and optimize human and system factors [20]. The outcome measure will be rigorously evaluated for its validity and reliability.

**Study design**

The study will encompass original descriptive cross-sectional analyses, comparative research, and

mixed-method research. Only peer-reviewed articles on patient safety competence will be included, to ensure high-quality and reliable information. Grey literature will be excluded as it does not meet our criteria for being valid, rigorous, and peer-reviewed.

**Inclusion and exclusion criteria**

**Inclusion.** All published studies that examine factors related to the patient safety competence of registered or licensed nurses will be included. The measurement of patient safety competence among clinical nurses serves as the primary outcome in the included studies. According to the CPSI [20], the competence should cover various attributes, including (1) patient safety culture; (2) teamwork; (3) communication; (4) safety, risk, and quality improvement; (5) optimised human and system factors; and (6) recognition, response, and disclosure of patient safety incidents. The participants in the included studies will be licensed or certified clinical nurses. The selected articles will be peer-reviewed, written in English, and published from January 2012 to August 2023.

**Exclusion.** Studies that focus exclusively on a single attribute, such as communication or medication competence, will be excluded. Research exploring patient safety competence in populations other than nurses (e.g., hospitalists and medical students) will also be excluded. The review will not include studies in which the participants are individuals without official nursing licenses, including nursing students and patients' family members. Review articles, theses and dissertations, conference abstracts, editorials, opinion articles, case studies, and qualitative studies will be excluded. Articles not available in full text will also be excluded.

**Study selection**

Using the Covidence platform, two independent reviewers will conduct the article screening process by evaluating the titles and abstracts and classifying them into the categories of relevant, irrelevant, or unsure. Disagreements regarding irrelevant articles will be resolved through discussion between the two reviewers. Only articles classified as relevant or unsure during the initial screening are selected for the subsequent step of full-text screening, which will be conducted by the same two reviewers. During this stage, the reviewers will each compile their own list of relevant articles, which will then be compared. Any discrepancies will be resolved through discussion. For any unresolved discrepancies, a third reviewer will be consulted, and the final decision will be made by the entire team.

**Data extraction**

Two researchers will collect information independently based on the following criteria: the author(s), country, study design, sample size, clinical setting, clinical experience, instrument to measure patient safety competence, and factors affecting patient safety competence. Any discrepancies between the results obtained by the two researchers are resolved through discussion or with the involvement of a

third reviewer.

**Quality assessment.**

The JBI critical appraisal checklist will be used for a strict quality appraisal process [31]. The objective of the appraisal is to assess a study's methodological quality and identify any potential bias in its design, conduct, and analysis [29]. Two reviewers will independently evaluate the quality of every study included in the analysis. Any discrepancies between the reviewers regarding the risk of bias would be resolved through discussion, with the inclusion of a third reviewer when required. The results of the critical evaluation are reported through narrative descriptions and a table.

**Data synthesis**

Due to the expected diversity in research methods and outcome measures, the researchers will employ a narrative synthesis to incorporate the study findings, rather than conduct a meta-analysis. Recognising that individual and organisational factors associated with patient safety competence, content analysis is used to categorise the factors influencing clinical nurses' patient safety competence into two groups: individual and organisational factors. Previous studies on nurses' competence have examined both individual and organisational factors [32, 33].

**Ethics and dissemination**

Ethical approval was not required for this review as it does not involve the collection of primary population data. The results will be presented at professional conferences and peer-reviewed open access journals.

**Author contributions**

JHP designed the protocol with methodological insights from NJL and content input from HSGL and GHP. NJL provided critical oversight in both methods and content. Each co-author has read and confirmed the final manuscript.

**Funding**

None declared.

**Competing interest**

Not required.

**Provenance and peer review**

Not commissioned. Externally peer-reviewed.

**Open access**

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# PRISMA-P 2015 Checklist

**This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al:** Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

| Section/topic | # | Checklist item | Information reported | | Line number(s) |
|---|---|---|---|---|---|
| | | | Yes | No | |
| **ADMINISTRATIVE INFORMATION** | | | | | |
| **Title** | | | | | |
| Identification | 1a | Identify the report as a protocol of a systematic review | ✓ | ☐ | 2page 41 |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | ☐ | ✓ | |
| **Registration** | 2 | If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract | ✓ | ☐ | 3page 19 |
| **Authors** | | | | | |
| Contact | 3a | Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author | ✓ | ☐ | Submission system |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | ✓ | ☐ | 6page 23 |
| **Amendments** | 4 | If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments | ☐ | ✓ | |
| **Support** | | | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | ✓ | ☐ | 6page 30 |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | ✓ | ☐ | 6page 30 |
| Role of sponsor/funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | ✓ | ☐ | 6page 30 |
| **INTRODUCTION** | | | | | |
| **Rationale** | 6 | Describe the rationale for the review in the context of what is already known | ✓ | ☐ | 2page 25 |
| **Objectives** | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | ✓ | ☐ | 3page 25 |
| **METHODS** | | | | | |

| Section/topic | # | Checklist item | Information reported | | Line number(s) |
|---|---|---|---|---|---|
| | | | Yes | No | |
| **Eligibility criteria** | 8 | Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review | ✓ | ☐ | 4page 41<br>4page 60 |
| **Information sources** | 9 | Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage | ✓ | ☐ | 3page 34 |
| **Search strategy** | 10 | Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated | ✓ | ☐ | 3page 41 |
| ***STUDY RECORDS*** | | | | | |
| Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | ✓ | ☐ | 5page 21 |
| Selection process | 11b | State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis) | ✓ | ☐ | 5page 21 |
| Data collection process | 11c | Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators | ✓ | ☐ | 5page 34 |
| **Data items** | 12 | List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications | ✓ | ☐ | 3page 58 |
| **Outcomes and prioritization** | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | ✓ | ☐ | 4page 29 |
| **Risk of bias in individual studies** | 14 | Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis | ✓ | ☐ | 5page 47 |
| ***DATA*** | | | | | |
| **Synthesis** | 15a | Describe criteria under which study data will be quantitatively synthesized | ☐ | ✓ | |
| | 15b | If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., $I^2$, Kendall's tau) | ☐ | ✓ | |
| | 15c | Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression) | ☐ | ✓ | |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | ✓ | ☐ | 5page 60 |
| **Meta-bias(es)** | 16 | Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies) | ✓ | ☐ | 3page 33<br>4page 43 |
| **Confidence in cumulative evidence** | 17 | Describe how the strength of the body of evidence will be assessed (e.g., GRADE) | ☐ | ✓ | |

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**Jong-Hyuk Park[1], Nam-Ju Lee[1,2], Hanseulgi Lee[1], Gihwan Park[1]**

[1] College of Nursing, Seoul National University, Jongno-gu, Seoul, South Korea

[2] The Research Institute of Nursing Science, Seoul National University, Jongno-gu, Seoul, South Korea

Correspondence to Dr Nam-Ju Lee; njlee@snu.ac.kr.

## Abstract

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Patient safety has become a fundamental element of healthcare quality. However, despite the ongoing efforts of various organisations, patient safety issues remain a problem in the healthcare system. Given the crucial role of nurses in the healthcare process, improving patient safety competence among clinical nurses is important. In order to promote patient safety competence, it is essential to identify and strengthen the relevant factors. This protocol is for a systematic review aiming to examine and categorise the factors influencing patient safety competence among clinical nurses.

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In all dimensions of the healthcare process, nurses are responsible for patient safety [12]. Nurses, who spend more time with patients than other healthcare professionals, play a vital role in identifying patient safety risks and ensuring high-quality care [12-14]. Through careful monitoring of patient

conditions, quick identification of risks, and supervision of the healthcare process, they actively contribute to patient safety [13, 15]. In addition, nursing activities such as medication administration, infection control, and fall prevention have a direct impact on patient safety [16]. Therefore, maintaining high levels of patient safety competence among nurses is crucial for decreasing patient safety issues and enhancing the quality of patient care [13, 17].

The Quality and Safety Education for Nurses (QSEN) project identified the fundamental elements of quality and safety competence in nursing, including patient-centred care, teamwork and collaboration, evidence-based practice, quality improvement, safety, and informatics [18]. These core principles improve evidence-based standards with a systemic perspective and enhance the quality of patient care [19]. In addition, the Canadian Patient Safety Institute (CPSI) outlines crucial aspects of patient safety competence, including the ability to recognise, respond to, and disclose patient safety incidents, foster patient safety culture, promote effective teamwork and communication, ensure safety and manage risks, promote quality improvement, and optimise both human and system factors [20].

The definition of patient safety competence encompasses the attitude, skills, and knowledge that prevent unnecessary risk and harm to patients [18, 21]. This competence helps prevent patient safety incidents and addresses latent problematic issues in the healthcare system [13, 22]. A recent study revealed that patient safety competence can reduce preventable adverse events, including medication errors, surgical site infections, urinary tract infections, and ventilator-associated pneumonias [13].

In addition to recognising the significance of the patient safety competence of nurses, there are many aspects of patient safety competence that require further investigation and understanding [23]. First, it is important to identify the factors relevant to patient safety competence and enforce the contributing factors. A study by Huh et al. revealed that demographic factors such as age, education level, patient safety education, and experience in patient safety activities are associated with patient safety competence [16]. However, prior studies have focused primarily on the individual attributes of patient safety competence and have not emphasised the organisational factors [24]. Patient safety is a complex process within the context of a system that requires collaborative efforts from both the individual and the organisation [14,25].

Although there are limited reviews of patient safety competence instruments [26, 27], there are currently no systematic reviews of the factors that contribute to the patient safety competence of clinical nurses. A previous review by Okuyama et al. [26] conducted in 2011 explored patient safety competence across diverse healthcare professionals. However, the patient safety competence of clinical nurses may differ from other healthcare professionals. In addition, most recent instruments of patient safety competence may not have been included in that review. Mortensen et al. [27] published a scoping review of the instruments of patient safety competence in nursing. However, scoping reviews have

methodological limitations that offer a general overview rather than a comprehensive in-depth analysis and they do not include a formal quality appraisal process [28]. Moreover, there is a lack of consensus on the definition of patient safety competence and its conceptual framework in that study.

This protocol aims to provide guidance for a systematic review to identify the factors affecting the patient safety competence of clinical nurses. To foster a comprehensive understanding of patient safety competence, we will categorise those factors into two domains: individual and organisational. Moreover, this study will encompass research that has examined the core concept of patient safety competence based on the CPSI framework. This review would essentially provide a starting point for identifying the determinants of patient safety competence.

## Study objectives

The purpose of this research is to examine the factors that influence the patient safety competence of clinical nurses. The specific research questions include: 1) what is the definition of patient safety competence, 2) what instruments for assessing patient safety competence are examined in this research, and 3) what factors affect the patient safety competence of clinical nurses?

## Methods

Before conducting this review, we thoroughly searched the International Prospective Register of Systematic Reviews, which revealed no ongoing systematic reviews of the factors influencing the patient safety competence of clinical nurses. To conduct a systematically organised review, this protocol was developed based on the Joanna Briggs Institute (JBI) Methodology for Systematic Reviews of Effectiveness. The JBI checklist, an organised tool to promote and support evidence-based practice, provides a rigorous systematic review process [29]. Some elements were updated and modified from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol [30]. We registered this systematic review with the International Prospective Register of Systematic Reviews (CRD42023422486). The systematic review started in August 2023 and included a preliminary search and pilot study selection process to screen the search results based on the eligibility criteria.

## Search strategy (PICO) and data sources

This systematic review will explore the determinants of patient safety competence among clinical nurses (P-population). The study will examine the impact of various factors that either enhance or impair patient safety competence (I-indicator), comparing their effects on nurses exposed to these factors to those who are not exposed (C-comparison). The primary outcome to be measured will be the level of patient safety competence (O-outcome). According to the PICO statement guidelines, the search strategy was developed in consultation with a health sciences librarian. Four databases, including EMBASE, CINAHL, Ovid-Medline, and Cochrane Library will be explored from January 2012 to

August 2023 (Appendix A). The reason for selecting this period is that the Medical Subject Headings (MeSH) for patient safety was introduced in 2012. The specific search strategy is presented (Table 1). In order to conduct a more thorough examination, we will use both backward and forward citation search methods.

Table 1. Search terms identified to screen for Ovid-Medline

| ***Search Topic*** | ***Search Terms*** |
|---|---|
| #1. Competence | ("abilit*" or "skill*" or "knowledge" or "behavio*" or "perception*" or "performance*" or "attitude*" or "competence*" or "efficac*").ti,ab. OR Exp Clinical competence/ |
| #2. Patient safety | Exp patient safety/ OR "patient safety".ti,ab. |
| #3. Nurse | Exp nurses/ OR "nurs*".ti,ab. |
| #4. Time | January 2012 - August 2023 |
| #1 AND #2 AND #3 AND #4 | |

## Population

This review will include studies involving clinical nurses directly engaged in providing patient care in hospitals. According to a previous study, clinical nurses consist of registered nurses or licensed practical/vocational nurses providing direct care to their patients in hospitals [31]. Therefore, this study aims to encompass a diverse group of clinical nurses, including medical, surgical, and intensive care unit nurses. To minimize variations in competence attributed to distinct professional roles, articles exclusively focused on nurses not directly participating in independent frontline patient care, such as nursing students and nurse managers, will be excluded.

## Indicator

This study will explore multiple influencing factors that serve as indicators of patient safety competence. The JBI quality appraisal tools employ a rigorous assessment process to evaluate the validity and reliability of indicators. A diverse and heterogeneous range of tools is expected to be employed in the study.

## Comparator

This systematic review will allow for comparisons based on exposure to the indicators. Comparisons can be made between clinical nurses who have been exposed to specific factors and those who have not. Furthermore, the study enables comparisons across different hospital settings providing valuable insights into the variations in patient safety competence.

## Outcome

The primary outcome will be patient safety competence, which encompasses complex patient safety principles, including the CPSI's patient safety competence. This competence includes the ability to recognize, respond to, and disclose patient safety incidents; manage safety, risks, and quality improvement; communicate effectively; foster teamwork; understand patient safety culture; and optimize human and system factors [20]. The outcome measure will be rigorously evaluated for its validity and reliability.

## Study design

The study will encompass original descriptive cross-sectional analyses, comparative research, and mixed-method research. Only peer-reviewed articles on patient safety competence will be included, to ensure high-quality and reliable information. Grey literature will be excluded as it does not meet our criteria for being valid, rigorous, and peer-reviewed.

## Inclusion and exclusion criteria

**Inclusion.** All published studies examining factors related to the patient safety competence of clinical nurses directly involved in patient care in the hospital setting will be included. The measurement of patient safety competence among clinical nurses serves as the primary outcome in the included studies. According to the CPSI [20], the competence should cover various attributes, including (1) patient safety culture; (2) teamwork; (3) communication; (4) safety, risk, and quality improvement; (5) optimised human and system factors; and (6) recognition, response, and disclosure of patient safety incidents. The selected articles will be peer-reviewed, written in English, and published from January 2012 to August 2023.

**Exclusion.** Articles exclusively focusing on nurses who are not directly engaged in frontline patient care, such as nurse managers, will be excluded. The review will not include studies in which the participants are individuals without official nursing licenses, including nursing students and patients' family members. Research exploring patient safety competence in populations other than nurses (e.g., hospitalists and medical students) will also be excluded. Studies that focus exclusively on a single attribute, such as communication or medication competence, will be excluded. Additionally, to maintain methodological clarity with measurable indicators, qualitative studies will be excluded. Furthermore, review articles, theses and dissertations, conference abstracts, editorials, opinion articles, and case studies will be excluded. Articles not available in full text will also be excluded.

## Study selection

Using the Covidence platform, two independent reviewers will conduct the article screening process by evaluating the titles and abstracts and classifying them into the categories of relevant and irrelevant.

Disagreements regarding irrelevant articles will be resolved through discussion between the two reviewers. Only articles classified as relevant during the initial screening will be selected for the subsequent step of full-text screening, which will also be conducted by the same two reviewers. During this stage, the reviewers will each compile their own list of relevant articles, which will then be compared. Any discrepancies will be resolved through discussion. For any unresolved discrepancies, a third reviewer will be consulted, and the final decision will be made by the entire team.

## Data extraction

Two researchers will collect information independently based on the following criteria: the author(s), country, study design, sample size, clinical setting, clinical experience, instrument to measure patient safety competence, and factors affecting patient safety competence. Any discrepancies between the results obtained by the two researchers will be resolved through discussion or with the involvement of a third reviewer.

## Quality assessment.

The JBI critical appraisal checklist will be used for a strict quality appraisal process [32]. The objective of the appraisal is to assess a study's methodological quality and identify any potential bias in its design, conduct, and analysis [29]. Two reviewers will independently evaluate the quality of every study included in the analysis. Any discrepancies between the reviewers regarding the risk of bias will be resolved through discussion, with the inclusion of a third reviewer when required. The results of the critical evaluation will be reported through narrative descriptions and a table. The outcomes of the quality appraisal will play a pivotal role in assessing the overall quality and reliability of the included studies. Since this review will encompass peer-reviewed articles, no study will be excluded solely based on its quality rating.

## Data synthesis

Due to the expected diversity in research methods and outcome measures, the researchers will employ a narrative synthesis to incorporate the study findings, rather than conduct a meta-analysis. Recognising that individual and organisational factors associated with patient safety competence, content analysis will be used to categorise the factors influencing clinical nurses' patient safety competence into two groups: individual and organisational factors. Previous studies on nurses' competence have examined both individual and organisational factors [33, 34].

## Patient and public involvement

This study will not include any patient involvement.

## Ethics and dissemination

Ethical approval was not required for this review as it does not involve the collection of primary population data. The results will be presented at professional conferences and peer-reviewed open access journals.

## Author contributions

JHP designed the protocol with methodological insights from NJL and content input from HSGL and GHP. NJL provided critical oversight in both methods and content. JHP wrote the first draft of this manuscript. NJL and HSGL critically revised the protocol and manuscript. All authors confirmed the final manuscript. The guarantor of the study (JHP) accepts full responsibility for the finished work.

## Funding

None declared.

## Competing interest

Not required.

## Provenance and peer review

Not commissioned. Externally peer-reviewed.

## Open access

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## Appendix A - search strategies

| Database | | Number | Search strategy |
|---|---|---|---|
| **Embase** | | #1 | 'abilit*':ab,ti OR 'skill*':ab,ti OR 'knowledge':ab,ti OR 'behavio*':ab,ti OR 'perception*':ab,ti OR 'performance*':ab,ti OR 'attitude*':ab,ti OR 'competence*':ab,ti OR 'efficac*':ab,ti |
| | | #2 | 'clinical competence'/exp |
| | | #3 | 'patient safety'/exp |
| | | #4 | 'patient safety':ab,ti |
| | | #5 | 'nurses'/exp |
| | | #6 | 'nurs*':ab,ti |
| | | #7 | #1 OR #2 |
| | | #8 | #3 OR #4 |
| | | #9 | #5 OR #6 |
| | | #10 | #7 AND #8 AND #9 |
| | | #11 | #10 AND [01-01-2012]/sd NOT [01-09-2023]/sd |
| **Ovid-Medline** | | 1 | ("abilit*" or "skill*" or "knowledge" or "behavio*" or "perception*" or "performance*" or "attitude*" or "competence*" or "efficac*").ti,ab. |
| | | 2 | exp Clinical competence/ |
| | | 3 | exp Patient safety/ |
| | | 4 | "patient safety".ti,ab. |
| | | 5 | exp nurses/ |
| | | 6 | "nurs*".ti,ab. |
| | | 7 | 1 or 2 |
| | | 8 | 3 or 4 |
| | | 9 | 5 or 6 |
| | | 10 | 7 and 8 and 9 |
| | | 11 | limit 10 to yr="2012 - 2023" |
| **CINAHL** | | S1 | TI ( “abilit*” OR “skill*” OR “knowledge” OR “behavio*” OR “perception*” OR “performance*” OR “attitude*” OR “competence*” OR “efficac*” ) OR AB ( “abilit*” OR “skill*” OR “knowledge” OR “behavio*” OR “perception*” OR “performance*” OR “attitude*” OR “competence*” OR “efficac*” ) |
| | | S2 | MH “clinical competence” |
| | | S3 | MH “patient safety” |
| | | S4 | TI ( “patient safety” ) OR AB ( “patient safety” ) |
| | | S5 | MH “nurses” |
| | | S6 | TI ( “nurs*” ) OR AB ( “nurs*” ) |
| | | S7 | S1 OR S2 |
| | | S8 | S3 OR S4 |
| | | S9 | S5 OR S6 |
| | | S10 | S7 AND S8 AND S9 |
| | | S11 | Limiters - Full Text; Publication Date: 20120101-20230831 |
| **Cochrane Library** | | #1 | (abilit* or skill* or knowledge or behavio* or perception* or performance* or attitude* or competence* or efficac*):ti,ab |
| | | #2 | MeSH descriptor: [Clinical Competence] explode all trees |
| | | #3 | MeSH descriptor: [Patient Safety] explode all trees |
| | | #4 | (patient safety):ti,ab |
| | | #5 | MeSH descriptor: [Nurses] explode all trees |
| | | #6 | (nurs*):ti,ab |
| | | #7 | #1 or #2 |
| | | #8 | #3 or #4 |
| | | #9 | #5 or #6 |
| | | #10 | #7 and #8 and #9 |

| | | | |
|---|---|---|---|
| | | #11 | #10 with Cochrane Library publication date from Jan 2012 to Aug 2023 |

# PRISMA-P 2015 Checklist

**This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al:** Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

| Section/topic | # | Checklist item | Information reported | | Line number(s) |
|---|---|---|---|---|---|
| | | | Yes | No | |
| **ADMINISTRATIVE INFORMATION** | | | | | |
| **Title** | | | | | |
| Identification | 1a | Identify the report as a protocol of a systematic review | ✓ | ☐ | Page1, Line 6 |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | ☐ | ✓ | |
| **Registration** | 2 | If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract | ✓ | ☐ | Page2, Line 7. |
| **Authors** | | | | | |
| Contact | 3a | Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author | ✓ | ☐ | Page1, Line14. |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | ✓ | ☐ | Page8, Line 10-14. |
| **Amendments** | 4 | If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments | ☐ | ✓ | |
| **Support** | | | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | ✓ | ☐ | Page8, Line18. |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | ✓ | ☐ | Page8, Line18. |
| Role of sponsor/funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | ✓ | ☐ | Page8, Line18. |
| **INTRODUCTION** | | | | | |
| **Rationale** | 6 | Describe the rationale for the review in the context of what is already known | ✓ | ☐ | Page3, Line50. |
| **Objectives** | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | ✓ | ☐ | Page4, Line22.<br>Page4, Line50-57. |

| Section/topic | # | Checklist item | Information reported | | Line number(s) |
|---|---|---|---|---|---|
| | | | Yes | No | |
| **METHODS** | | | | | |
| **Eligibility criteria** | 8 | Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review | ✓ | ☐ | Page6, Line 17 – 52. |
| **Information sources** | 9 | Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage | ✓ | ☐ | Page4, Line 59-Page5, Line 8. |
| **Search strategy** | 10 | Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated | ✓ | ☐ | Page4, Line 59.<br><br>Page5, Line 10-25. |
| ***STUDY RECORDS*** | | | | | |
| Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | ✓ | ☐ | Page6, Line57. |
| Selection process | 11b | State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis) | ✓ | ☐ | Page6, Line57-Page7, Line11. |
| Data collection process | 11c | Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators | ✓ | ☐ | Page7, Line15-22. |
| **Data items** | 12 | List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications | ✓ | ☐ | Page7, Line17. |
| **Outcomes and prioritization** | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | ✓ | ☐ | Page6, Line29. |
| **Risk of bias in individual studies** | 14 | Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis | ✓ | ☐ | Page7, Line26-39. |
| ***DATA*** | | | | | |
| **Synthesis** | 15a | Describe criteria under which study data will be quantitatively synthesized | ☐ | ✓ | |
| | 15b | If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., $I^2$, Kendall's tau) | ☐ | ✓ | |
| | 15c | Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression) | ☐ | ✓ | |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | ✓ | ☐ | Page7, Line45. |
| **Meta-bias(es)** | 16 | Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies) | ☐ | ✓ | |

| Section/topic | # | Checklist item | Information reported | | Line number(s) |
|---|---|---|---|---|---|
| | | | Yes | No | |
| **Confidence in cumulative evidence** | 17 | Describe how the strength of the body of evidence will be assessed (e.g., GRADE) | ☐ | ✓ | |