

A methodological framework for rigorous systematic reviews: Tailoring comprehensive analyses to clinicians and healthcare professionals

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ABSTRACT

Systematic reviews represent a fundamental study design, providing the highest level of evidence across diverse research inquiries, encompassing both public health and clinical research and practice. However, for healthcare professionals, the process of selecting, synthesizing, and interpreting evidence can be challenging, and requires specialized skills. Therefore, it is imperative to explore innovative solutions aimed at simplifying and making the traditional systematic review process more accessible while ensuring the validity and reliability of results.

In this perspective, our research objective is to develop a systematic review framework that, while maintaining a rigorous methodological approach, streamlines the process for healthcare professionals. This study describes such approach in every phase, from the collection of evidence to the writing of the text, creating a guide for the healthcare professional who approaches this type of research. The qualitative and organizational analysis tools are also described, providing useful information for the use of non-paid programs.

This systematic review aims to develop a framework with a rigorous methodological approach that allows simplify the process for clinicians and healthcare professionals. The implementation of this methodology in clinical practice offers new perspectives to ensure a thoughtful consideration and application of scientific evidence and opens the way to innovative and easily accessible solutions to facilitate the conduct of systematic reviews in the clinical care setting.

1. Introduction

Systematic reviews represent a crucial study design, providing the highest level of evidence across diverse research inquiries, encompassing both public health and clinical research and practice. Within the evidence hierarchy, they occupy the highest levels and, over the last decade, the number of published reviews has significantly increased [1]. Systematic reviews demonstrate statistical robustness and ability to elucidate potentially significant findings by aggregating and synthesizing individual studies. Additionally, they contribute to recognizing deficiencies and methodological limitations within the current medical

and public health literature, aid in pinpointing potential sources of variation among investigations, and stimulate crucial avenues for future research. The credibility and dependability of evidence derived from systematic reviews hinge on the employed methodology, underscoring its pivotal role in the valid interpretation and application of findings [2]. Several studies have assessed the time required to complete such a complex investigation, estimating a period exceeding a thousand hours. More than half of this time is allocated to pre-analysis, database retrieval, and development, approximately two hundred hours for drafting reports and manuscripts, one hundred hours for statistical analysis, and the remaining time for other administrative functions [3].

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In the complex realm of clinical practice, undertaking a traditional systematic review poses a notable challenge for healthcare professionals in terms of time and resources [4]. The extensive amount of biomedical scientific literature makes the selection and synthesis process a demanding endeavor for healthcare professionals engaged in daily patient care. [5]. Therefore, researchers today, more than ever, need to know how and where to search due to the exponential increase in the production of scientific contributions. Biomedical bibliographic databases, such as PubMed, Embase, CINAHL, Scopus, or Web of Science, stand as foundational pillars in accessing scientific information, aggregating and indexing bibliographic records from a variety of biomedical journals [6]. However, navigating through this extensive collection of data requires specific expertise and a substantial time commitment [7]. Furthermore, the search and inclusion of grey literature, encompassing unofficially published documents such as research reports, dissertations and conference proceedings should also be considered [8]. Grey literature could be an important resource in systematic reviews but it demands a critical selection and evaluation approach [9], as the essence of a systematic review lies in its ability to rigorously collect and analyze all relevant empirical evidence to address a specific research question [10].

This methodological approach ensures the robustness and completeness of the data extracted, making the systematic review a fundamental tool in evidence-based medicine [11]. However, for healthcare professionals, the process of selecting, synthesizing, and interpreting evidence can be challenging, because it requires specialized skills [12]. Despite the undeniable importance of systematic reviews in guiding clinical decisions, the intrinsic challenges in the conductive process may discourage widespread adoption of this methodology among clinicians directly involved in patient care. Therefore, it is imperative to explore innovative solutions aimed at simplifying and making the classic systematic review process more accessible while ensuring the validity and reliability of results [13].

1.1. Research methodology objectives

In this perspective, our research objective is to develop a systematic review framework that, while maintaining a rigorous methodological approach, streamlines the process for healthcare professionals. The integration of this methodology into clinical practice could open new avenues to ensure that scientific evidence is adequately considered and applied in the daily decisions of healthcare professionals, identifying innovative solutions to facilitate the conduct of systematic reviews in clinical care settings, thereby enhancing the overall quality of clinical decisions.

2. Material and methods

2.1. Research design

We have developed a research methodology designed to accurately comprehend and summarize evidence from primary studies, drawing inspiration from the PRISMA guidelines for conducting systematic reviews [14]. The approach adopted in this review methodology places significant emphasis on a comprehensive literature search and a rigorous evaluation process, paying particular attention to the methodological quality and relevance of selected studies. The data extraction process is carried out uniformly, ensuring consistency, and the extracted data are subsequently synthesized to provide a comprehensive and nuanced overview. This research design has been carefully crafted to align with the specific requirements of a systematic review, addressing the challenges and opportunities presented by primary literature while maintaining the highest standards of scientific rigor and integrity.

2.2. Systematic review protocol registration

Before initiating the literature search for a systematic review, it is

advisable to register the review protocol within the International PROSPERo Register Of systematic reviews (PROSPERO) database (<https://www.crd.york.ac.uk/prospero/>) of the National Institute of Health Research. This step serves to guarantee that the review is carried out with the highest levels of transparency and integrity.

2.3. Formulation of the research question

To specifically define the research question and formulate search strings that align with scientific databases, it is advisable to employ the PICO framework [15]. Use of the PICO framework enables to structure and refine the research question by systematically examining the effectiveness and appropriateness of an intervention within a specified population, ensuring a comprehensive and accurate exploration of the research question (Fig. 1). This methodological tool is fundamental to develop structured research questions for conducting systematic reviews and focuses on the following key aspects:

P (Population or problem): Defines the patient group or population of interest, as well as the specific conditions or problems that these individuals may exhibit [16]. For example, it could pertain to patients affected by a specific disease or medical condition.

I (Intervention): Refers to the action or series of actions to be studied. It can be a medical treatment, a procedure, a therapy, or any other type of clinical intervention. The goal is to clearly identify which intervention will be examined to determine its effectiveness or impact.

C (Comparator): Serves to identify a control condition with which to compare the intervention. The comparator may be the absence of intervention, a placebo, or another type of intervention considered standard in clinical practice.

(Outcome): Indicates the results or outcomes expected to be measured or observed because of the intervention [17]. These outcomes may encompass aspects such as mortality, quality of life, side effects, clinical benefits, and many others.

2.4. Inclusion and exclusion criteria

In defining the scope of the review, it is imperative to establish precise inclusion and exclusion criteria [18]. The primary focus will be on original studies published in peer-reviewed journals. More specifically, the targeted primary studies include empirical research articles. This approach is designed to guarantee the utilization of only high-quality and relevant sources, minimizing the potential impact of records lacking rigorous quality controls. Additional inclusion criteria may involve considerations such as sample size, study design, timeframe covered, and geographic or regional context of the analysis. For example, preference may be given to studies with larger sample sizes, those employing recognized standardized methodologies, and those

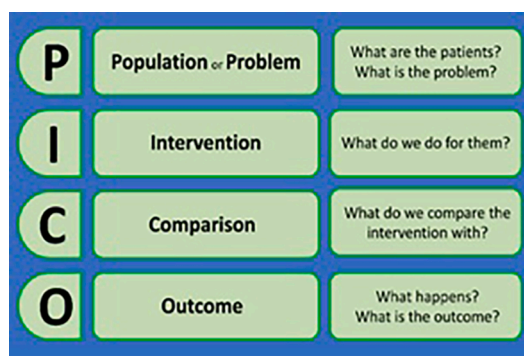


Fig. 1. PICO Framework. **Legend:** Phases of the PICO (patient/population, intervention, comparison and results) methodology.

addressing specific time periods or geographic contexts of particular relevance. Language of publication is a crucial criterion, and only articles in the predominant languages within the field of medical research will be considered to ensure data comprehensibility and accessibility. Conversely, certain criteria will guide the exclusion of studies. Publications not directly aligning with the review objectives or failing to meet defined quality standards will be excluded. The absence of complete or retrievable data in a publication may also warrant exclusion. Pilot or preliminary studies, publications lacking a rigorous peer-review process, and those relying solely on self-reported data without verification may also be excluded. The article selection process will be conducted with utmost objectivity. Two independent reviewers will assess each publication [19]. This dual assessment is intended to ensure that decisions are based on thorough evaluations and remain uninfluenced by individual biases. In instances of discrepancies during the selection, a third reviewer will be engaged to facilitate consensus and uphold the integrity of the selection process.

2.5. Search strategy

The search strategy process should be conducted through the implementation of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) methodology [14]. Adopting PRISMA ensures precise and transparent execution and reporting of the systematic review. This initial step is crucial for gaining a thorough understanding of current practices and official recommendations in the study field. Furthermore, it is imperative to note that the research question, constructed through the PICO framework [15–17], serves as the foundation for developing specific search strings. Such search strings, aligned with the predefined inclusion and exclusion criteria, should be carefully crafted, incorporating the use of thesaurus terms such as MeSH (Medical Subject Headings) and a range of relevant text words. This comprehensive approach aims to enhance both specificity and sensitivity of the literature search, ensuring a thorough and systematic exploration of relevant primary studies. Subsequently, a comprehensive and systematic search should be carried out across primary literature databases, using boolean operators such as AND, OR, NOT with keywords derived from the previously developed research question. Thesaurus terms and text words for each PICO concept should be first combined through the Boolean operator OR. Then the resulting search strings for the different concepts should be combined among them through the Boolean operator AND. A search strategy template is made available in [Supplementary File 1](#). To ensure objectivity and reduce the risk of bias, this search should be conducted by at least two researchers [20]. Collaborative efforts among the researchers enable a comparative analysis of the results, thereby enhancing the reliability of the selection process. Upon completion of the database search, records can be managed using a spreadsheet application [21] through a six-steps process: downloading references, preparing worksheets, removing any duplicate references, screening references based on title and abstract, screening the full text of references, and compiling a list of articles to include in the review. This approach utilizes a spreadsheet application, a widely accessible tool for many researchers, avoiding the need for additional expenses related to specialized reference management software [21]. The use of a spreadsheet application aligns with our commitment to maximize the accessibility and adoption of the proposed methodology across a wide range of researchers. In case of disagreements in the selection, a third reviewer will be involved to ensure an impartial decision [20] (Fig. 2).

2.6. Assessment of quality and bias

The assessment of articles should involve two reviewers evaluating the risk of bias and methodological quality. Any conflicts that may arise during this phase of the systematic review process should be resolved by involving a third author of the review. To conduct a rigorous evaluation

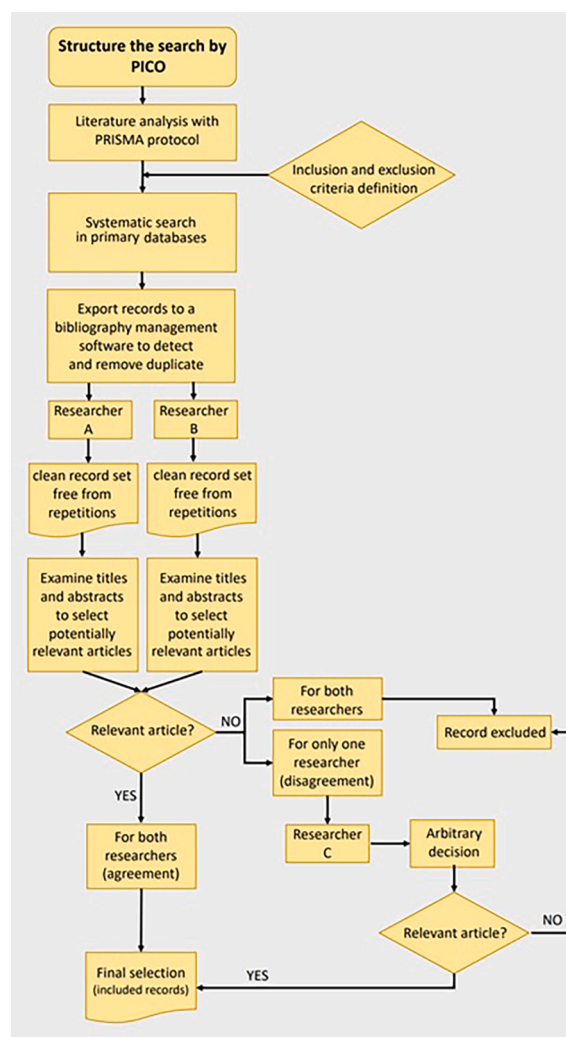


Fig. 2. Search Strategy Methodology. **Legend:** PICO: patient/population, intervention, comparison and outcomes.

of the selected literature, validated and specific checklists suitable for each type of study included in the systematic review should be used.

In the protocol of this review methodology, the option was chosen to use the quality and bias risk assessment checklists provided by JBI [22]. Subsequently, each study should be assigned a quality score, following the criteria established by Pimsen et al. [23]. This score is based on the percentage of items identified with a positive outcome from the original JBI checklist: studies with a JBI score above 70 % will be categorized as high quality; studies with a score between 50 % and 69.9 % will be classified as medium quality; studies with a score below 49.9 % will be categorized as low quality. Detailed tables related to these checklists should be provided both in the systematic review [supplementary file](#) and in the main data extraction table, outlining them as “general characteristics of the studies”. In [Supplementary File 1](#), fillable table templates are provided for assessing the risk of bias and methodological quality in accordance with the JBI framework [22] and according to the evaluation criteria expressed by Pimsen et al. [23].

2.7. Assessment of evidence certainty

The assessment of the certainty of evidence should always adhere to a specific, validated, and reproducible methodology. The framework proposed by the Oxford Centre for Evidence-Based Medicine (OCEBM) in 2011 [24] presents a straightforward and applicable methodology, suitable even for clinicians and healthcare professionals with less

experience. This classification system categorizes studies into five levels of evidence based on their design and research quality. Studies of the highest level, such as systematic reviews of randomized controlled trials and high-quality individual studies, are assigned to the first level of evidence. On the contrary, studies relying solely on expert opinions or lacking empirical data are classified at the fifth and final level. Intermediate studies, including lower-quality randomized controlled trials, cohort studies, and research such as case series or case-control studies, are respectively assigned to the second, third, and fourth levels. The level of evidence of some studies may be downgraded or upgraded based on various factors, such as methodological quality, accuracy of results, and the direct or indirect applicability of the data (Table 1).

The levels of evidence, in accordance with the OCEBM framework [24], should always be reported in the tables and, more precisely, in those describing the results of individual studies (Supplementary File 1).

2.8. Data extraction

When conducting a systematic review, ensuring the accuracy of data extraction is pivotal for validating the results. Therefore, a structured data extraction form meticulously designed to capture relevant information from the selected studies for inclusion must be used. The data to be extracted encompasses author details, publication year, country of origin, study type (e.g., clinical trial, observational study), aim, population and setting, inclusion and exclusion criteria, limitations, intervention, results, and risk of bias assessed using the JBI checklist. To ensure accuracy and comprehensiveness, it is advisable for two independent reviewers to perform the data extraction. In instances of disparities in the extracted data, a consensus approach can be employed, potentially involving a third reviewer.

Table 1
OCEBM Evidence Certainty Framework.

Evidence Level	Description	OCEBM Level
High-Quality Evidence (*****)	This level includes results from well-conducted systematic reviews of (RCTs) with extensive follow-up and consistent outcomes. Systematic reviews aggregate data from multiple studies to provide a more comprehensive and reliable view of the available evidence	Level 1
Moderate-Quality Evidence (****)	This category comprises results from moderately well-conducted RCTs or well-conducted observational studies with consistent findings. While these pieces of evidence offer a lower level of certainty compared to Level 1, they are still considered reliable.	Level 2
Moderate-Quality Evidence (***)	This level includes results from studies with significant limitations, such as RCTs with methodological issues or observational studies with potential sources of bias. While they may provide useful insights, evidence at this level is less reliable.	Level 3
Low-Quality Evidence (**)	This level encompasses results from studies with substantial limitations, such as observational studies with a high risk of bias or non-generalizable data. Evidence at this level is the least reliable among those considered.	Level 4
Low-Quality Evidence (*)	This category is based on expert opinions in the field and not on empirical evidence. Expert opinions can offer qualitative insights but do not represent direct evidence	Level 5

Legend: RCTs = randomized controlled trials. Adapted from Oxford Centre of Evidence Based Medicine (OCEBM), Howick et al. (2011).

2.9. Descriptive synthesis

After completing the data extraction process, the focus shifts to result synthesis. During this phase, employing a narrative approach proves advantageous for succinctly summarizing the findings and collected data, organizing them into specific domains or categories aligned with the primary objectives of the review. For instance, results can be categorized into clinical, organizational, or managerial domains, depending on the nature of the research question. Additionally, integrating visual tools such as algorithms or flowcharts is advisable to provide a clear and easily interpretable overview of the synthesized data. These visual representations not only enhance the comprehensibility of the results but also aid in exploring similarities and differences among studies, analyzing relationships within the data, and evaluating the strength of evidence.

Ultimately, the synthesis process should lead to the generation of a comprehensive summary of knowledge relevant to the specific review question. These synthesized pieces of information constitute a valuable resource for informing clinical and policy decisions, thereby contributing to an evidence-based approach in various fields of research and application.

2.10. Visual synthesis

For a visual synthesis of intervention effects, it is recommended to use the Harvest plot [25]. This approach, endorsed by the Cochrane Handbook for Systematic Reviews of Interventions [26], proves particularly advantageous when addressing challenges posed by heterogeneous studies [27]. The Harvest plot serves as a graphical representation akin to the traditional Forest plot, but its adaptability based on the reviewer's objective or the characteristics of the included studies underscores its notable strength. Importantly, the Harvest plot facilitates the visual depiction of effects alongside various study details, including reference, sample size, nature and direction of associations, and p-values. This ensures a structured and comprehensive presentation of pertinent data, enhancing clarity and synthesis. The flexibility of this methodology is crucial, particularly when the results of systematic reviews are not easily amenable to meta-analysis or pooled analysis. Consequently, the Harvest plot offers a nuanced and informative representation, serving as a practical tool that enhances clarity in data synthesis and proves adaptable for various reviews. A comprehensive guide, accompanied by examples, for executing the Harvest plot has been recently developed in a newly established methodology [28] and is made available in Supplementary File 2.

2.11. Data analysis

In the context of a systematic review, there may be instances where conducting a pooled analysis becomes necessary, particularly when multiple studies yield similar or comparable data on a specific topic. Pooled analysis is a statistical technique that involves pooling the findings of several epidemiological studies [29]. It proves beneficial when individual study outcomes fail to provide definitive conclusions, or when there is uncertainty regarding the feasibility of a formal meta-analysis. However, pooled analysis can only be carried out if the included studies utilize the same study design and statistical models. Furthermore, the reliability of results is enhanced when the respective populations are homogeneous.

If individual-level data from the included studies are accessible, the outcomes of a pooled analysis are deemed more dependable. To conduct a pooled analysis, several steps should be adhered to, including data extraction and collection, computation of combined indices such as mean, proportion, or variance, and calculation of confidence intervals. The computation of these indices is contingent upon the type of data reported in the articles: for continuous data, extraction of both mean and standard deviation is performed. When these values are unavailable,

median and range can be extracted, which can then be used to estimate mean and standard deviation (automatically calculated by the provided spreadsheet file) [30]. For categorical data, the most appropriate index is the odds ratio (OR), and only the relevant portion should be completed in the provided spreadsheet. A user-friendly guide, accompanied by a spreadsheet file, is provided as [Supplementary File 3](#) for convenient reference. Alternatively, if you want to conduct a statistical analysis that requires the use of a *meta-analysis*, it is essential to rely on an expert in the field of biostatistics. The complexity and precision needed to integrate and synthesize data from multiple studies necessitate specific skills and a thorough understanding of statistical methodologies. Only a biostatistician can ensure the accuracy and reliability of the results, thereby ensuring a comprehensive and informative assessment of the available evidence.

3. Discussion and implications for research

This systematic review methodology, grounded in the PRISMA guidelines, embodies a methodical approach accessible to physicians and healthcare professionals. Its stringent framework integrates the JBI methodology for evaluating quality and risk of bias and the OCEBM framework to appraise evidence certainty [31–33]. Moreover, this methodology ensures broad accessibility by obviating the requirement for statistic software. Despite the solidity of the proposed methodology, we advocate for ongoing refinement and expansion within the research community. This adaptive stance not only facilitates the assimilation of emerging evidence but also embraces technological advancements, for instance, remaining open to incorporating new features of Artificial Intelligence, ensuring continuous relevance and effectiveness in practice. Moreover, this methodology offers the potential to reduce the time required for conducting systematic reviews by providing comprehensive guidance and tools. This is particularly beneficial for researchers actively engaged in clinical practice, allowing them to better manage their workload. Additionally, the integrated nature of this approach highlights its ability to support a clustered analytical framework. This becomes especially relevant when multiple primary studies present harmonized data on a specific topic. Such capability enhances the method's versatility, providing a statistically robust overview.

3.1. Limitations

One possible limitation of this methodology is the absence of a *meta-analysis* in accordance with the research objectives. The chosen framework for the systematic review was specifically structured to support clinicians and healthcare professionals, focusing on a pooled analysis rather than a *meta-analysis*. To undertake advanced statistical analyses, it is advisable to seek assistance from a statistical team with expertise in the field. This limitation emphasizes the method's practicality for healthcare practitioners while acknowledging the necessity of statistical expertise for more intricate analyses. An additional limitation may be the inapplicability of the framework proposed by the OCEBM for assessing the certainty of evidence in qualitative studies. Such framework, specifically designed for the analysis of quantitative studies, does not encompass the elements required to assess the trustworthiness of qualitative evidence. Consequently, this could represent a deficiency in the overall research evaluation process, particularly when attempting to integrate the findings of qualitative studies into contexts of scientific evidence synthesis.

4. Conclusions

This systematic review methodology aims to develop a framework that, while maintaining a rigorous methodological approach, significantly simplifies the process for clinicians and healthcare professionals. The implementation of this methodology in clinical practice not only offers new perspectives to ensure a thoughtful consideration and

application of scientific evidence in daily decisions but also opens the way to innovative and easily accessible solutions to facilitate the conduct of systematic reviews in the clinical care setting, substantially contributing to the generation of secondary scientific evidence.

5. Ethics statements

No ethical approval was required for the purposes of this study. This systematic review methodology was implemented following the guidelines of good clinical practice.

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CRediT authorship contribution statement

Stefano Mancin: Conceptualization, Methodology, Writing – original draft, Writing – review & editing, Investigation, Visualization. **Marco Sguanci:** Conceptualization, Methodology, Writing – original draft, Writing – review & editing, Investigation, Visualization. **Giuliano Anastasi:** Writing – original draft, Writing – review & editing. **Lea Godino:** Writing – original draft, Writing – review & editing. **Alessio Lo Cascio:** Writing – original draft, Writing – review & editing. **Emanuela Morengi:** Writing – original draft, Writing – review & editing, Data curation, Formal analysis. **Michela Piredda:** Methodology, Writing – review & editing, Visualization. **Maria Grazia De Marinis:** Methodology, Writing – review & editing, Visualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ymeth.2024.03.006>.

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