

**ORIGINAL RESEARCH**

# A scoping review identifies comments suggesting modifications to PRISMA-P 2015

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**Abstract**

**Objectives:** To identify, summarize, and analyze published comments relevant to the PRISMA-P (Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocols) 2015 reporting guideline for systematic review protocols, with special emphasis on suggestions for guideline modifications.

**Methods:** We included documents (eg, empirical studies and social media posts) that included comments relevant to PRISMA-P 2015. We searched bibliographic databases (eg, Embase, MEDLINE, Scopus, from January 1st 2015 to February 2nd 2024) and other sources (eg, BMJ rapid responses, BMC Blog Network, from January 1st 2015 to April 22nd 2024). Two authors independently assessed documents for inclusion, extracted data, and categorized comments. We categorized comments as “suggestion for modification to the wording of an existing PRISMA-P 2015 item,” “suggestion for a new item,” “suggestion for deletion of an existing PRISMA-P 2015 item,” or “additional comment.” We categorized each comment into themes and provided a summary and examples of the proposed suggestions. We analyzed the characteristics of the suggestions by describing the rationale and comparing with existing PRISMA-P 2015 guidance.

**Results:** We assessed full text of 1912 potentially eligible documents and included 28 documents with 38 comments. 11 comments suggested modifications to existing guideline items. Multiple comments proposed modifications to items related to eligibility criteria (three comments made different suggestions, for example, one comment suggested to include reporting guidance relating to retracted papers) and data synthesis (three comments made different suggestions, eg, one comment suggested to add reporting guidance relating to prediction intervals for random-effects meta-analyses). There were 11 comments suggesting new items. The data items section of PRISMA-P 2015 received the most comments (five comments made different suggestions, eg, three comments suggested to add content on prespecifying whether authors plan to extract information on funding and conflicts of interest among the included studies). None of the included comments suggested deleting items or content. Most of the suggestions provided a rationale directly in the document, and around two-thirds of the suggestions referred to content in addition to PRISMA-P 2015 or asked for more extensive guidance than what is included.

**Conclusion:** The issues raised provide context to authors, peer reviewers, editors, and readers of systematic review protocols using PRISMA-P 2015 and inform the planned update of the guideline. © 2025 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

**Keywords:** PRISMA-P 2015; Reporting guidelines; Reporting; Systematic review protocols; Systematic reviews; Comments

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## 1. Introduction

Results from systematic reviews of health research may have a profound impact on patient care. When appropriately designed, conducted, and reported, systematic reviews

### What is new?

#### Key findings

- We identified 38 published comments relevant to PRISMA-P 2015. Comments commonly proposed modifications to the eligibility criteria ( $N = 3$ ) and data synthesis ( $N = 3$ ) and proposed new content related to the data items ( $N = 5$ ).
- Most of the suggestions provided a rationale directly in the document often because they proposed changes directly linked to an empirical investigation. Around two-thirds of the suggestions referred to content in addition to PRISMA-P 2015 or asked for more extensive content than what is included.

#### What this adds to what is known?

- Our review precedes the planned update of PRISMA-P 2015. The forthcoming revision needs to consider which changes ought to be implemented without introducing unnecessary complexity.

#### What is the implication and what should change now?

- The issues raised provide context to authors, peer reviewers, editors, and readers of systematic review protocols using PRISMA-P 2015 and inform the planned update of the guideline.

provide a rational basis for clinical practice guidelines, for therapeutic decision-making, and for planning further research.

A key part of a systematic review is to prespecify in a protocol the methodological details. To avoid the systematic review methods being modified based on the features of potential studies available and to facilitate the detection of important changes in the review process, the protocol should clearly report key aspects, for example, aim, eligibility criteria, outcome measurements, and statistical analysis plans [1,2]. Sometimes, authors register their systematic review in registration platforms like the International Perspective Register of Systematic Reviews (PROSPERO). Though PROSPERO is not intended for publication of full protocols, authors often inaccurately refer to a PROSPERO record as a “protocol” (Box 1).

Accurate and transparent reporting is a prerequisite for systematic review findings to be implemented into patient care accurately. Unfortunately, important aspects of systematic review protocols are often inaccurately reported. An empirical study investigating random samples of 50 PubMed-indexed systematic review protocols and 50

protocols uploaded to PROSPERO found that aspects related to administrative (eg, the role of the review sponsor) and methodological (eg, methods for assessing publication bias) issues were often not reported [3]. Other studies have reported similar findings [4,5].

To facilitate good reporting of systematic review protocols, the Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocols (PRISMA-P) guideline was published in 2015. It consists of 17 items (totaling 26 subitems) covering aspects related to administrative information, introduction, and methods of a review [6,7].

In the 10 years since the publication of PRISMA-P 2015, the context of research and systematic reviews has evolved substantially. Moreover, the PRISMA guideline for reporting completed systematic reviews was updated in 2020 and included changes to protocol-relevant items. Whether such modifications to PRISMA items are relevant to review protocols has yet to be considered. Furthermore, as PRISMA-P 2015 preceded PRISMA 2020, there is now a lack of harmonization between the two guidelines. Therefore, an update of PRISMA-P 2015 has been planned [8].

Several researchers have commented on the usability of PRISMA-P 2015 or items in PRISMA 2020 that are potentially relevant for protocols, either in publications or on websites. For example, Puljak et al. suggested that the PRISMA-P 2015 item about reporting the rationale of the review could be revised to incorporate reporting of whether other systematic reviews address the same or largely similar questions [9]. An overview of such comments would provide context to authors, peer reviewers, editors, and readers of systematic review protocols using PRISMA-P 2015 and inform the planned update of the reporting guideline.

The objective of this study was to identify, summarize, and analyze published comments relevant to PRISMA-P 2015, with special emphasis on suggestions for guideline modifications.

## 2. Methods

### 2.1. Design

We conducted a scoping review following the methods outlined in our protocol (available in OSF, <https://osf.io/mqv3d>, see Appendix 1 for protocol amendments). Our approach was based on the Joanna Briggs Institute Manual for Evidence Synthesis for scoping reviews [10] and followed the same methodology used in a previous similar scoping review [11]. We reported the review according to the PRISMA extension for scoping reviews (PRISMA-ScR) [12].

### 2.2. Terminology

We use the term ‘documents’ to refer to texts that include comments relevant to PRISMA-P 2015. This may

### Box 1 Differences between systematic review protocols and registrations.

A systematic review protocol is distinct from a registry entry for a review. While both resources serve to minimize bias, increase transparency and trustworthiness, and facilitate the detection of important changes in the review process, they have different purposes. Registration offers a concise and easily accessible summary of the core review methods, helping to reduce unintended duplication and enabling researchers planning a new review to search register listings to identify similar reviews. By comparison, a protocol complements the full review by providing a more detailed explanation of the review objectives and methods allowing authors to outline different strategies and provide their rationale. This not only reduces issues related to multiplicity, but also ensures a better understanding of the review process and facilitates future replications or updates of the review. While protocols, when adequately reported with a sufficient level of detail, provide a full analysis plan, the level of details for registrations depend on the chosen platform. In PROSPERO (<https://www.crd.york.ac.uk/prospere>), for example, authors are asked to provide details of the planned synthesis, including a rationale for the selected methods as well as any planned investigations of subgroups.

A systematic review protocol outlines in detail the preplanned objectives and methods intended to be used in the review. This helps identify and address potential issues before embarking on a review and provides a methodological approach to prevent arbitrary decision-making during the review process. There are several options for making a systematic review protocol publicly available. One option is to publish a protocol in a scientific journal, where it will benefit from external peer review feedback before publication, whereas another option is to upload a PDF version of the protocol to open repositories such as Open Science Framework (OSF) (<https://osf.io>).

A systematic review registry entry captures key elements of the review protocol. It records details of, for example, inclusion and exclusion criteria and planned outcomes. Depending on the registration platform, entries can include descriptions of data syntheses. The registration creates a public record with a unique identification number, allowing the registry entry to be linked to completed review publications. PROSPERO is one of the most widely used platforms for registering systematic reviews. It not only allows authors to register their reviews but also provides the option to clarify any subsequent amendments (date-stamped) and upload full protocols.

cover empirical studies, editorials, blogs, and social media posts.

We use the term “comments” to refer to the statements relevant to PRISMA-P 2015 expressed in the included documents. By “relevant to PRISMA-P 2015” we imply that comments are related directly to PRISMA-P 2015 or to items relating to the introduction, methods, or other information sections of PRISMA 2020, the extensions for abstracts published with PRISMA 2020, or the extension for searching (PRISMA-S), as these guidelines were published or updated after 2020, and comments on these sections could be potentially relevant for reporting guidance for systematic review protocols.

### 2.3. Eligibility criteria

We included documents written in any language with explicit comments relevant to PRISMA-P 2015. To be included, the documents had to mention PRISMA somewhere in the text (ie, not necessarily in the title or abstract). We included documents published after 2015 (publication year of PRISMA-P). We included opinion pieces (eg, commentaries and editorials) as well as empirical studies. We also included comments posted on key websites (eg, the Enhancing the QUality and Transparency Of health Research, Network Blog, <https://www.equator-network.org/category/blog/>) and social media. To be included, documents had to suggest changes to specific protocol-relevant guideline sections or reflect on aspects related to using PRISMA-P 2015. Thus, we excluded empirical studies that investigated the use of PRISMA-P 2015 without suggesting any modifications.

Documents commenting on other aspects of PRISMA-P 2015 (eg, explaining the basis of the guideline) were excluded. We also excluded documents that only had generic comments (eg, briefly mentioning that PRISMA-P 2015 is a resource) or had only comments on implementation or endorsement of PRISMA-P 2015. Finally, we excluded documents with comments suggesting the development of new extensions and comments addressing application of PRISMA-P to a specific subgroup of reviews.

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### 2.4. Information sources and search for documents

In previous similar reviews, striking an appropriate balance between search sensitivity and specificity was found to be a challenge [11,13]. Therefore, we used multiple approaches to identify documents.

First, we performed a systematic search in two databases: Embase and MEDLINE (both databases searched through Ovid, from January 1st 2015 to February 2nd 2024). We used the search strategies described in Appendix 2. One author (C.H.N.) developed the search

strategy based on experiences from a previous study investigating comments on reporting guidelines for randomized trial protocols (Standard Protocol Items: Recommendations for Interventional Trials 2013) and full publications of completed trials (Consolidated Standards of Reporting Trials 2010) [11]. The search strategy was peer-reviewed by an information specialist using the Peer Review of Electronic Search Strategies 2015 evidence-based checklist [14].

Second, we performed a focused search among documents citing PRISMA-P 2015. We used Scopus (from January 1st 2015 to February 2nd 2024) to identify studies citing the PRISMA-P 2015 statement or explanation and elaboration publications. We then used the search terms in [Appendix 3](#) and the refine search function to search within the citing publications (thereby not inspecting each document citing PRISMA-P 2015).

Third, we used Google Scholar (from January 1st 2015 to May 14th 2024) to conduct full-text searches. We used standard phrases (eg, “could be strengthened” or “should be adapted”) from the comments identified through the database searches as well as phrases based on the statement and explanation and elaboration publications of PRISMA-P 2015 and noteworthy changes made in PRISMA 2020. Thus, the search phrases were developed iteratively ([Appendix 4](#)). We sorted the search records by relevance and stopped screening when no additional documents had been identified for at least 50 records.

Fourth, we searched key websites (eg, the Enhancing the QUALity and Transparency Of health Research Network website, BMJ rapid responses, and BMC Blog Network) for additional documents (from January 1st 2015 to April 22nd 2024). We searched proceedings from Cochrane Colloquia and the International Congresses on Peer Review and Scientific Publication (conferences held from 2015 to 2023) for conference abstracts with PRISMA or PRISMA-P in the title and/or abstract. We conducted preprint searches in medRxiv, OSF preprints, and Figshare (from January 1st 2015 to May 1st 2024) for preprints with PRISMA or PRISMA-P in the title and/or abstract. Finally, we searched social media sites (eg, X, LinkedIn, and ResearchGate) for posts on PRISMA-P 2015 or PRISMA 2020 (from January 1st 2015 to May 17th 2015).

## 2.5. Selection of documents for inclusion

From the searches in Embase, MEDLINE, and Scopus, we used Covidence to remove duplicates and manage search records. As a pilot test to train and align screeners, two authors (C.H.N. and N.S.) independently initially screened titles and abstracts of 100 search records for obvious exclusions. After 100 screened records, we assessed the number of disagreements in the screening, but also reviewed full texts of the excluded records to ensure

that no eligible documents were excluded. We repeated this process until we had screened 400 records, after which a satisfying level of agreement (ie, less than 5% disagreements) was reached, and no eligible documents were identified among the excluded records. For pragmatic reasons, one author (N.S.) screened titles and abstracts of the remaining search records from here on. One author (N.S.) then electronically screened full texts to exclude records with no mention of any of the relevant reporting guidelines. Finally, two authors (C.H.N. and N.S.) independently screened full texts of potentially eligible documents. Disagreements were resolved by discussion. Documents not written in English were translated using Google Translate for screening purposes [15].

One author (C.H.N. or N.S.) performed the additional searches. Any documents identified through these searches were assessed for inclusion by 2 authors (C.H.N. and N.S.) independently.

## 2.6. Data extraction

Two authors (C.H.N. and N.S.) independently extracted data and categorized comments from included documents. Disagreements were resolved by discussion. Data were extracted into an Excel sheet that was pilot tested based on five included documents. We extracted the following basic characteristics of each document: first author, publication year, publication type (eg, opinion piece or empirical study), and reporting guideline considered (eg, PRISMA-P 2015). We also extracted the exact wording of the comments. One document could contain several comments. We considered comments as distinct if they related to separate topics or separate items or sections of PRISMA-P 2015.

For each comment, we categorized it as “suggestion for modification to the wording of an existing PRISMA-P 2015 item,” “suggestion for a new item,” “suggestion for deletion of an existing PRISMA-P 2015 item,” or “additional comment.” Comments were categorized as “suggestion for modification to the wording of an existing PRISMA-P 2015 item,” when they suggested additions, deletions, or amendments related to existing recommendations in PRISMA-P 2015.

We noted the PRISMA-P 2015 topic the comment was addressing (eg, introduction or methods), and, when relevant, the specific PRISMA-P 2015 item number. For comments categorized as “suggestion for modification to the wording of an existing PRISMA-P 2015 item,” “suggestion for a new item,” and “suggestion for deletion of an existing PRISMA-P 2015 item,” one author (C.H.N.) phrased a key point that was verified by a second author (N.S.). Moreover, two authors (C.H.N. and N.S.) independently categorized the characteristics of such comments (ie, by describing the rationale provided in the documents) and

compared the proposed content with existing PRISMA-P 2015 guidance.

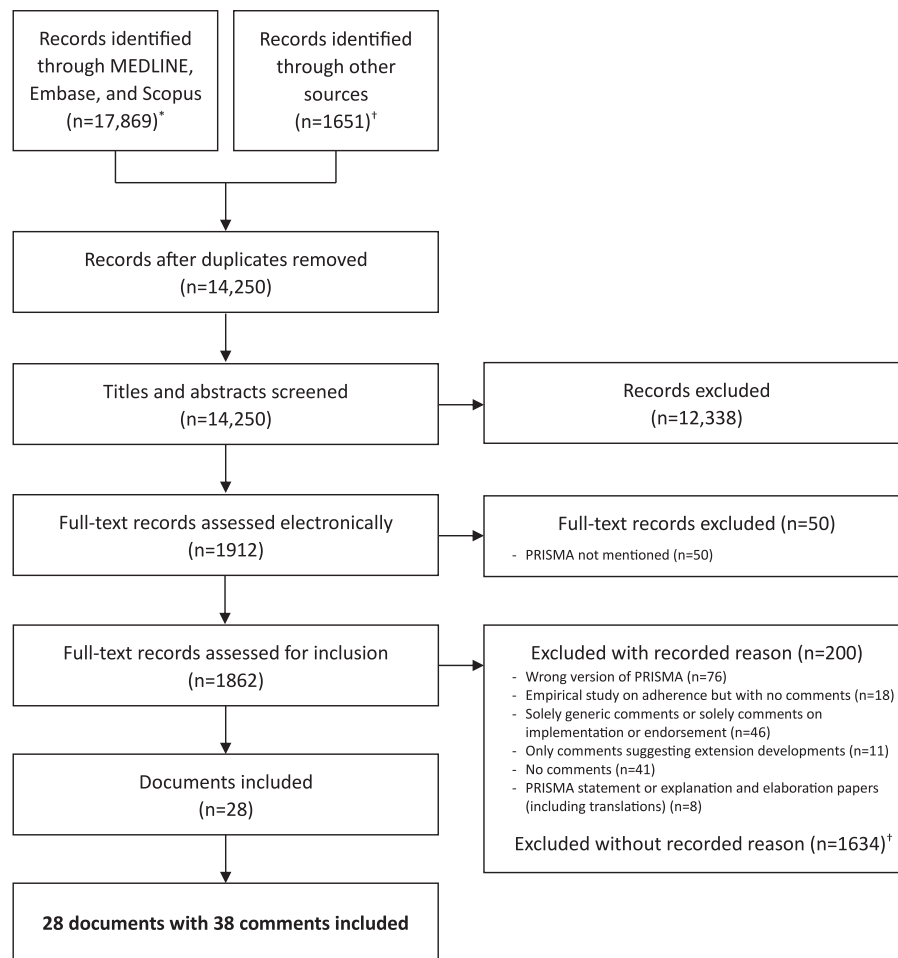
## 2.7. Charting the data

We categorized the comments into themes to merge similar topics and noted the number of included documents and comments within each category and theme. The themes were related to the topics and items addressed in PRISMA-P 2015. We qualitatively mapped the themes addressed by the documents. For comments categorized as “suggestion for modification to the wording of an existing PRISMA-P 2015 item,” “suggestion for a new item,” and “suggestion for deletion of an existing PRISMA-P 2015 item,” we provided a summary and examples of the proposed suggestions. We analyzed the characteristics of such comments by describing the rationale provided for the suggestions in the document. We also compared each suggestion with existing PRISMA-P 2015 and PRISMA 2020 guidance and noted

whether the proposed content is already included is included to some extent (ie, in cases where the comments asked for more extensive guidance than what is included) or is not included. The coding was done by two authors (C.H.N. and N.S.) independently and verified across the author group. For comments categorized as “additional comments,” we listed them in a table and provided a brief overview.

## 3. Results

We assessed full text of 1912 potentially eligible documents and included 28 published documents with 38 comments (Fig) [3,5,9,16–40]. The documents were either empirical studies (54%), opinion pieces (32%), or social media posts (14%). The 28 documents had comments primarily intended for PRISMA-P 2015 (43%) or items indirectly related to PRISMA-P 2015 (ie, those relating to



\*Number of records identified in the databases; \*Number of full text records reviewed through other sources. These searches were performed by one author, and we did not record exclusion reasons. All eligible documents were verified for inclusion by a second author.

Figure 1. Flow chart of the inclusion of documents.



the introduction, methods, or other information sections of PRISMA 2020 that we deemed potentially relevant for reporting guidance for systematic review protocols, 46%, Table 1). The majority of the 38 comments were related to the methods section (29 comments, 76%) of the reporting guidelines.

3.1. Suggestions for modifications to the wording of existing guideline items

In total, 11 comments suggested modifications to existing guideline items. The comments covered all main sections of PRISMA-P 2015 but were mostly related to the methods (nine comments) section. Around two-thirds of the suggestions (seven comments) were directly related to PRISMA-P 2015.

Multiple comments were related to the eligibility criteria (item 8) and data synthesis (items 15a, 15b, 15c, and 15d) sections of PRISMA-P 2015. Three comments made different suggestions related to the eligibility criteria item (eg, one comment suggested to include reporting guidance related to retracted papers in PRISMA 2020, and we deemed this suggestion potentially relevant for reporting guidance for systematic review protocols), and 3 comments

made different suggestions to the data synthesis items (eg, one comment suggested to add reporting guidance related to prediction intervals for random-effects meta-analyses in PRISMA 2020, and we deemed this suggestion potentially relevant for reporting guidance for systematic review protocols). The remaining PRISMA-P 2015 topics were discussed by single comments (see Table 2 for an overview of the comments and Appendix 5 for full quotes).

3.2. Suggestions for new items or deletion of existing guideline items

Eleven comments suggested new items. Almost all comments were related to the methods section (10 comments). Around two-thirds of the suggestions (seven comments) were directly related to PRISMA-P 2015.

The data items section of PRISMA-P 2015 received the most comments. Five comments made different suggestions. Three comments suggested adding content on prespecifying whether authors plan to extract information on funding and conflicts of interest among the included studies; one comment suggested adding content on prespecifying whether authors plan to extract information on ethical approval of included studies, and one comment suggested adding content on prespecifying whether authors plan to extract information on the type of journal (see Table 3 for an overview of the comments and Appendix 6 for full quotes).

None of the included comments suggested deleting items or content.

3.3. Characteristics of the proposed suggestions

Most of the comments making suggestions for modifications of existing guideline items (11 comments) and new items (11 comments) provided a rationale for the suggestion directly in the document. In most cases, the authors conducted an empirical study investigating reporting in a sample of systematic reviews or systematic review protocols and proposed changes on the basis of their findings. For example, Elia et al. investigated reporting and methods of 118 systematic reviews and found that funding sources and authors' conflicts of interest among the included studies were often not reported. Furthermore, they found that very few of the systematic reviews analyzed the impact of funding and conflicts of interest on the results of the review. Therefore, they suggested adding content on prespecifying whether authors plan to extract information on funding and conflicts of interest among the included studies [23].

In total, 17 (77%) of the suggestions for modifications of existing guideline items and new items referred to content in addition to PRISMA-P 2015 or asked for more extensive guidance than what is included. For example, Avenell et al. suggested adding guidance on reporting exclusion criteria related to retracted papers [18]. Planned methods for managing retracted papers are not included in PRISMA-P 2015.

Table 1. Characteristics of documents with comments relevant for PRISMA-P 2015

Document characteristics	N (%) of included documents <sup>a</sup>
Publication type	
Empirical study <sup>b</sup>	15 (54)
Opinion piece <sup>c</sup>	9 (32)
Social media post	4 (14)
Document publication year	
Median (range)	2022 (2015–2024)
Reporting guideline considered	
PRISMA-P 2015	12 (43)
PRISMA 2020 (protocol-relevant items) <sup>d</sup>	13 (46)
Other <sup>e</sup>	3 (11)
Number of comments per document <sup>f</sup>	
1	23 (82)
2	2 (7)
3	1 (4)
4	2 (7)

<sup>a</sup> Values reported as number (percentage) of included documents, unless indicated otherwise.  
<sup>b</sup> Empirical studies include, for example, cross-sectional studies.  
<sup>c</sup> Opinion pieces include, for example, commentaries and letters.  
<sup>d</sup> This includes comments on items relating to the introduction, methods, or other information sections of PRISMA 2020 that we deemed potentially relevant for reporting guidance for systematic review protocols.  
<sup>e</sup> Other include PRISMA 2020 for Abstracts and PRISMA-S, and both PRISMA-P 2015 and PRISMA 2020.  
<sup>f</sup> Number of comments in each published document (one document could contain multiple relevant comments).

**Table 2.** Comments presenting suggestions for modifications to the wording of existing guideline items (11 comments in eight documents)

PRISMA-P 2015 section and topic	Item	Document ID	Comment primarily intended for	Key point	Rationale <sup>a</sup>	PRISMA-P update team reflections
Administrative information; role of sponsor or funder	5c	Frost 2022	PRISMA-P 2015	Add explanation and guidance on reporting the role of the review sponsor	Empirical study found that the role of the review sponsor was often not reported in systematic review protocols	PRISMA-P 2015 already contains some guidance on this
Introduction; rationale	6	Puljak 2023	PRISMA-P 2015 and PRISMA 2020 introduction section <sup>b</sup>	Include guidance to check if other systematic reviews address the same or largely similar questions directly in the reporting guideline (and not solely in the accompanying explanation and elaboration paper) based on searches in multiple databases and registration platforms	Authors interpret existing literature on redundant systematic reviews and present ideas for preventing them	PRISMA-P 2015 explanation and elaboration publication and expanded PRISMA 2020 checklist already contain guidance on this
Methods; eligibility criteria	8	Avenell 2022	PRISMA 2020 methods section <sup>b</sup>	Include guidance on reporting exclusion criteria related to retracted papers	Empirical study found that systematic reviews sometimes included retracted trials and that the review findings often were likely to change if retracted trials were removed	PRISMA-P 2015 and PRISMA 2020 do not contain guidance on this
		Booth 2019	PRISMA-P 2015	Include more detailed guidance on context, including the specific details of setting, time, and PICO elements that should be reported	Authors argue that current guidelines only address specific elements of context in systematic reviews and are not suitable in meeting challenges related to complex interventions	PRISMA-P 2015 already contains some guidance on this
		Helbach 2022 <sup>c</sup>	PRISMA 2020 methods section <sup>b</sup>	Include guidance on reporting language restrictions directly in the reporting guideline (and not solely in the expanded checklist)	Empirical study found that language restrictions were often not reported in systematic reviews	PRISMA-P 2015 and expanded PRISMA 2020 checklist already contain guidance on this

(Continued)

Table 2. Continued

PRISMA-P 2015 section and topic	Item	Document ID	Comment primarily intended for	Key point	Rationale <sup>a</sup>	PRISMA-P update team reflections
Methods; search strategy	10	Neeleman 2024	PRISMA 2020 methods section <sup>b</sup>	Include more extensive reporting of the search strategies with specification of platforms, institutional access, field codes (besides the search terms), and storage of the search results and of the full labeled dataset (detailing all records screened and their labeling decisions) of included and excluded records	A simulation study was only to some extent able to replicate a systematic review search query and was not able to reproduce the exact same data set. Reproducibility was challenging based on the information provided in the review (e.g., use of thesaurus terms and searches without specific search fields, as differences between access platforms and changes in the thesaurus can affect the retrieved records)	PRISMA-P 2015 and PRISMA 2020 already contain some guidance on this
Methods; data synthesis	15a-15 d	Booth 2020	PRISMA-P 2015	Include guidance on reporting alternative options for how data will be analysed and the condition for selection of options when finalising the protocol	Empirical study found that many PROSPERO records have multiple versions and that much of the information recommended in PRISMA-P 2015 was not reported. Suggestion linked to, but not directly based on, the findings	PRISMA-P 2015 already contains some guidance on this
		Borg 2023	PRISMA 2020 methods section <sup>b</sup>	Add reporting of prediction intervals for random-effects meta-analyses	Empirical study found that systematic reviews rarely reported prediction intervals	PRISMA-P 2015 does not contain guidance on this, but PRISMA 2020 explanation and elaboration publication does
		Frost 2022	PRISMA-P 2015	Add explanation and guidance on reporting procedures for doing a qualitative data synthesis	Empirical study found that procedures for doing qualitative data synthesis were often not reported in systematic review protocols	PRISMA-P 2015 already contains some guidance on this
Methods; meta-biases	16	Frost 2022	PRISMA-P 2015	Add explanation and guidance on reporting the methods for assessing publication or outcome reporting bias	Empirical study found that the methods for assessing meta-biases were often not reported in systematic review protocols	PRISMA-P 2015 already contains some guidance on this

(Continued)



Table 2. Continued

PRISMA-P 2015 section and topic	Item	Document ID	Comment primarily intended for	Key point	Rationale <sup>a</sup>	PRISMA-P update team reflections
Methods; confidence in cumulative evidence	17	Frost 2022	PRISMA-P 2015	Add explanation and guidance on reporting the methods for assessing confidence in cumulative evidence	Empirical study found that the methods for assessing confidence in cumulative evidence were often not reported in systematic review protocols	PRISMA-P 2015 already contains some guidance on this

PRISMA-P 2015, Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocols; PRISMA 2020, Preferred Reporting Items for Systematic reviews and Meta-Analyses; PICO, population, intervention, comparison, and outcome.

<sup>a</sup> Rationale for suggestion provided directly in the document.

<sup>b</sup> Suggestion relating to items in the introduction, methods, or other information sections of PRISMA 2020. The comment was therefore potentially relevant for reporting guidance on systematic review protocols.

<sup>c</sup> Comment also applicable to PRISMA-P 2015 item 11b on selection process.

The remaining suggestions addressed content already covered in the PRISMA-P 2015 guideline statement or in the explanation and elaboration publication.

### 3.4. Additional comments

In total, 16 comments were categorized as additional comments (Appendix 7). The comments presented different reflections. For example, one comment highlighted that the PRISMA reporting guidelines do not ensure that a study is novel or answers an important research question [17].

## 4. Discussion

### 4.1. Summary of main findings

Comments on PRISMA-P 2015 made different suggestions for modifying the wording of existing guideline items and adding new items; no comments suggested deleting the content. Comments covered all aspects of the guideline, most often related to the methods items. Multiple comments proposed modifications to the wording of items related to the eligibility criteria and data synthesis, and several comments proposed adding new content related to data items of PRISMA-P 2015. Most suggestions provided a rationale directly in the document, often the direct result of an empirical investigation. Around two-thirds of the suggestions referred to content in addition to PRISMA-P 2015 or asked for more extensive guidance than what is included.

### 4.2. Strengths and weaknesses

Our review informs the planned update of PRISMA-P 2015 [8]. We conducted several thorough searches and used multiple approaches to identify documents. However, searching for documents with comments is challenging

since there is no unique format or indexing for these. Also, while we included documents in any language, we did not search specifically for documents in languages other than English by using non-English search terms. We may therefore have missed potentially relevant documents but find it unlikely that these would substantially change our findings. We solely included documents that explicitly mentioned PRISMA somewhere in the text and may have missed nuances, reflections, or unpublished materials.

### 4.3. Other similar studies

Our findings complement previous studies focusing on adherence and endorsement of PRISMA-P 2015. Empirical studies have reported that adherence to PRISMA-P 2015 is suboptimal in systematic review protocols and PROSPERO registrations [3–5].

A scoping review of comments on Standard Protocol Items: Recommendations for Interventional Trials 2013 and Consolidated Standards of Reporting Trials 2010 identified 114 comments, mostly suggesting modifications to existing items or addition of new content [11]. However, only 12 of those comments were related to aspects of trial protocols. Moreover, a mapping review based on 60 sources providing guidance on systematic reviews and meta-analyses identified a comprehensive bank of items that were considered for inclusion in the development of PRISMA 2020 [41]. Thus, all reviews identified multiple suggestions for adding new content to the reporting guidelines, but no suggestions to delete content.

### 4.4. Mechanisms and perspectives

PRISMA-P 2015 aims to advice on the minimum content relevant for reporting systematic review protocols, primarily evaluating therapeutic efficacy. Not all comments identified

**Table 3.** Comments presenting suggestions for new items (11 comments in eight documents)

PRISMA-P 2015 section and topic	Document ID	Comment primarily intended for	Key point	Rationale <sup>a</sup>	PRISMA-P update team reflections
Administrative information	Olivan 2015	PRISMA-P 2015	Add content on obtaining ethics approval for the systematic review	Not provided	PRISMA-P 2015 does not contain guidance on this
Methods (in general)	Post on X, #2	PRISMA 2020 methods section <sup>b</sup>	Add content on the methodological guide for the systematic review	Not provided	PRISMA-P 2015 explanation and elaboration publication and PRISMA 2020 already contain some guidance on this
Methods; data management	Elia 2016	PRISMA-P 2015	Add content on duplicate publications	Empirical study found that the number of duplicates identified was rarely reported in systematic reviews	PRISMA-P 2015 explanation and elaboration publication already contains guidance on this
Methods; data collection process	Post on X, #1	PRISMA 2020 methods section <sup>b</sup>	Add content on contacting authors to identify eligible studies	Not provided	PRISMA-P 2015 explanation and elaboration publication and PRISMA 2020 already contain guidance on this
Methods; data items	Benea 2020	PRISMA 2020 methods section <sup>b</sup>		Empirical study found that reporting of funding source and authors' financial conflicts of interest was suboptimal in systematic reviews	PRISMA-P 2015 and PRISMA 2020 already contain guidance on study funding. PRISMA 2020 already contains guidance on study conflicts of interest (not as a separate item)
	Elia 2016	PRISMA-P 2015	Add content on reporting information on funding and conflicts of interest among the included studies as a dedicated item	Empirical study found that the source of funding and authors' conflicts of interest among the included studies were rarely reported in systematic reviews	
	Jin 2023	PRISMA-P 2015		Empirical study found that source of funding among the included studies was rarely reported	
	Elia 2016	PRISMA-P 2015	Add content on extracting information on ethics approval of included studies	Empirical study found that ethics approval of the included studies was rarely reported in systematic reviews	PRISMA-P 2015 does not contain guidance on this
	Rice 2021	PRISMA-P 2015	Add content on extraction and reporting information on the type of journal (includes checking the journal is open access, listed in the Directory of Open Access Journals, and a member of the Committee On Publication Ethics as well as reviewing journal websites for characteristics of predatory journals)	Authors argue that results from studies published in predatory journals can alter review findings and recommendations. Suggestion based on personal experiences	PRISMA-P 2015 does not contain guidance on this

(Continued)

Table 3. Continued

PRISMA-P 2015 section and topic	Document ID	Comment primarily intended for	Key point	Rationale <sup>a</sup>	PRISMA-P update team reflections
Methods; data collection process	Hill 2023	PRISMA 2020 methods section <sup>b</sup>	Add content on the use of artificial intelligence in the data extraction (including the exact methods of how the artificial intelligence was used, version of technology, date of use, any processes for calibration of the system, any validation processes with levels of agreement achieved, and exact enquiries used to request information)	In authors' experience, Bing AI and Microsoft Edge can be used as verification of data extraction in reviews. Suggestion based on personal experiences	PRISMA-P 2015 does not contain guidance on this, but PRISMA 2020 does
Methods; meta-bias(es)	Elia 2016	PRISMA-P 2015	Add content on reporting suspected misconduct, including what should be considered misconduct	Empirical study found that research misconduct was sometimes identified, but rarely reported in systematic reviews	PRISMA-P 2015 does not contain guidance on this

PRISMA-P 2015, Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocols; PRISMA 2020, Preferred Reporting Items for Systematic reviews and Meta-Analyses.

<sup>a</sup> Rationale for suggestion provided directly in the document.

<sup>b</sup> Suggestion relating to items in the introduction, methods, or other information sections of PRISMA 2020. The comment was therefore potentially relevant for reporting guidance on systematic review protocols.

in our review provided clear rationale and some suggestions addressed content already included in PRISMA-P 2015. Furthermore, some comments were related to methods and conduct rather than reporting. To avoid introducing unnecessary complexity, the planned update of the guideline needs to consider which suggestions are relevant and which new items are most important.

New methodological developments have emerged or received increasing attention since the publication of PRISMA-P 2015. Some emerging concepts, (eg, journal features, artificial intelligence, and conflicts of interest) were mentioned by one or more included comments. Additional themes such as open data with potentially increased access to clinical study reports may be worth considering for the planned update of PRISMA-P 2015, even though this concept was not mentioned by the included comments [42]. Also, an increased complexity in trial designs with new emerging types (eg, remote clinical trials [43], patient-centric trials [44], basket trials, umbrella trials, and platform trials [45,46]) may indirectly impact on how systematic review protocols should be planned and reported.

Among the 16 additional comments, most of them reflected on the potential challenges of PRISMA-P 2015. This contrasts with the wide use of the reporting guideline and probably indicates that the threshold for publicly commenting on challenges is lower than for commenting on strengths.

Furthermore, authors who decide to make a publicly available comment may have a particular interest in a certain topic.

#### 4.5. Implications

PRISMA-P 2015 is a highly cited reporting guideline, highlighting its usefulness for authors conducting systematic reviews. While there, to our knowledge, is no formal registration of PRISMA-P 2015 endorsers, the PRISMA 2020 reporting guideline is endorsed by multiple journals [47], many of which might also endorse PRISMA-P 2015. Furthermore, important review organizations, such as Cochrane, enforce review authors to comply with PRISMA-P 2015 [48]. We suggest that our findings provide context to users of the reporting guideline (eg, review authors, peer reviewers, editors, and readers).

Though most of the comments provided a rationale for their suggestions, we did not analyze the strength or quality of the reasoning, and the suggestions were often based on single empirical studies. Therefore, we plan to seek evidence supporting or refuting some of the suggestions. For example, one comment suggested adding content on artificial intelligence, a topic that has been investigated multiple times [49–53]. The findings from these supporting projects will jointly inform the planned update of PRISMA-P 2015, and the relevance of proposed

suggestions will be decided through the forthcoming consensus process [8].

## 5. Conclusion

We identified 38 published comments on PRISMA-P 2015, covering all aspects of the reporting guideline, but often related to the methods section. Multiple comments proposed modifications to the wording of items related to eligibility criteria and data synthesis, and several comments proposed adding new content related to the data items section. The issues raised provide context to authors, peer reviewers, editors, and readers of systematic review protocols using PRISMA-P 2015 and inform the planned update of the guideline.

## Data statement

The dataset used and analyzed during this study is available in OSF (<https://osf.io/q3w92>).

## CRedit authorship contribution statement

**Camilla Hansen Nejstgaard:** Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Nina Sondrup:** Writing – review & editing, Methodology, Investigation, Data curation, Conceptualization. **An-Wen Chan:** Writing – review & editing, Methodology, Conceptualization. **Kerry Dwan:** Writing – review & editing, Methodology, Conceptualization. **David Moher:** Writing – review & editing, Methodology, Conceptualization. **Matthew J. Page:** Writing – review & editing, Methodology, Conceptualization. **Larissa Shamseer:** Writing – review & editing, Methodology, Conceptualization. **Lesley A. Stewart:** Writing – review & editing, Methodology, Conceptualization. **Asbjørn Hróbjartsson:** Writing – review & editing, Methodology, Conceptualization.

## Declaration of competing interest

C.H.N., A-W.C., K.D., D.M., M.J.P., L.S., L.A.S., and A.H. are members of the PRISMA-P 2025 steering group. The authors declare no additional conflicts of interest.

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## Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jclinepi.2025.111760>.

## Data availability

The data are uploaded to OSF. A link for the data is included in the manuscript.

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