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ORIGINAL RESEARCH

Author adherence and experiences with PRISMA-P 2015: a cross-sectional study

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Abstract

Objectives: This study aimed to explore systematic review protocol authors' adherence to and experiences with the Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocols (PRISMA-P) 2015 reporting guideline.

Methods: We randomly sampled 100 non-overlapping systematic review protocols from May 2021 to May 2024: 50 from PubMed-indexed journals and 50 from Open Science Framework (OSF)/the International Prospective Register of Systematic Reviews (PROSPERO). Two authors independently assessed adherence to the 26 PRISMA-P 2015 items as fully, partially (ie, when some, but not all, aspects of an item were reported according to predefined criteria), or not reported (or not applicable). We analysed adherence within the 2 protocol types separately. Forty-three systematic review protocol authors were invited for interviews on their experiences with using PRISMA-P 2015. We used a semistructured interview guide, involving 3 prespecified themes: level of experience, views on using PRISMA-P 2015, and reflections on the guideline's strengths and challenges. We applied framework analysis to the interview transcripts.

Results: Among the 50 PubMed protocols, the median proportion of fully reported applicable PRISMA-P items was 60% (IQR 52%−64%). The median proportion for OSF/PROSPERO protocols was 45% (IQR 38%−58%). Across both types of protocols, >25% were found not to report 6 items: protocol amendments, role of funder, criteria for quantitative synthesis, methods for planned summary other than quantitative meta-bias(es), and confidence in the cumulative evidence. In both types of protocols, >25% were found to partially report 11 items. Fifteen authors participated in the interviews. Through the interviews, suggestions for updating PRISMA-P 2015 emerged. Most suggestions concerned either adding or modifying existing content, for example, to report conflicts of interest, or clarify guidance on how to report data synthesis when no meta-analysis is planned; other suggestions were more general, for example, to add links to the Elaboration and Explanation paper.

Conclusion: Adherence to some PRISMA-P 2015 items was low among 50 PubMed systematic review protocols and even lower among 50 OSF/PROSPERO protocols. Six items were often not reported across both types of protocols. The interviewed authors suggested various additions and modifications to the guideline. Findings from this study provide context for users of the reporting guideline and will inform a forthcoming update of PRISMA-P 2015.

Keywords: PRISMA-P 2015; Reporting guidelines; Systematic review protocols; Systematic reviews; Adherence; Author interview

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Plain Language Summary

Researchers collect and summarise findings from several studies to better understand a specific health issue. These summaries are called systematic reviews. Health care guidelines are often based on results from systematic reviews. This makes systematic reviews very important for health care professionals and patients. To make sure that these results can be trusted and used, systematic reviews need to be done in a clear way. It needs to be so clear that other researchers can understand and repeat it. One way to do this is to write in detail how the review is planned before starting it. This is called a protocol. It can be useful with a guide to help authors write protocols with enough details. Such a guideline for writing protocols exists and is called PRISMA-P. It includes a checklist of 26 different items that should be described in a protocol. However, research shows that authors may not follow such guidelines closely. So far, no research has looked at how protocol authors use PRISMA-P or what makes it easier or harder to follow. In our study, we wanted to explore how protocol authors use PRISMA-P and what they think about it. We checked 100 protocols to see how well all 26 PRISMA-P items were described. We also interviewed 15 protocol authors about how they use PRISMA-P and if they had suggestions for improving it. We found that in more than 25% of the protocols, 6 specific items were not described. We also found that in more than 25% of the protocols, 11 other items were only partially described. The interviewed authors suggested many ways to improve PRISMA-P. For example, they suggested making instructions clearer on how to follow the individual items. They also suggested adding new content to PRISMA-P. Our findings will make it easier to read, write, and evaluate protocols for systematic reviews. The findings can also be used for a future update of PRISMA-P.

1. Introduction

Findings from systematic reviews often form the core of clinical practice guidelines and, as such, may have profound impact on patient care. Detailed, a priori publicly available protocols ensure trustworthy systematic reviews by defining key methodology, such as eligibility criteria, outcome measurements, risk of bias assessment, and statistical analyses [1]. Publicly available protocols enable readers to identify deviations from planned methods, reducing the chance of arbitrary or biased decision-making during the review process, which may threaten the validity of a systematic review [2,3].

Various options exist for making a protocol publicly available before carrying out the review. One option is to submit the protocol for publication in a scientific journal, although there may be a fee to authors (article processing charge) associated with this. Other options are to share citable documents by uploading the key methodological details or the full protocol to registries or open repositories, such as Open Science Framework (OSF) [4] and the International Prospective Register of Systematic Reviews (PROSPERO) [5]. Both registers are free to submit to and access, thus reducing one major barrier to sharing protocol information.

To optimise the reporting of systematic review protocols, the Preferred Items for Reporting Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guideline was published in 2015. The guideline covers aspects related to administrative information, introduction, and methods in 17 main items and 9 subitems [6,7]. PRISMA-P 2015 (henceforth referred to as PRISMA-P) is endorsed by multiple organisations, such as Cochrane [8], Campbell Collaboration [9], and Joanna Briggs Institute [10], as well as numerous medical journals.

Previous studies have found that important methodological aspects of systematic review protocols remain inadequately reported [11,12]. This suboptimal reporting may, to some extent, depend on protocol authors' use and perception of PRISMA-P. However, little is known about how protocol authors interpret PRISMA-P items in practice or the contextual factors that enable or hinder uptake.

The aim of our study was to explore systematic review protocol authors' adherence to and experiences with applying the PRISMA-P reporting guideline.

2. Methods

2.1. Design

This study comprises 2 parts: We used a cross-sectional study design for analysing adherence to PRISMA-P across systematic review protocols, combined with an interview study exploring protocol authors' experiences with using PRISMA-P. This study represents 1 of 2 elements of a supporting project for the forthcoming update of PRISMA-P [13]. The methods were outlined in our protocol [14]. We reported the study according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline [15] and the Standards for Reporting Qualitative Research (SRQR) [16].

2.2. Cross-sectional study on adherence to PRISMA-P across systematic review protocols

2.2.1. Eligibility criteria

We included systematic review protocols, defined as such by the protocol authors in the title, abstract, or objectives, written in English, and published or registered

What is new?

Key findings

- Among the 50 PubMed protocols, the median proportion of fully reported applicable items was 60% (IQR 52%−64%). The median proportion among 50 OSF/PROSPERO protocols was 45% (IQR 38%−58%).
- Items often not reported were on protocol amendments, funder role, criteria for quantitative synthesis, methods for planned summary other than quantitative, meta-bias(es), and confidence in cumulative evidence.
- Through interviews with 15 protocol authors, suggestions for updating PRISMA-P 2015 emerged. Most suggestions regarded adding or modifying existing content, for example, to report conflicts of interest, or how to report data synthesis when no meta-analysis is planned; other suggestions were more general, for example, to add links to the Elaboration and Explanation paper.

What this adds to what is known?

- We assessed adherence to PRISMA-P 2015 in non-overlapping PubMed, PROSPERO, and OSF systematic review protocols.
- Systematic protocol authors suggested various modifications to updating PRISMA-P 2015 related to clarifying existing guidance and adding content to better align with evolving research methodology.

What is the implication and what should change now?

- Findings from this study provide contexts for all users of the reporting guideline and will inform the update of PRISMA-P 2015.

between May 2021 and May 2024. Protocols were eligible if the authors stated using PRISMA-P to guide any aspects of the protocol or if they included the phrase ''PRISMA-P protocol'' in the title and used headings throughout the protocol identical to the PRISMA-P headings. We included 2 types of protocols: (1) publications of systematic review protocols from PubMed-indexed journals (henceforth referred to as PubMed protocols) and (2) publicly available systematic review protocols uploaded to OSF or PROSPERO (henceforth referred to as OSF/PROSPERO protocols). We used full protocols from PROSPERO rather than registration records because the registration records typically provide only a summary of the protocol containing fewer details. To ensure 2 non-overlapping samples, we only included OSF/PROSPERO protocols that were not linked to protocols published in peer-reviewed scientific journals (verified by searching for protocol title, authors, and registration number in PubMed). We excluded protocols for other types of reviews (eg, scoping reviews) and protocols for reviews of nonhuman studies. We also excluded protocols for Cochrane Reviews and Joanna Briggs Institute Reviews, as systematic review protocols developed within these organisations are regulated and follow strict guidelines for conduct and reporting.

2.2.2. Search and selection of systematic review protocols

We identified PubMed protocols using the search strategy in Appendix A based on a strategy developed and validated to retrieve systematic reviews [17]. We identified OSF/PROSPERO protocols by searching for ''systematic review protocol'' in OSF and by searching in PROSPERO for registration records for which full protocols had been uploaded. Searches were conducted in June 2024. We used the random number generator in Excel to draw random samples from PubMed, OSF, and PROSPERO. The selected records were assessed for inclusion by one author (M.B.E.) and verified by a second author (C.H.N.). Discrepancies were resolved by discussion. The process was repeated until we had included 50 PubMed protocols and 50 OSF/PROSPERO protocols. The sample size of 100, divided into 2 groups of 50, was pragmatically chosen and based on experiences from previous similar studies [11,18]. The OSF/PROSPERO protocols consisted of 25 protocols from OSF and 25 from PROSPERO, sampled using the random number generator in Excel.

2.2.3. Data extraction and assessment of reporting

After piloting the process, authors (M.B.E. and J.S.) independently extracted data into a pretested Excel sheet, capturing data and assessment of reporting. We extracted data on the following: publication year, journal, name and country of first author, number of authors, study design of included studies, type of planned data synthesis, and reference to PRISMA-P (ie, how authors referred to PRISMA-P and which documents were cited). Discrepancies were resolved through discussion and by arbitration from a third author when necessary (C.H.N.).

Each of the 26 items and subitems in the PRISMA-P reporting guideline was assessed as fully, partially, or not reported (or not applicable) depending on predefined and piloted criteria. The criteria were based on the guidelines of PRISMA-P [6,7], criteria from a previous study [11], and with added decision rules when necessary. For each item, we outlined aspects that should be reported for the item to be assessed as fully reported (for detailed criteria and aspects, see Appendix B). In partially reported items (ie, when some, but not all, aspects of an item were

reported), the missing information was noted. For each protocol, we looked for attachments of PRISMA-P checklists completed by the protocol authors and compared this assessment with ours.

2.2.4. Data analysis

We analysed adherence to PRISMA-P overall by estimating the median proportion of fully reported applicable PRISMA-P items across the included protocols. We also estimated the proportions of protocols with different adherence levels, reported in 10% increments. We provided a description of the differences between PRISMA-P checklists completed by the protocol authors and our assessments. Additionally, we analysed adherence at item level by estimating the proportion of protocols assessed as fully, partially, or not reported for each of the 26 items in PRISMA-P. We defined items as ''often not reported'' if it was found not to be reported in >25% of the protocols. We provided a qualitative description of what information was typically missing for items with a high proportion of partially reported assessments (ie, by >25% of the protocols).

We analysed the 2 protocol types separately. We did not perform any direct statistical comparison between the 2 types of protocols, but we qualitatively noted potentially important differences. All analyses were carried out using Microsoft Excel.

2.3. Interview study for exploring protocol authors' experiences with using PRISMA-P

2.3.1. Identification of potential interviewees

We invited 24 corresponding authors from the sample of systematic review protocols based on the principles of maximum variation sampling [19], referring to the authors' level of experience (ie, how often they had conducted systematic reviews) and geographical locations of the corresponding authors. Up to 2 reminders were sent if we received no reply to our initial invitation. The authors were invited by email, in which it was stated that findings from the interview would be published in an anonymised format only (Appendix C). As expected, based on previous experiences [20], this first step of sampling was inefficient, and we converted to snowball sampling based on suggestions from interviewees and our personal network. Using this method, we invited 17 additional systematic reviewers. Inclusion was stopped at the point of saturation, which was initially evaluated after the first 8 interviews and repeated after the following 3−4 interviews. The evaluation of saturation involved assessing the emergence of new themes and considering whether the interviewees represented a broad level of experience and geographical locations.

2.3.2. The interviewer and reflexivity

Interviews were conducted by one author (M.B.E.), who was a research assistant with a master's degree in physiotherapy. She had formal training in qualitative methods as well as extensive clinical experience with interviewing patients but had not previously conducted qualitative research. She had no prior experience with PRISMA-P and therefore no strong beliefs or assumptions about the reporting guideline before the interviews. We acknowledge that positioning the study as a supporting project for the PRISMA-P update when inviting protocol authors may have shaped how interviewees described their experiences.

2.3.3. Interview procedures and content

The interviews were guided by a piloted, semistructured interview guide (Appendix D) covering prespecified themes related to (1) the protocol authors' level of experience in conducting systematic reviews and writing review protocols, (2) their views on using PRISMA-P, and (3) their reflections on the strengths and challenges of the guideline. The interviews were conducted through open-ended questions around the prespecified themes supported by prompts. For example, when the authors were asked to describe their experiences with using PRISMA-P, a prompt would be if they used the guideline item per item or more as a generic framework. The interview guide was piloted separately on protocol authors from our network. As the pilot interviews only resulted in insignificant changes to the interview guide, the pilot interviews were included in our sample.

We conducted the interviews via video calls (Microsoft Teams), which enabled us to interview authors from various geographical locations. The calls were conducted in a closed, private room and were recorded and live transcribed. Relevant quotes were identified from the transcripts by one author (M.B.E.) and verified by a second author (C.H.N.). The identified quotes were anonymised using a reference number before being transferred to NVivo 14 (Lumivero, released 2023) and used in the analysis.

We obtained information on basic characteristics of interviewees and nonresponders (ie, authors who declined or did not respond to our invitation) from the interviews, publications, and websites on educational background, sex (male/female), location of the primary institution, type of primary institution, and number of co-authored published systematic review protocols and full reviews (identified through PubMed).

2.3.4. Data analysis

We applied framework analysis to the transferred quotes from the interview transcripts to identify themes raised across participants, analysing the data following 5 steps: (1) familiarisation with the data, (2) framework component identification, (3) indexing the framework components, (4) charting the data and organising the data in a matrix within the framework components populating units of analysis, and (5) mapping and interpreting patterns across and within the framework components and units of analysis [19,21]. This approach enabled us to investigate the transcripts within the prespecified themes as well as allowed new

themes to emerge from the data. An audit trail documenting the iterative analysis steps was compiled, applying codes representing each phase to the individual quotes as well as visualising them in coding tree mind maps (Appendix E). Steps 1 to 4 were conducted by 2 authors (M.B.E. and C.H.N.). The interpretation of the charted data (Step 5) was done across the author group.

The quotes used for illustrating findings were stated verbatim but linguistically refined to enhance clarity. For example, we removed filler or repetitive words (indicated by square brackets), and we corrected standard English grammar while still maintaining the original meaning of the statements. Explanatory text to ensure correct understanding was also indicated by square brackets. Author identification numbers were inserted in round brackets for anonymisation.

3. Results

3.1. Cross-sectional study on adherence to PRISMA-P across systematic review protocols

3.1.1. Included systematic review protocols

The geographical continent of the first author's primary institution was Europe for most of the 100 included protocols (35%). Most of the PubMed protocols had first authors with a primary institution in Asia (46%), whereas most of the OSF/PROSPERO protocols had first authors with a primary institution in Europe (46%). Only 24% of the protocols had an available PRISMA-P checklist completed by the protocol authors, and this was more often available for PubMed protocols (36%) than for OSF/PROSPERO protocols (14%) (Table 1). Of the PubMed protocols, 33 (66%) were registered in PROSPERO, 9 (18%) were registered in OSF, 6 (12%) were registered in the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY), and 2 (4%) did not report any protocol registration.

3.1.2. Protocol adherence to PRISMA-P

Among the 50 PubMed protocols, the median proportion of fully reported applicable PRISMA-P items was 60% (IQR 52%−64%). None of the protocols fully reported all items, and only 2% reported at least 80% of the applicable items (Figure 1A).

Among the 50 OSF/PROSPERO protocols, the median proportion of fully reported applicable PRISMA-P items was 45% (IQR 38%−58%). Again, none of the protocols fully reported all items, and only 2% reported at least 80% of the applicable items (Figure 1B).

Twenty-four protocols out of the 100 in the overall sample had accompanying PRISMA-P checklists completed by the protocol authors. Among these protocols, the median proportion of fully reported applicable PRISMA-P items was 65% (IQR 57%−71%). Most often, the discrepancies between completed PRISMA-P checklists and our assessments were related to contributions (item 3b), data management (item 11a and 11c), data synthesis (item 15d), and meta-biases (item 16). We found more discrepancies between the authors' and our assessments in OSF/PROSPERO protocols than in PubMed protocols. The protocol authors often assessed items as fully reported, whereas we assessed them as partially reported. An example was item 16, where either only the method for assessing publication bias or selective outcome reporting was reported. Protocol authors also reported items as not applicable, whereas we assessed them as not reported. For example, item 17 was reported as not applicable in the author-completed checklist, despite no reason not to assess the confidence in the cumulative evidence.

3.1.2.1. Adherence to the individual PRISMA-P items in PubMed protocols. Among the PubMed protocols, items often not reported were on amendments (item 4), role of the sponsor or funder (item 5c), criteria for quantitative synthesis (item 15a), methods for planned summary other than quantitative (item 15d), methods for assessing meta-bias(es) (item 16), and methods for assessing confidence in cumulative evidence (item 17) (Table 2).

Eleven of the items were often partially reported. For example, authors often stated the criteria and procedure for assessing risk of bias but did not describe methods for using the risk of bias assessment in the analysis (item 14; 54% of protocols assessed as partially reported). Two of the items often partially reported were also found among the items often not reported (item 15d, and item 16) (Table 2, Table 3).

3.1.2.2. Adherence to the individual PRISMA-P items in OSF/PROSPERO protocols. Among the OSF/PROSPERO protocols, items often not reported were on identification as a protocol for a systematic review (item 1a), protocol authors' contributions (item 3b), amendments (item 4), sponsor (item 5b), role of the sponsor or funder (item 5c), criteria for quantitative synthesis (item 15a), proposed additional analyses (item 15c), methods for planned summary other than quantitative (item 15d), methods for assessing meta-bias(es) (item 16), and methods for assessing confidence in cumulative evidence (item 17) (Table 2).

Thirteen of the items were often partially reported. For example, authors often stated how they would handle duplicates in their data management but did not describe how they would handle multiple publications of the same study (item 11a; 82% of protocols assessed as partially reported). Five of the items often partially reported were also found among the items often not reported (item 3b, item 5b, item 15a, item 15d, and item 16) (Table 2, Table 3).

The greatest difference between the 2 types of protocols in items partially or not reported was related to identification as a systematic review (item 1a), protocol authors' contributions (item 3b), sponsor (item 5b), methods of combining data (item 15b), and proposed additional analyses (item 15c) (Table 2).

Table 1. Characteristics of included systematic review protocols[a]

Characteristics	Total	PubMed	OSF/PROSPERO
Publication year			
2021	23 (23)	15 (30)	8 (16)
2022	32 (32)	15 (30)	17 (34)
2023	26 (26)	10 (20)	16 (32)
2024	19 (19)	10 (20)	9 (18)
Number of authors, median (range)	5 (1-17)	5 (2-16)	5 (1-17)
Continent of first author's primary institution			
Africa	6 (6)	3 (6)	3 (6)
Asia	26 (26)	23 (46)	3 (6)
Europe	35 (35)	12 (24)	23 (46)
North America	20 (20)	7 (14)	13 (26)
Oceania	4 (4)	0 (0)	4 (8)
South America	9 (9)	5 (10)	4 (8)
Study design of included studies			
No restrictions on study design	25 (25)	9 (18)	16 (32)
Mixed study designs[b]	13 (13)	7 (14)	6 (12)
Observational studies	17 (17)	10 (20)	7 (14)
Qualitative studies	3 (3)	-	3 (6)
Randomised trials	36 (36)	21 (42)	15 (30)
Other[c]	6 (6)	3 (6)	3 (6)
Planned analysis methods			
Any type of meta-analysis	64 (64)	41 (82)	23 (46)
Qualitative synthesis	21 (21)	6 (12)	15 (30)
Both meta-analysis and qualitative/ descriptive analysis	14 (14)	3 (6)	11 (22)
Not reported	1 (1)	-	1 (2)
Protocol authors' referral to PRISMA-P			
To guide design or conduct	31 (31)	21 (42)	10 (20)
To guide reporting	24 (24)	10 (20)	14 (28)
Guide both design/conduct and reporting	7 (7)	3 (6)	4 (8)
Unclear[d]	38 (38)	16 (32)	22 (44)
Citation of PRISMA-P papers			
PRISMA-P statement	38 (38)	18 (36)	20 (40)
PRISMA-P elaboration and exploration	33 (33)	20 (40)	13 (26)
Both	10 (10)	6 (12)	4 (8)
None	19 (19)	6 (12)	13 (26)
Completed PRISMA-P checklist available			
Yes	24 (24)	18 (36)	6 (12)
No	76 (76)	32 (64)	44 (88)

OSF/PROSPERO, Open Science Framework/International Prospective Register of Systematic Reviews; PRISMA-P, Preferred Reporting Items for Systematic Review and Meta-analysis protocols.

[a] Data presented as number of protocols (%) unless indicated otherwise.

[b] Mixed study design included mostly randomised trials and cohort studies.

[c] Other included, for example, clinical practice guidelines, studies characterised as ''quantitative'' or ''longitudinal,'' or unclear definition of included studies.

[d] Unclear included, for example, protocols in which the authors stated that ''PRISMA-P was followed.''

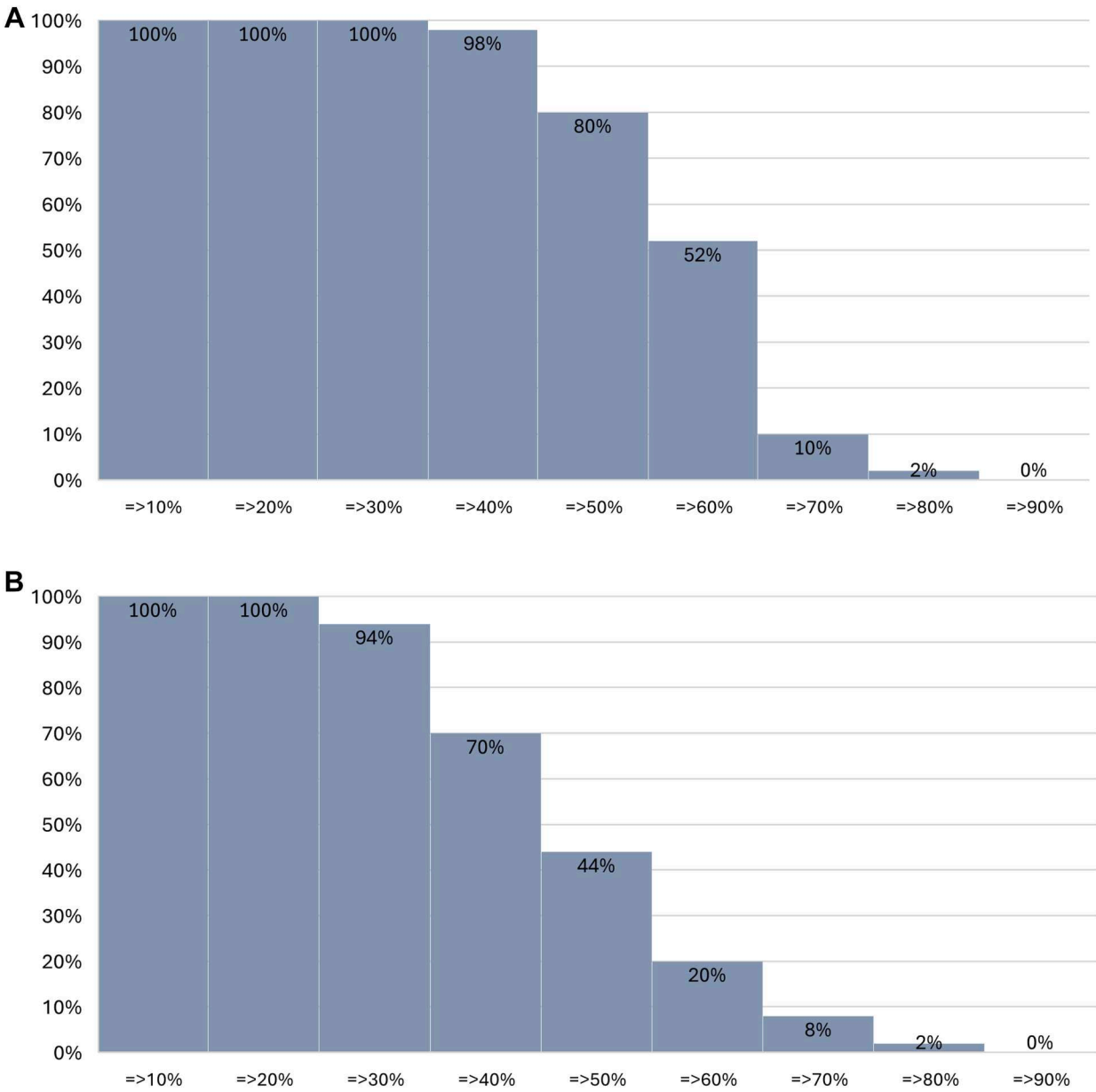

Figure 1. A, Proportions of protocols with a minimum adherence level[a] to PRISMA-P items among systematic review protocols published in PubMed protocols. B, Proportions of protocols with a minimum adherence level[a] to PRISMA-P items among systematic review protocols uploaded to OSF/PROSPERO. [a]Median proportion of fully reported applicable items. OSF/PROSPERO, Open Science Framework/International Prospective Register of Systematic Reviews; PRISMA-P, Preferred Reporting Items for Systematic Review and Meta-analysis protocols 2015.

3.2. Interview study for exploring protocol authors' experiences with using PRISMA-P

We emailed 43 authors with invitations for the interviews. We received responses from 19 authors, of which 15 (35%) participated. Eleven of the participants were recruited through snowball sampling and our personal network. The interviews were conducted between July 9, 2024, and October 16, 2024, and lasted a mean of 29 minutes (range 20–44). Basic characteristics of interviewed protocol authors and nonresponders are available in Appendix F. One author had technical problems, so the interview could not be recorded. Instead, notes were rigorously made throughout the interview and verified by the interviewee at the end of the interview.

Through the interviews, several suggestions for updating PRISMA-P emerged. The following section presents the findings from the analysis of the interview transcripts, organised under the 3 prespecified themes, with selected quotes used to illustrate participants' perspectives.

Table 2. Adherence to PRISMA-P items across systematic review protocols published in PubMed-indexed journals and uploaded to OSF/PROSPERO[a]

		Fully reported		Partially reported		Not reported	
Section and topic	**Item**	**PubMed**	**OSF/PROSPERO**	**PubMed**	**OSF/PROSPERO**	**PubMed**	**OSF/PROSPERO**
Administrative information							
Identification	1a	50 (100)	34 (68)	-	-	-	16 (32)
Update	1b	-	1 (100)	-	-	-	-
Registration	2	44 (94)	-	2 (4)	-	1 (2)	-
Contact	3a	50 (100)	44 (88)	-	4 (8)	-	2 (4)
Contribution	3b	7 (14)	9 (18)	42 (84)	17 (34)	1 (2)	24 (48)
Amendments	4	11 (22)	10 (20)	2 (4)	4 (8)	37 (74)	36 (72)
Sources	5a	49 (98)	39 (78)	-	-	1 (2)	11 (22)
Sponsor	5b	1 (3)	7 (25)	32 (94)	10 (36)	1 (3)	11 (39)
Role of sponsor or funder	5c	9 (27)	6 (22)	-	-	25 (74)	21 (78)
Introduction							
Rationale	6	49 (98)	41 (82)	1 (2)	5 (10)	-	4 (8)
Objectives	7	42 (84)	40 (80)	8 (16)	9 (18)	-	1 (2)
Methods							
Eligibility criteria	8	25 (50)	29 (58)	25 (50)	21 (42)	-	-
Information sources	9	36 (72)	30 (60)	14 (28)	19 (38)	-	1 (2)
Search strategy	10	43 (86)	35 (70)	7 (14)	7 (14)	-	8 (16)
Data management	11a	5 (10)	3 (6)	38 (76)	41 (82)	7 (14)	6 (12)
Selection process	11b	40 (80)	44 (88)	9 (18)	4 (8)	1 (2)	2 (4)
Data collection process	11c	5 (10)	2 (4)	41 (82)	41 (82)	4 (8)	7 (14)
Data items	12	33 (66)	33 (66)	17 (34)	13 (26)	-	4 (8)
Outcomes and prioritisation	13	32 (64)	20 (40)	18 (36)	25 (50)	-	5 (10)
Risk of bias in individual studies	14	22 (44)	17 (34)	27 (54)	28 (56)	1 (2)	5 (10)
Criteria for quantitative synthesis	15a	23 (52)	15 (43)	9 (21)	9 (26)	12 (27)	11 (31)
Methods of combining data	15b	33 (77)	12 (34)	8 (19)	18 (51)	2 (5)	5 (14)
Additional analyses	15c	39 (89)	20 (57)	-	-	5 (11)	15 (43)
Summary other than quantitative	15d	15 (30)	19 (38)	17 (34)	13 (26)	18 (36)	18 (36)
Meta-bias(es)	16	15 (30)	9 (18)	21 (42)	18 (36)	14 (28)	23 (46)
Confidence in cumulative evidence	17	24 (48)	23 (46)	-	1 (2)	26 (52)	26 (52)

OSF/PROSPERO, Open Science Framework/International Prospective Register of Systematic Reviews; PRISMA-P, Preferred Reporting Items for Systematic Review and Meta-analysis protocols 2015.

[a] Data presented as number of protocols (% of applicable items) for each type of protocol. Data may not add up to 100% due to rounding.

3.2.1. Theme 1: the protocol authors' level of experience with conducting systematic reviews and writing review protocols

The authors had varying levels of experience with conducting systematic reviews and writing review protocols and represented all continents (Appendix F).

3.2.1.1. Protocol authors' comments on using protocols for systematic reviews. The authors emphasised the value of having a protocol before conducting a systematic review. One author argued:

> *"It will be more effective, more efficient, more capable of being monitored […] We know that a protocol is going to help reduce the potential for bias in decision making later in the review […] So, I absolutely support having a protocol to begin with, making a lot of those decisions a priori."* [Author 5]

Generally, all authors routinely made protocols for their systematic reviews publicly available, either by publishing them or uploading them to open registries or repositories. The authors highlighted several advantages of publishing protocols, for example, that protocol publication almost guaranteed publication of the full review in the journal and that the peer review process ensured integrity. One author mentioned:

> *"We've got some feedback with the peer review [for the submitted protocol], which actually improved the systematic review."* [Author 7]

Table 3. Most frequent reasons for our assessment of PRISMA-P items to be partially reported

PRISMA-P item	N (%) protocols assessed as partially reported	Information typically missing from the protocol
3b: Contributions	42 (84%) PubMed protocols 17 (34%) OSF/PROSPERO protocols	Guarantor of the review
5b: Sponsor	32 (94%) PubMed protocols 10 (36%) OSF/PROSPERO protocols	Funding source declared but unclear if funder and sponsor are identical
8: Eligibility criteria	25 (50%) PubMed protocols 21 (42%) OSF/PROSPERO protocols	Time frame for follow-up
9: Information sources	14 (28%) PubMed protocols 19 (38%) OSF/PROSPERO protocols	Period for searches
11a: Data management	38 (76%) PubMed protocols 41 (82%) OSF/PROSPERO protocols	Procedures for managing multiple publications of the same study
11c: Data collection process	41 (82%) PubMed protocols 41 (82%) OSF/PROSPERO protocols	Procedures for selecting data from multiple reports of the same study
12: Data items	17 (34%) PubMed protocols 13 (26%) OSF/PROSPERO protocols	Specific data items not provided (often only overall data categories specified)
13: Outcomes and prioritisation	18 (36%) PubMed protocols 25 (50%) OSF/PROSPERO protocols	Necessary specifications of outcome measurements or scales (often only prioritisation and rationale provided)
14: Risk of bias in individual studies	27 (54%) PubMed protocols 28 (56%) OSF/PROSPERO protocols	Procedures for using the risk of bias assessment in the analysis
15a: Data synthesis	9 (26%) OSF/PROSPERO protocols	Methods for meta-analysis stated, but under which criteria only briefly mentioned (if at all)
15b: Data synthesis	18 (51%) OSF/PROSPERO protocols	Summary measures such as odds ratio or relative risks (often only methods for combining data, methods for assessing heterogeneity, and software specified)
15d: Data synthesis	17 (34%) PubMed protocols 13 (26%) OSF/PROSPERO protocols	Briefly mentioned that data will be analysed qualitatively, but specific procedures not stated
16: Meta-bias(es)	21 (42%) PubMed protocols 18 (36%) OSF/PROSPERO protocols	Procedures for assessing risk of selective reporting (often only procedures for assessing publication bias specified)

OSF/PROSPERO, Open Science Framework/International Prospective Register of Systematic Reviews; PRISMA-P, Preferred Reporting Items for Systematic Review and Meta-analysis protocols 2015.

3.2.2. Theme 2: the protocol authors' views on using PRISMA-P

3.2.2.1. Protocol authors' reasoning on using PRISMA-P. Several authors explained that using PRISMA-P was a normal practice in their research group, and some authors found the process of developing a protocol more efficient and organised when using PRISMA-P. One author mentioned:

> *"I know how helpful it could be to use a reporting guideline to get an overview of what topics I have to address, which steps I have to consider when I write a protocol or conduct the systematic review."* [Author 3]

3.2.2.2. Protocol authors' use of PRISMA-P. Seven authors stated that they used each PRISMA-P item while writing the protocol, 2 of them used the reporting guideline as an overall framework initially to guide the structure of the protocol and then checking compliance with each PRISMA-P item after completing the protocol. One author mentioned:

> *"We use it as a general guide for the structure of the protocol. And when we finish, we'll go back to the checklist to be sure, we've not missed anything else."* [Author 12]

Nine authors mentioned using both the PRISMA-P checklist and the Elaboration and Explanation paper. When they found an item especially difficult, they would consult the Elaboration and Explanation paper for clarification. In contrast, 4 authors used only the PRISMA-P checklist, as they intuitively or by experience knew what each item implies. One author mentioned:

> *"But lately, I'm only using the checklist, because I already know the guidance [the Elaboration and Explanation paper]."* [Author 11]

Table 4. Protocol authors' reflections on strengths and challenges of PRISMA-P

Reflections	Examples of quotes from protocol authors
Strengths, overall	
Increase consistency and transparency of protocols	''I think PRISMA-P is a great tool for improving the transparency and the quality of systematic review protocols, particularly for making the review protocols more complete. I think, it ensures that the key elements are addressed, and it will make the reviews more reliable and easier to reproduce'' (Author 8).
Straightforward and helpful in creating a systematised structure and basically working as a recipe for writing a protocol, thus minimizing the risk of forgetting important content and reducing the time needed to write the protocol	''To have it set out for you and to see all of the different parts that need to be there in a concise space helps to ensure a complete protocol, that you don't forget anything […] It's just all very logically laid out and complete'' (Author 5). ''It is straightforward to help me structure the protocol […] I go [to PRISMA-P] and I save time because I will have only the items that are relevant to [the] protocol […]'' (Author 15).
Helpful when writing the first systematic review protocol	''I think PRISMA-P is very, very helpful in guiding people, who are new to the field, in what [they] should include in the protocol'' (Author 7).
Strengths, item or section level	
Appropriate number of items	''I think it's good, it's enough. I think there shouldn't be something more, because it can be quite too much […] it can be quite confusing. So, the number of items, I think matches perfectly'' (Author 3). ''I've never found something that's unnecessary, when we've been building our protocols'' (Author 10).
Specifically helpful items or sections of PRISMA-P	''In terms of all the institutional affiliations, e-mail addresses, physical addresses, the contributions and the guarantor. Those kinds of small details can help you get your manuscript published, because you don't have to go back and forth with the editor'' (Author 14).
Challenges, overall	
Sometimes used inappropriately, for example, when authors say they adhere to it, but they do not	''A potential challenge might be the lack of immediate mechanisms to verify if a protocol truly adheres to PRISMA-P […] Authors state that they adhere to the PRISMA-P, but [the protocol] actually does not'' (Author 13).
A bit overwhelming for inexperienced researchers without training in systematic reviews	''But you have to have experience to make the most of it. I guess that both the pro and the con of it is that if you know how to use it, you can use it really well'' (Author 1).
Challenges, item or section level	
The PICO model as the imperative framework, which does not always fit different clinical scenarios	''In my protocol for my systematic review [there] is no meta-analysis so that section was not applicable to me, and I can't really assess all the items related to meta-analysis - how [do] you describe that section?'' (Author 15).
PRISMA-P is heavily focused on meta-analyses	''My first systematic review was a methodological systematic review, so it's not very similar to a clinical systematic review. As we know, the PRISMA-P is more focused on clinical reviews'' (Author 8).

PICO, Population, Intervention, Comparison, Outcome; PRISMA-P, Preferred Reporting Items for Systematic Review and Meta-analysis protocols (PRISMA-P) 2015.

3.2.3. Theme 3: the protocol authors' reflections on the strengths and challenges of PRISMA-P

All authors shared reflections on the strengths and challenges of PRISMA-P. The reflections were partially related to the reporting guideline in general, such as that it increases transparency and quality of the protocols, or that the use of the Population, Intervention, Comparison, Outcome (PICO) model as the imperative framework does not always fit different clinical scenarios or review designs. Other reflections were related to specific items, such as that the number of items in the checklist is appropriate or that the items in the meta-analysis are difficult to adhere to if the review is, for example, a methodological review or does not include a meta-analysis. Table 4 provides a summary of the reflections on strengths and challenges.

3.2.4. The protocol authors' suggestions for updating PRISMA-P

Thirteen authors shared suggestions for updating PRISMA-P. Some suggestions were more general, such as to realign the guideline to the evolving methodologies in research and add links to, for example, the Elaboration and Explanation paper. Other suggestions were more specifically related to adding content, such as recommendations on protocol abstracts or protocol authors' conflicts of interest. Finally, some suggestions were related to modifying or clarifying existing items and their explanations, such as guidance on reporting protocol amendments or on how to report data synthesis when no meta-analysis is planned.

Some suggestions were mentioned by 1 protocol author, while other suggestions were raised by several authors.

Table 5. Suggestions from protocol authors for the coming update of PRISMA-P

Suggestions raised	Examples of quotes from protocol authors
General suggestions	
Update is needed	''And I think that also PRISMA-P should be updated a little bit faster, because we know the ecosystem of systematic reviews is rapidly evolving'' (Author 3).
Add tutorials on using PRISMA-P	''It would be helpful in the future having tutorials or explanations and videos in short courses in the business statement platform'' (Author 4).
Ensure consistency between PRISMA-P and registration platforms	''I also hope that PRISMA-P could have more collaboration with the registration platforms to make the protocol registration more efficient and actually less heterogenous. There are a lot of platforms, and according to my experience, the platforms were not very consistent with each other and some of them were not based on the items required by PRISMA-P. So, if the new PRISMA-P could collaborate with these platforms. I think, for example, if you could develop a web-based protocol development tool, and after I finish the protocol, I can directly register by clicking some button. That'll be perfect'' (Author 8).
Translate PRISMA-P to other languages	Yes, I think so [answered when asked if it would be helpful to translate PRISMA-P]'' (Author 2).
Keep the checklist simple and relevant	''Yeah, my main message is, if there's anything we can do to shorten things and keep what really matters, for the transparency and completeness of the reporting, I think it's good for authors'' (Author 15).
Add links to guidance on appropriate review methods	''I just wonder, is there a way to potentially integrating a linking into more principled documents on what are the appropriate methods to be used? Because that would help people [...], for instance, risk of bias'' (Author 10).
Add links to the Elaboration and Explanation paper	''Perhaps one thing that, I would add in the actual checklist is a link to the [Elaboration and Explanation] paper [...]. It would be more direct, they [PRISMA-P users] would just click and go to it and some people, I believe, are not even aware that there's an explanation paper, so having that on the actual checklist paper could be helpful'' (Author 9).
Suggestions on adding content	
Add content on protocol abstract	''Maybe some information on how to write an abstract when you publish a protocol'' (Author 3).
Add content on data access	''Add in a section related to open science and practice'' (Author 15).
Add content on conflicts of interest among review authors	''Does it cover conflicts of interest?'' (Author 10).
Add content on reporting citation searching	''The TARCiS statement for citation searching. This has some aspects that are missing in PRISMA-P'' (Author 3).
Add content on reporting the use of automation or other artificial intelligence related tools	''In item 11, on data management, screening, and the extraction, there are a lot of teams that are using different methods like automation [...]. So, maybe such items could be expanded for researchers to specify software that they used. And also, if they have used automation, what is the reliability of this automation method'' (Author 12).
Add content on gender equity	''Our sense of gender [...] [is a] new topic that needs to be considered. So, one thing to consider is, of course, how reporting guidelines should take into account, or have items related to, how to integrate sex agenda or other identity variables related to equity'' (Author 15).
Add content on directed acyclic graphs for determining causal review questions	''How different causal tools could be used to help guide the [...] research question. For example, a directed acyclic graph or a logic model to be able to visualise your inclusion/exclusion criteria to make sure that you're also thinking about confounding variables. So, at different stages different additional things can help you think about [this], specifically [with] a causal question and in particular a causal question with non-randomised studies'' (Author 1).
Suggestions on modifying existing content	
Clarify guidance on reporting plans for registration	''When we are writing the protocol, we haven't really gotten to the stage of registration. So, most of the time, protocols don't have information on the registration. So instead, maybe 'plans for registration' could replace it'' (Author 12).
Clarify guidance on how to report amendments	''And having maybe a component on [...] deviations from the protocol [...]. Maybe that can be something you can add here, just noting that there may be deviations and how to handle them'' (Author 10).
Clarify guidance on reporting theoretical underpinning of the review	''One [thing ie not covered in PRISMA-P] is that there is no mention about explaining the theoretical underpinning of the review. And systematic reviews have been criticised in recent years for not articulating their theoretical perspective. Then putting it in the protocols would be a really good place to start and that's really important for qualitative reviews in particular'' (Author 5).
Provide guidance on how to refer to previous reviews to prevent redundant systematic reviews	''That item [PRISMA-P item 6] says, you have to state what is already known on the topic, but I think that is too general because there is a lot of research on redundant systematic reviews, or systematic reviews not supported by previously published RCTs [randomised trials] or other

(*Continued*)

Table 5. Continued

Suggestions raised	Examples of quotes from protocol authors
	systematic reviews, and I think that item should state more clearly that you need to know the body of evidence before starting a systematic review protocol'' (Author 11).
Provide guidance related to frameworks other than PICO or different review types	''It specifically mentions PICO for [research] questions and that might be something to reconsider. Where I work, in public health, we do a lot of reviews of exposures and environmental factors and social determinants of health, as well as qualitative. So, PICO isn't always appropriate for that'' (Author 5).
Integrate guidance from PRISMA Search	''There's an opportunity to integrate more of, for example, PRISMA Search because the search is an essential element when conducting a systematic review'' (Author 13).
Clarify guidance on choice of synthesis methods	''How they manage data, how they group data, and how they made the decision to synthesise the results, that is, most of the times, not clear to me when I read a systematic review. So, having those items in PRISMA and having some examples, like with the [Elaboration and Explanation] paper, I believe that was the most helpful for me'' (Author 9).
Clarify guidance on reporting data synthesis when no meta-analysis is planned	''If anything were to be added to PRISMA-P, it might be around planning the synthesis and you'll be aware of, for example, the SWiM guideline by Campbell et all, where they've tried to give some suggestions about how to plan a narrative or non-statistical synthesis in a bit more rigorous manner. So, possibly expanding that'' (Author 5).

PICO, Population, Intervention, Comparison, Outcome; PRISMA-P, Preferred Reporting Items for Systematic Review and Meta-analysis protocols 2015.

Table 5 provides a summary of the suggestions. All suggestions are included regardless of the number of authors mentioning them.

4. Discussion

4.1. Summary of main findings

None of the included protocols adhered to all applicable PRISMA-P items. Among the 50 PubMed systematic review protocols, the median proportion of fully reported applicable PRISMA-P items was 60% (IQR 52%−64%). Among the 50 OSF/PROSPERO systematic review protocols, the median proportion of fully reported applicable items was 45% (IQR 38%−58%). Items often not reported across both types of protocols were protocol amendments (item 4), role of the funder (item 5c), criteria for quantitative synthesis (item 15a), methods for planned summary other than quantitative (item 15d), meta-bias(es) (item 16), and confidence in cumulative evidence (item 17). The interviewed authors suggested several modifications to the guideline. Some suggestions regarded adding or modifying existing content, for example, to report conflicts of interest, or how to report data synthesis when no meta-analysis was planned. Other suggestions were more general, for example, to add links to the Elaboration and Explanation paper.

4.2. Strengths and limitations of the study

Our study demonstrates various strengths in its transparent methodology and its originality. The study combines methods of both quantifying adherence to PRISMA-P and compiling protocol authors' experiences with the guideline. This data corroboration enhances the validity of the findings by providing a more nuanced and comprehensive understanding of the impact of the reporting guideline. Second, our random sample contains protocols from both PubMed as well as from OSF and PROSPERO. No other study has sampled from all 3 sources. This approach ensures a wide-ranging sample in relation to, for example, clinical fields, review methodologies, and data sources.

Nonetheless, our study has some limitations. Although the interviewed authors constituted almost all continents and levels of experience, the sample was, for feasibility, selected. Eleven of the 15 interviewed authors were included through snowball sampling or our personal network. Also, the protocol authors explicitly stated using PRISMA-P in the sampled protocols. Both aspects could be reflected in a higher adherence or an affected attitude toward the reporting guideline.

4.3. Other similar studies

Several methodological studies have found low adherence to PRISMA-P in published systematic review protocols and in PROSPERO registrations. Koensgen et al [22], Booth et al [12], and Rainkie et al [23] all observed inadequate adherence in several of the same items identified in our study (eg, items 15a, 15c, 16, and 17). Koensgen et al and Booth et al reported several additional items with inadequate adherence. However, Koensgen included systematic review protocols from 2012 to 2013 that were prior to the launch of PRISMA-P. Booth et al used registration records from PROSPERO, whereas we used the uploaded full protocols. Finally, Rainkie et al and Booth et al omitted certain items from their assessments, which, in our study, showed inadequate adherence (eg, items 3b, 4, 5b, and 5c).

No studies have explored protocol authors' views on PRISMA-P. However, several studies have been conducted on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline, which is relatable

to ours because PRISMA-P was purposefully aligned with the PRISMA guideline [24,25] and shares a similar structure, key items, and terminology. An online survey of 181 authors publishing reviews in nursing journals explored the perception of the PRISMA guideline. The respondents stated that the PICO framework was limiting and inflexible and also that the reporting guideline ensured quality, trustworthiness, and methodological rigor of the review [26]. The same issues were mentioned by the interviewed authors in our study concerning PRISMA-P.

In another study, Schniedermann interviewed 21 authors of systematic reviews on their views on PRISMA (both the original 2009 and the updated 2020 versions). Consistent with our findings, he found that the way the reporting guideline was applied depended on the author's level of experience. Less experienced authors used it intensively for the structure of the review, whereas more experienced authors were familiar with the item details and did not consult the guideline directly during the review process [27].

4.4. Interpretations of our findings

This study assessed reporting completeness rather than methodological quality and rigor. Adherence to PRISMA-P indicates compliance with reporting guidance and transparency and should not be interpreted as a measure of study quality.

We identified items with incomplete adherence that were mentioned by the interviewed protocol authors as especially challenging. An example is the item on methods for planned summary other than quantitative (item 15d), where the description of the item in the PRISMA-P checklist is very brief. However, the Elaboration and Explanation paper provides various details on how to report the item adequately, along with model examples from existing published protocols [7]. Some authors may not be familiar with the Elaboration and Explanation paper or simply do not use it.

Insufficient adherence to several items, together with the author's views from the interviews, suggests that certain PRISMA-P items are perceived as complex and challenging to fully adhere to. Some of the insufficiently reported items are central to transparency and for enabling subsequent use of the review's results, such as protocol amendments (item 4), funding (item 5a-c), and meta-bias(es) (item 16). Other items may also be important but challenging to apply, for example, when the study design is not framed around the PICO framework or the data synthesis is not a meta-analysis (items 15a-d). Nevertheless, it is important to note that none of the interviewed authors suggested deleting any items, even when asked directly.

Registrations and full protocols serve distinct purposes, and while both outline key methodology, they often differ substantially in terms of comprehensiveness. Although some registry or repository protocols have been peer reviewed before upload, they usually have not gone through formal quality assessment at submission [28]. Journals typically require information on, for example, contributor statements and funder disclosures, independent of the actual protocol text. Therefore, even if the protocol does not address these items, the journal requirements ensure this information is added as part of the published manuscript. This could partly explain the differences observed between the PubMed protocols and OSF/PROSPERO protocols (eg, in items 1a, 3b, and 5b) in our study.

4.5. Implications for reporting systematic review protocols and further research

The findings in our study provide information on authors' views and practices with PRISMA-P for all users of the reporting guideline, such as systematic reviewers, policy makers, and educators. By identifying potentially challenging items and key areas, our results highlight where particular attention is required when reporting and reading systematic review protocols. These understandings will inform targeted improvements to guidance and training and thereby support higher-quality protocol development.

Alongside other supporting projects, our results will contribute to the evidence base for the forthcoming update of PRISMA-P, which will include a planned Delphi survey [13]. More specifically, items identified as particularly challenging (eg, protocol amendments [item 4], funding [items 5a-c], data synthesis [items 15a-d], and meta-bias(es) [item 16]) may need rephrasing or clarification. Furthermore, strengths, challenges, and suggestions for changes raised in the interviews with protocol authors will also be considered for inclusion in the Delphi survey. This may include, for example, suggestions on adding content on conflicts of interest or data access or incorporating hyperlinks to provide direct access to the Elaboration and Explanation document. As we identified multiple suggestions for changes, the PRISMA-P update team will revise and prioritise the raised suggestions and potential modifications while still ensuring that the guideline remains straightforward and does not contain an excessive number of items. An updated reporting guideline aligned with contemporary research methods will promote the completeness and transparency of reporting in systematic review protocols. This could facilitate more rigorous and transparent conduct of systematic reviews and ultimately reinforce the trustworthiness of their findings.

5. Conclusion

Adherence to some PRISMA-P items was low among 50 PubMed systematic review protocols and even lower among 50 OSF/PROSPERO protocols. Six items were often not reported across both types of protocols: protocol amendments, funder role, criteria for quantitative synthesis, methods for planned summary other than quantitative, meta-bias(es), and confidence in cumulative evidence. The interviewed authors suggested various additions and modifications to the guideline. Findings from this study provide context for users of

the reporting guideline and will inform a forthcoming update of PRISMA-P.

CRediT authorship contribution statement

Mette B. Engmose: Writing − review & editing, Writing − original draft, Methodology, Investigation, Formal analysis, Data curation. **An-Wen Chan:** Writing − review & editing, Methodology, Conceptualization. **Kerry Dwan:** Writing − review & editing, Methodology, Conceptualization. **Carsten Hinrichsen:** Writing − review & editing, Methodology, Conceptualization. **Asbjørn Hróbjartsson:** Writing − review & editing, Methodology, Conceptualization. **David Moher:** Writing − review & editing, Methodology, Conceptualization. **Matthew J. Page:** Writing − review & editing, Methodology, Conceptualization. **Josefina Salazar:** Writing − review & editing, Methodology, Data curation. **Larissa Shamseer:** Writing − review & editing, Methodology, Conceptualization. **Lesley A. Stewart:** Writing − review & editing, Methodology, Conceptualization. **Camilla H. Nejstgaard:** Writing − review & editing, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Ethics statement

According to the Danish Act on Research Ethics Committees, interview-based studies not involving clinical trials, health related information, or biological samples do not require ethical approval. This study was therefore exempted from such procedures.

Declaration of competing interest

D.M. is on the editorial board on the Journal of Clinical Epidemiology. A-W.C., K.D., A.H., D.M., M.J.P., L.S., L.A.S., and C.H.N. are members of the PRISMA-P update steering group. The authors declare no additional conflicts of interest.

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Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jclinepi.2026.112350.

Data availability

The data are available from OSF, a link is included in the manuscript.

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