Journal of Clinical Epidemiology 183 (2025) 111800

Journal of Clinical Epidemiology

ORIGINAL RESEARCH

Use of the pragmatic-explanatory continuum indicator summary tool in low- and middle-income country settings: systematic review

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Accepted 14 April 2025; Published online 22 April 2025

Abstract

Objectives: To systematically review and characterize the literature on using the pragmatic-explanatory continuum indicator summary (PRECIS) tools in low- and middle-income countries (LMICs), focusing on successes, challenges, and potential improvements to enhance applicability across diverse settings.

Study Design and Setting: A systematic search of PubMed to identify peer-reviewed articles applying PRECIS tools to LMIC-based research. Data extraction focused on trial characteristics, modifications, and use of PRECIS tools. Narrative synthesis was used to outline successes, challenges, and recommendations.

Results: A total of 40 articles met the selection criteria. The PRECIS tools were mostly (n = 39, 97.5%) used for purposes other than trial design. Significant variation was seen in methods of use and reporting. Most (n = 32, 80%) used PRECIS-2, valued for its reliability, ability to quantify pragmatism, assess trial design, and identify research gaps. Challenges included the tools' subjectivity, absence of information needed for scoring, interpretation of scores, and application to non-Western contexts and multinational trials. Recommendations for improvement included refining scoring criteria, translating guidance, and developing additional educational resources.

Conclusion: The PRECIS tools have successfully supported research globally and are perceived as reliable research tools with multiple strengths. Further guidance and refinement would enable consistent application and reporting, particularly as the tools have frequently been used for purposes other than their original intention. Most challenges were similar to high-income settings; however, translation and application of the tools to traditional medicine, international trials, and research-naïve settings were highlighted as LMIC-focused issues requiring consideration.

Keywords: Low- and middle-income countries; Trial design; Systematic review; Randomized controlled trial; Pragmatic trial; Explanatory trial

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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https://doi.org/10.1016/j.jclinepi.2025.111800

Plain Language Summary

The pragmatic-explanatory continuum indicator summary (PRECIS) tools were created to help researchers design better studies. The tools were developed mainly by researchers from developed Western nations. Therefore, it is possible that the PRECIS tools are not as relevant to other places. To help improve the usefulness of the tools in all settings, our team wanted to learn from the experiences of people who had already used PRECIS in low- and middle-income countries. We systematically searched for academic papers on this topic published before May 2022 and found 40 relevant articles. The articles showed that the PRECIS tools had been successfully used in many, often unexpected, ways to support research. Some researchers struggled with using the tool to assess research conducted by others, as relevant information was not available. Researchers recommended translating the tools to other languages and asked for more guidance to use the tool in specific circumstances, such as Chinese herbal medicine and large international research projects. Advice on the best ways to use the PRECIS tools and report the findings would also be beneficial. We share these findings to help those designing the next version of the tool make it useful for researchers working in all parts of the world.

1. Introduction

The pragmatic-explanatory continuum indicator summary (PRECIS) tool and its subsequent iterations have standardized the assessment of explanatory and pragmatic aspects of trials (Box 1) [1]. The latest versions of the PRECIS tool (PRECIS-2 and PRECIS-2-Provider-Strategies [PRECIS-2-PS]) consist of nine key domains that can each be rated from 1 (most explanatory) to 5 (most pragmatic) and plotted on a graph to visually demonstrate where a trial design falls along the pragmatic-explanatory continuum [2−4]. Although the creators of the tools intended them to be used in the trial planning phase to guide design decisions, the tools have since been used to refine trial conduct [5], carry out process evaluations of pilot trials [6], and characterize the evidence base within a specialty [7]. Work is underway to develop the PRECIS-3 tool [8], which represents an opportunity to ensure this prominent trial methodology tool applies to all intended users.

Input to the design and validation of the PRECIS tools has predominantly been from trialists in high-income countries (HICs), reflecting the existing inequities in trial conduct and methodology research globally [9−11]. Trials in low- and middle-income countries (LMICs) are more commonly conducted in vulnerable populations and vastly different social, ethical, cultural, and contextual realities that impact trial design and outcomes [12−15]. Such considerations may not be adequately reflected in the PRECIS tools given the perspectives considered during their development. However, the PRECIS tools have been used for designing and reporting LMIC trials, which provide a potentially rich source of information about the applicability of the tool in these contexts.

Our objective was to systematically review and characterize the literature on the use of the PRECIS tools in LMICs to help refine the tool and ensure applicability in these settings.

2. Material and methods

This systematic review is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (Appendix 1) and the protocol was registered on PROSPERO (CRD42022332177).

2.1. Eligibility criteria

All articles published in peer-reviewed journals, in any language, describing the application of any of the PRECIS tools (PRECIS, PRECIS-2, or PRECIS-2-PS) to a trial conducted in at least one LMIC, defined based on the 2022 World Bank classification criteria [16], were included in this review. Articles citing one of the PRECIS tools without describing its application to a trial and those that applied PRECIS to research based solely in HICs were excluded.

2.2. Search strategy and study selection

A search (Appendix 2) was performed via PubMed from initiation in 1966 until May 16, 2022 (date of the search), by identifying original peer-reviewed articles that mentioned PRECIS in the title, full text, or abstract, and those that cited any of the primary PRECIS publications by the creators [2−4,17,18].

2.3. Screening and extraction process

Titles and abstracts, and subsequently full texts, were screened independently by 2 team members (A.B. and T.T., or A.H. and T.T.) to select articles that applied any version of the PRECIS tool to LMIC-based research using Rayyan QCRI [19]. Data were extracted independently by 2 researchers (A.H. and T.T.) using Google Forms, with data exported to Google Sheets (Google LLC) for analysis. Any disagreements in screening or data extraction were resolved by consensus. The parameters for data extraction

What is new?

Key findings

- Experiences applying the pragmatic-explanatory continuum indicator summary (PRECIS) tools to trials conducted in low- and middle-income countries (LMICs) were described in 40 articles with most researchers using them for reasons other than their intended purpose of trial design.
- Challenges were experienced in the allocation and interpretation of scores whereas successes included their utility in assessing trial design, quantifying pragmatism, and identifying research gaps.
- Recommendations to improve usability included translation of the tools, providing additional guidance, and specifying scoring criteria.

What this adds to what is known?

- The findings reinforce previous recommendations and highlight LMIC-focused considerations, including the application of the PRECIS tools to traditional medicine, international trials, and research-naïve health-care environments.
- Reviewing this topic from an LMIC lens adds a valuable equity-promoting perspective as the PRECIS tools were created with limited input from LMIC-based researchers.

What is the implication and what should change now?

- The review contributes to current efforts to develop the next iteration of the tool (PRECIS-3) by outlining LMIC-specific issues that require consideration to make the tool applicable to all settings.

encompassed publication year, study aims and design, version and purpose of using PRECIS, process for applying PRECIS (raters and training), reporting of PRECIS results (scores, rationales, and diagrams), interrater agreement, and direct quotes regarding experiences of use (successes, challenges, and recommendations). Characteristics of studies (purpose and setting) to which PRECIS had been applied were also extracted according to standard definitions [20,21]. In circumstances where full-text articles or information required for data extraction were not available, attempts were made to contact the corresponding author.

2.4. Analysis and synthesis

Descriptive statistics and narrative synthesis were used to outline findings from included articles. Quantitative meta-analysis, sensitivity analyses, heterogeneity, risk of reporting bias, and certainty assessments were not conducted in view of the review's descriptive nature. Articles were divided into two groups based on whether PRECIS was used to assess 1 trial (eg, as part of a trial protocol) or multiple trials (eg, as part of a systematic review). Successes and challenges in applying PRECIS to LMICs were compared across articles to identify any recurring topics. Analyses and syntheses were conducted using Google Sheets.

3. Results

3.1. Study selection

Our search strategy identified 986 articles, of which 484 were excluded after screening titles and abstracts, and an additional 462 during full-text review (Fig). A total of 40 articles met the eligibility criteria and were included in the qualitative synthesis.

3.2. Study characteristics

Characteristics of included studies are summarized in Table 1 with article-level details provided in Appendix 3. Half of the studies (n = 20) were published between January 2020 and May 2022. The majority (n = 32, 80%) used PRECIS-2, whereas none used PRECIS-2-PS. The PRECIS tools were applied to a single trial in 18 (45%) and multiple trials in 22 (55%) articles. For the former case, PRECIS assessments mostly accompanied published trial

Box 1 Explanatory and pragmatic trials.

French statisticians Joseph Schwartz and Daniel Lellouch clarified modern understanding of trials in their seminal 1967 paper "Explanatory and pragmatic attitudes in therapeutic trials" (reprinted in JCE, 2009) by distinguishing between the following 2 main approaches: explanatory trials aiming to confirm hypotheses about a mechanism of action of an intervention and pragmatic trials seeking to determine whether interventions work under "real-world" conditions [1]. Explanatory trials involve design decisions to reduce sources of variation to maximize the strength of inferences made about the impact of an intervention. Pragmatic trials intend to produce inferences useful for decision-makers choosing appropriate interventions to implement in health-care settings. Although the purpose of a trial is presented as a dichotomy, trial design choices are more complex and lie on a continuum. The PRECIS tools support trialists making such design choices in accordance with the primary aim of their trial, be it explanatory or pragmatic.

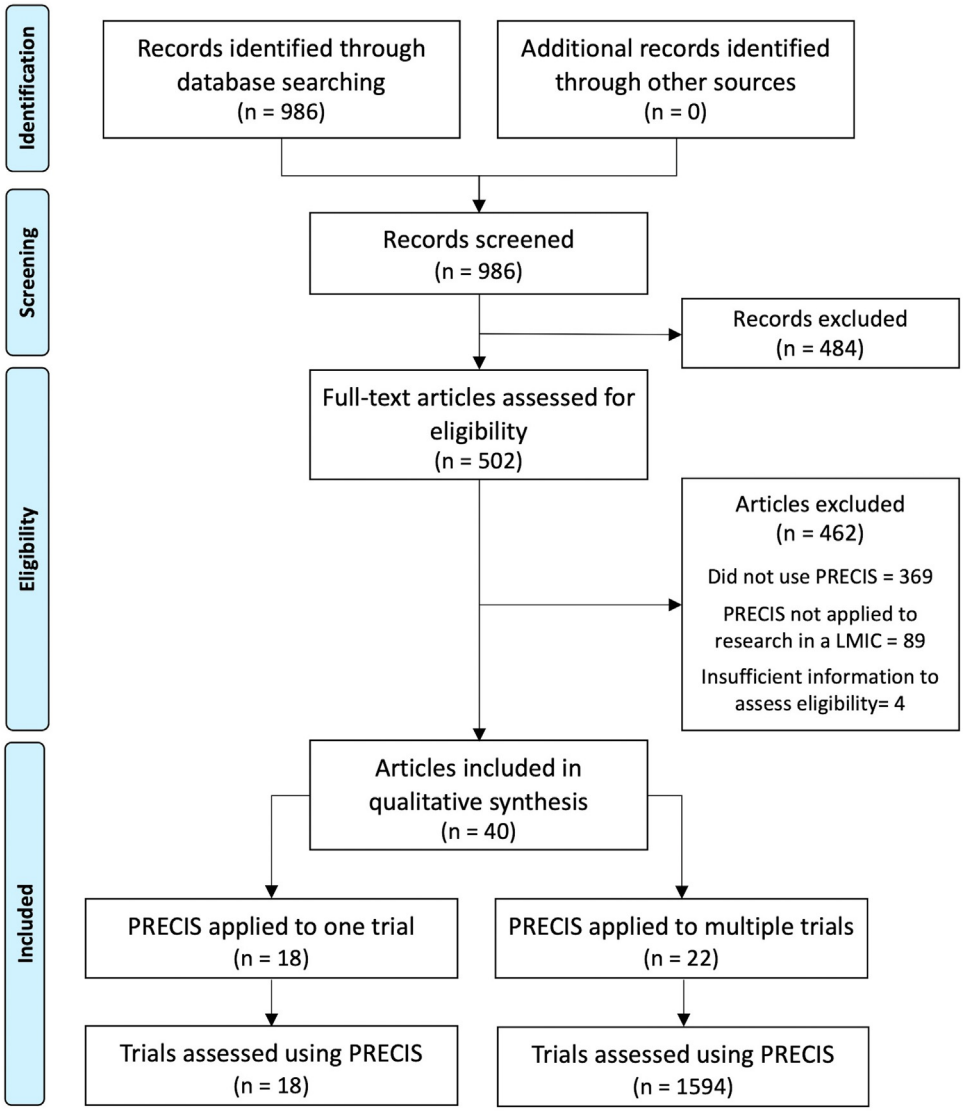

Figure. PRISMA flowchart. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses

protocols ($n = 12$) or results ($n = 5$) whereas PRECIS tools were often applied to multiple trials in the context of systematic ($n = 8$) or literature ($n = 8$) reviews. Two original research studies used PRECIS-2. Both cohort studies aimed to establish the proportion of patients that would have been eligible to take part in published clinical trials, which were characterized using PRECIS-2 [22,23].

3.3. Studies assessed using PRECIS tools

The PRECIS tools were applied to a total of 1612 studies. Of these, 385 (24%) were conducted in at least 1 LMIC, with 322 occurring exclusively in LMICs and 83 in a mixture of LMICs and HICs. The country where a trial was conducted was unclear in 20 (1%) instances. Additional information was available for extraction for 278 of the 385 (72%) trials conducted in at least 1 LMIC (Table 2). The number of participants in these trials ranged from 18 to 22,576. The majority were single-center studies ($n = 152$, 55%) evaluating a treatment intervention ($n = 208$, 75%) delivered in a hospital setting ($n = 223$, 80%) to adults ($n = 228$, 82%), who were individually randomized to the study ($n = 253$, 91%). None of the trials had a primary purpose of evaluating the basic mechanisms of action of an intervention, feasibility of a device, or interventions for supportive care. Similarly, none were conducted by providers of ancillary services (eg, emergency rescue or laboratories) or to study genetic intervention types (eg, gene transfer or stem cell therapy).

3.4. Purpose of using the PRECIS tools

The PRECIS tools have been used for a multitude of purposes (Table 3). Most commonly, trial protocols or results included PRECIS scores to report the trial's position on the pragmatic-explanatory continuum. This reporting

Table 1. Article characteristics

Characteristic	Articles (n = 40) n (%)
Year of article publication	
2010–2014	5 (12)
2015–2019	15 (38)
2020–2022	20 (50)
Version of the PRECIS tool used	
PRECIS	8 (20)
PRECIS-2	32 (80)
Article type	
PRECIS applied to one trial (n = 18)	
Trial evaluation	1 (2)
Trial results	5 (12)
Trial protocol	12 (30)
PRECIS applied to multiple trials (n = 22)	
Research article	2 (5)
Method article	4 (10)
Literature review	8 (20)
Systematic review and meta-analysis	8 (20)

PRECIS, pragmatic-explanatory continuum indicator summary.

Table 2. Characteristics of LMIC studies assessed using PRECIS tools

Characteristic	Studies (n = 278) n (%)
Participants	
Adults (≥18 years)	228 (82)
Mixture of children and adults	36 (13)
Children (<18 y)	6 (2)
Unknown	8 (3)
Sample size, median (IQR)	120 (68–502)
Multicenter study	119 (43)
Multicountry study	67 (24)
Unit of randomization	
Individual	253 (91)
Cluster	21 (8)
Within-subject	1 (<1)
Nonrandomized design	3 (1)
Health-care provider and intervention setting	
Hospital care	223 (80)
Ambulatory health care	28 (10)
Other	20 (7)
Unknown	7 (3)
Primary purpose	
Treatment	208 (75)
Prevention	31 (11)
Screening	2 (1)
Health services research	35 (12)
Diagnostic	2 (1)

was often performed to provide evidence for the claim that a trial is pragmatic. Another common use of the PRECIS tools was to characterize the pragmatic and explanatory features of a collection of studies. This characterization allowed authors to make recommendations about the types of trials that are needed in the future. For instance, Choi et al examined trials investigating methotrexate in rheumatoid arthritis and concluded that more pragmatic trials are needed to inform real-world practice [42]. Others used the characterization to evaluate the association between study characteristics and PRECIS scores. The PRECIS tools were also used to evaluate their use for novel purposes, appraise or inform study design, and establish the impact of trials categorized as pragmatic or explanatory on outcomes.

3.5. Use of the PRECIS tools

Details about the use of the PRECIS tools, including modifications, rating process, and reporting, are outlined in Table 4 and discussed in more detail below.

3.5.1. Modifications

A total of 10 articles described modifications to the PRECIS tools. Six of the eight articles using the original PRECIS tool reported modifications and all but one of these added some type of rating scale. Three groups of authors modified the tool to include a Likert scale [30,54,55], whereas two articles authored by Mansouri et al introduced a self-designed scale with scores ranging from 0 to 20 [58,59]. Bratton et al made modifications to the domains of the PRECIS tool by combining two existing ones and introducing an additional domain on blinding [52]. All four of the PRECIS-2 articles that made modifications to the tool introduced some type of classification of trials based on the average domain or overall score [48,51,53,56]. For instance, Gastaldon et al classed trials into three categories based on an average domain score; explanatory (average score ≤2.5), intermediate (2.5–3.5), or pragmatic (≥3.5) [48].

3.5.2. Rating process

Many articles did not report how many raters were involved (n = 17, 42%), whether they received training (n = 29, 72%), or how the final scores were reached (n = 17, 42%). In all but one case, three or fewer individuals were involved in PRECIS scoring whereas Checkley et al surveyed 35 investigators on the degree of pragmatism of a large multicentre trial [41]. Of the 11 articles with information about training, two reported exclusively using existing PRECIS resources (eg, publication, website), and eight reported carrying out pilot or calibration exercises. Choi et al created their own scoring template with specialty-specific examples, whereas Checkley et al produced examples and educational materials on PRECIS use [41,42]. Where multiple raters were involved and

Table 3. Purpose of using the PRECIS tools

Category	Articles	Description of the purpose of use	References
PRECIS applied to one trial			
Reporting	16	To report a study along the pragmatic-explanatory continuum.	[24–39]
Inform study design	1	To prospectively guide study design.	[40]
Evaluate study processes	1	To study aspects of implementation or mechanisms of impact.	[41]
PRECIS applied to multiple trials			
Characterization	12	To characterize a group of studies along the pragmatic-explanatory continuum, with or without assessing association with study characteristics.	[22,23,42–51]
Investigate use of the tool	6	To test the tool in different fields of study or for novel purposes, with or without modification.	[52–57]
Appraise methodology	2	To appraise the design methods of a study.	[58,59]
Establish impact on trial outcomes	2	To establish the impact of trial design, categorized using PRECIS, on primary outcomes.	[60,61]

PRECIS, pragmatic-explanatory continuum indicator summary.

information was available (n = 16), 11 used consensus discussion, two averaged their scores, and three used a combination of methods to arrive at the final PRECIS scores.

3.5.3. Reporting

Assessments using the PRECIS tools were reported as individual domain scores (n = 29, 72%), average domain scores (n = 6, 15%), or an overall average trial score (n = 4, 10%). All but 1 article applied PRECIS tools to a single trial and 12 of 22 articles where PRECIS was applied to multiple trials presented individual scores for each domain. One article provided individual domain scores as an example for four of 36 trials and an overall average score for the rest [23]. Rationales for assessments were provided in 10 articles, of which only 1 applied PRECIS to multiple trials [44]. Diagrammatic representation (ie, wheel) of an assessment was provided in 22 articles (55%), of which five used a single wheel to summarize multiple trials. No rationales or wheels were provided by 12 articles (30%). Interrater reliability was calculated in five articles; two reported reliability of overall PRECIS-2 scoring as 0.73 and 0.74, 2 reported reliability for individual domain scores ranging between 0.2 and 1.0, and Tosh et al reported reliability of 0.72 for the broad classification of studies [42,45,55–57].

3.6. Experience of using the PRECIS tools

Experiences of using the PRECIS tools were mainly reported in articles where the tools were applied to multiple trials, which have mostly informed the successes, challenges, and recommendations summarized in Table 5. No challenges to the use of the PRECIS tools were reported by any of the trial protocols or results articles (n = 17), and of these, only Lutge et al explicitly mentioned a success, noting that PRECIS provides a useful overview of trial design [30].

Successes of using the PRECIS tools were broadly related to their reliability and utility in assessment. Multiple authors chose to use the PRECIS tools due to their extensive previous

Table 4. Use of the PRECIS tools

Characteristic	Articles (n = 40) n (%)
Modifications made to the PRECIS tools	10 (25)
Number of raters involved in the scoring process	
1	7 (18)
2-3	15 (38)
>3	1 (2)
Unknown	17 (42)
Training or guidance provided for raters	11 (28)
Type of training or guidance provided (n = 11)[a]	
Written documents	7 (18)
Pilot testing or calibration exercise	8 (20)
Lecture or workshop	1 (2)
Arrival at final assessment	
Single rater	7 (18)
Consensus discussion	11 (28)
Average of ratings	2 (5)
Other	3 (8)
Unclear	17 (42)
Rationales for assessment	10 (25)
Diagrammatic representation of assessment	22 (55)
Detail of assessment results provided	
Individual domain scores	29 (72)
Average domain scores	6 (15)
Overall score only	4 (10)
Other	1 (2)

PRECIS, pragmatic-explanatory continuum indicator summary.
[a] Multiple types of training or guidance could have been used within a single article.

Table 5. Successes, challenges, and recommendations of PRECIS tool use

Category	Illustrative example
Successes	
Reliability and validity	"The PRECIS-2 tool is the most cited and reliable tool available to retrospectively evaluate the pragmatism-explanatory level of randomized controlled trials." [51]
Assessment of trial design	"First, it [PRECIS] helps researchers identify inconsistencies in the trial design and thus adjustments can be made, if appropriate, to keep in step with the objective of the trial. Second, PRECIS gives a clear indication of the generalizability or applicability of the trial results." [52]
Quantification of pragmatism	"The incorporation of PRECIS-2 classification of the trials as covariate in metaregression models results in larger estimates of pooled intervention effects in published trials than previously reported pooled effect sizes." [56]
Identification of research gaps	"Using the PRECIS-2 tool we found that very pragmatically conducted studies, which are designed to be externally valid, are missing in the field of perioperative beta-blocker therapy." [23]
Challenges	
Allocation of scores	"PRECIS-2 assessors were required to be familiar with routine care practice across fourteen countries. Consequently, a potential deficit in their knowledge may affect accuracy of the pragmatic score for trial design." [49]
Interpretation of scores	"[The study finding] flags a relevant issue: how many pragmatic features does a trial need to have to be reasonably labeled as pragmatic?" [53]
Evaluation of applicability	"We also assessed certain additional practical feasibility factors, such as costs and program sustainability, that are not measured by the PRECIS-2 tool." [61]
Recommendations	
Language	"The PRECIS-2 guidelines should be translated into Chinese. Related introductory articles should also be published in Chinese to promote a wider range of applications for PRECIS-2." [57]
Specificity	"PRECIS-2 criteria need to be further refined to achieve specificity sufficient to enable evaluators to perform quantitative judgment." [57]
Training	"[PRECIS-2] does not provide instructions on how to best train investigators to ensure consistent scoring. We have identified this as an area for future improvement when conducting PRECIS-2 surveys." [41]

PRECIS, pragmatic-explanatory continuum indicator summary.

use, perceived reliability, and validity. Two articles made direct comparisons to other available tools, noting that the PRECIS tools were more widely cited and comprehensive [51,54]. As per the intended aims of the PRECIS tools, articles highlighted their usefulness in assessing whether the intended pragmatic or explanatory objective was reflected in the trial design. The ability of the PRECIS-2 tool to quantify pragmatism was an important success. This quantification allowed authors to study the association between trial pragmatism with a multitude of variables, such as trial characteristics and outcomes. Assessments conducted with the PRECIS tools also allowed authors to gain insights into the research gaps within specific fields.

The main challenge concerning the use of the original PRECIS tool was a lack of a validated scoring scale, an issue addressed in the revised PRECIS-2. Other challenges (Table 5) included allocation and interpretation of scores and the inability of the PRECIS tools to fully assess trial applicability to real-world settings. Difficulties in scoring were experienced due to an absence of available information regarding trials and usual care and a lack of detailed guidance on the PRECIS tools, leading to inconsistent and subjective ratings. Authors reported that information needed to assign a score was particularly missing for the "'recruitment", "flexibility (adherence)", and "flexibility (delivery)" domains. Choi et al noted that sufficient information to score the "recruitment" domain was only available in two of the 96 studies they assessed [42]. Some authors did not have clarity on what score would constitute a pragmatic trial. Two articles noted that the PRECIS tools do not capture all factors (eg, cost) that would impact the external validity of a trial, with 1 article using the Reach, Effectiveness, Adoption, Implementation and Maintenance framework to supplement the PRECIS assessment of real-world applicability [61].

Recommendations to improve the use of the tool included translating the tool and related guidance. Further specification of scoring criteria was recommended by a few authors to ensure consistency in rating [48,57], whereas others recommended solving this issue by creating additional educational materials [41]. With regard to additional specifications, one group of authors raised the need to define how concepts within the PRECIS tools based on Western notions of medicine can be applied to the field of Chinese herbal medicine [57].

4. Discussion

This review of 40 articles describing the application of PRECIS tools to LMIC research complements and adds

to the findings of a recent citation analysis, which identified criticisms of PRECIS-2 to guide the development of PRECIS-3 [8]. Our findings are consistent and demonstrate broad applicability of the tools to research from all settings. To improve usability, we echo recommendations to provide additional guidance on the following: (i) scoring in the absence of information, (ii) use of results to categorize trials as pragmatic or explanatory, and (iii) application of the tool for purposes other than trial design. Specifically, additional guidance would enhance interrater reliability for retrospective assessments, which was frequently mentioned in included articles and elsewhere [45,52,62,63]. Although differences in opinion among raters at the trial design phase may promote necessary discussions [52], poor interrater reliability complicates evidence synthesis [56,60,64].

Although reported experiences were in line with those identified in HICs, additional considerations were encountered during the application of PRECIS to LMIC research. Authors raised aspects not adequately captured by PRECIS, such as cost and sustainability, that more significantly affect pragmatism in LMICs where resources for research are often limited [61]. The ''organization'' domain does account for these elements; however, considerations within the domain might need to be expanded when considering research-naïve health-care settings. Authors also raised the need to consider the applicability of the PRECIS tools beyond Western medical practice [57]. For instance, the ''Flexibility (delivery)'' domain may not be applicable in traditional medicine, which often relies on multimodal individualized treatments [65,66]. Assessment of multicountry trials was challenging due to researchers unfamiliarity with health-care across contexts [49]. Future work seems to be necessary to understand pragmatic considerations specific to international and traditional medicine trials, which may also benefit from the development of extensions to PRECIS-3 by interested parties supported by the developers of the tool. Finally, translation of PRECIS tools to other languages would enhance accessibility. Development of PRECIS-3 and associated guidance would benefit from considering these issues with input from LMIC-based researchers as codevelopers or through expert interviews.

Our findings differ from that of the citation analysis by reporting on real-world experiences of use rather than criticisms and outlining strengths alongside challenges. As such, this review adds two additional considerations for PRECIS-3. Firstly, operational guidance would ensure that PRECIS-3 is applied as intended and reported consistently. In practice, there was significant deviation from guidance and variation in the number of raters, methods for arriving at final assessments, and descriptions of using the PRECIS tools. The new iteration could include a table for reporting all relevant operational details, including reasons for deviating from guidance. Secondly, identified articles support the wide adoption of PRECIS tools in view of their reliability, use, and comparative advantages. The PRECIS tools supported trial design as well as trial process evaluations [41], reporting [30], identification of knowledge gaps [42], and exploration of associations between trial design and outcomes [60,61]. Previous authors have suggested that the tools could also be used as teaching aids, to assess generalizability of trials, and as part of submissions to funders and trial registries [67,68]. These strengths and use cases should be highlighted in PRECIS-3.

4.1. Limitations

Accounts of using the PRECIS tools may have been missed due to the sole use of PubMed, grouping countries based on income, and reporting bias, as use of PRECIS is not a required reporting item. Indeed, 16 articles did not report any impressions of using the tools. Reporting bias may also overestimate use of the tools for purposes other than trial design. Despite this, multiple successes, challenges, and recommendations were identified from peer-reviewed literature. To address these limitations and lack of in-depth reports on LMIC experiences of using the tools, the authors are using these results to guide a mixed methods study into the applicability of PRECIS-2 in South Asia.

5. Conclusion

This review examined the use of the PRECIS tools from the vantage point of LMIC research, highlighting universal and LMIC-specific considerations for the development of PRECIS-3 to improve applicability of this important trial design tool. The PRECIS tools have been frequently used for purposes other than what they were originally designed for and their application has been highly variable, suggesting the need for additional guidance. Appropriate approaches for applying the PRECIS tools to multinational trials and non-Western medicine require further consideration, as do the ways to capture resource considerations for research-naïve settings, preferably with input from LMIC researchers.

CRediT authorship contribution statement

Timo Tolppa: Writing − original draft, Visualization, Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Arishay Hussaini:** Writing − review & editing, Validation, Investigation, Formal analysis, Data curation. **Maham J. Ahmed:** Writing − original draft. **Amit Bhattarai:** Writing − review & editing, Investigation. **Diptesh Aryal:** Writing − review & editing, Supervision. **Madiha Hashmi:** Writing − review & editing, Supervision. **Arjen M. Dondorp:** Writing − review & editing, Supervision, Conceptualization. **Srinivas Murthy:** Writing − review & editing, Supervision, Conceptualization.

Declaration of competing interest

There are no competing interests for any authors.

Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jclinepi.2025.111800.

Data availability

Data extracted from included studies and questions guiding data extraction are available in Supplementary Appendix 3.

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