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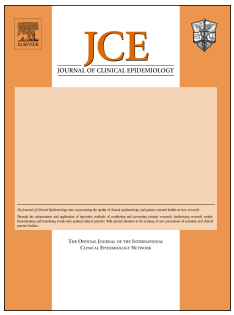

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Title Page

Reporting standards for child health research were few and poorly Implemented

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Abstract

Objectives: This study aims to identify existing reporting standards for child health research, assess the robustness of the standards development process, and evaluate the dissemination of these standards.

Study Design and Setting: We searched MEDLINE, the EQUATOR Network Library and Google to identify reporting standards for child health research studies. We assessed the adherence of the Guidance for Developers of Health Research Reporting Guidelines (GDHRG) by the identified reporting standards. We also assessed the use of the identified reporting standards by primary research studies, and the endorsement of the included reporting standards by journals.

Results: We identified six reporting standards for child health research, including two under development. Among the four available standards, their median adherence to the 18 main steps of the GDHRG was 58.35% (range: 27.8%-83.3%). None of these four reporting standards had been endorsed by pediatric journals indexed by the Science Citation Index. Only 26 primary research studies declared that they followed one of the reporting standards.

Conclusion: There is a quantitative and qualitative paucity of well-developed reporting standards for child health research. The available standards are also poorly implemented. This situation demands an urgent need to develop robust standards and ensure their implementation.

Keywords: reporting standard; child health research; adherence; dissemination; endorsement; EQUATOR

Running title: Reporting standard for child health research

Text word count: **2831**

What is new?

Key findings

- There is a quantitative and qualitative paucity of well-developed reporting standards for child health research.
- The available reporting standards for child health research are poorly implemented.

What this adds to what was known?

- This is the first study to investigate the quantity, quality, and impact of reporting standards for child health research.

What is the implication and what should change now?

- Robust reporting standards for child health research should be developed and ensured implementation.

1. Introduction

Reporting standards provide advice on how to report the methods and findings of research studies comprehensively and clearly, and are usually presented as checklists, flow diagrams, or explicit text statements [1]. There are 497 reporting standards indexed on the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network Library (http://www.equator-network.org) as on March 15, 2022. The uptake and application of these reporting standards in child health research may have been low because items within these standards often do not sufficiently cover the unique reporting needs for child health research [2].

Child health research differs from adult research in several key aspects. First, children and adults respond differently to medications because of the substantial differences in pharmacokinetics and pharmacodynamics between age groups [3]. In addition, the outcomes of interventions vary considerably across the pediatric age range [3]. Therefore, it is important to report these age-specific interventions, comparators, and outcome measurements. Second, in clinical trials involving children, ethical issues and the threshold for consent become more complicated [4]. Key aspects during the recruitment and informed consent process, such as whether the child engaged in the consent process, understood assent, who agreed to participate (the children or their guardians), and whether the children or their guardians received payment, should be transparently reported [5]. Third, the determination of an appropriate sample size is an important challenge of pediatric clinical trials [6]. Sample size calculations sometimes rely on empirical data from adult trials rather than direct data from pediatric trials due to the lack of pediatric clinical studies. To enable readers to determine if the sample size calculation is suitable in these circumstances, the sample size calculation method should be explicitly described. However, most child health studies had poor reporting quality and did not cover all of these important aspects [7-10]. Without adequate reporting, clinicians may not be able to decide wisely for pediatric patients, and peer reviewers and investigators may not be able to make an information-based assessment on ethical issue and research methodology. Additionally, inadequate reporting can also have an impact on systematic reviews.

Without detailed information on age, subgroup analyses for targeted pediatric age groups could not be performed in systematic reviews with a mixed adult and pediatric population. This may affect decision-makers' capacity to make policy and program decisions for a specific age group.

For the above reasons, specific reporting standards for child health research are needed [11]. However, to the best of our knowledge, to date there is no systematic review examining reporting standards for child health research. This is necessary because to enable the target users know about existing standards for child health research, and enhance their adoption. It will also highlight the deficiencies in existing standards and optimize the further development of such standards. We aim to address this knowledge gap by identifying the existing reporting standards for child health research, summarizing their main characteristics, exploring the reporting items unique to child health research, and assessing the robustness of the reporting standard development process, and evaluating their dissemination and application.

2. Methods

2.1. Data sources and search strategy

We systematically searched MEDLINE (via PubMed) with the assistance of an information retrieval expert (YC) for reporting standards that specifically addressed child health research [12]. We also searched the EQUATOR Network Library (https://www.equator-network.org/) and Google.com (https://google.com/) to identify additional records. We searched the databases from their inception until March 15, 2022. The detailed search strategy is presented in Supplementary Material Table S1.

2.2. Eligibility criteria

Two investigators (QL and QZ) independently screened the retrieved documents for reporting standards fulfilling the following criteria: (1) Standard has explicit statements guiding authors to report health research, and (2) Designed exclusively for child health research (i.e., studies on infants,

children and/or adolescents, with any definition or age limit). We excluded the following types of records: (1) duplicates; (2) standards for reporting diagnostic, treatment, and prognostic information by clinicians, such as the results of imaging and pathological findings; and (3) journals' instructions for authors. Disagreements were resolved by discussion, or solved with a third investigator (YC), if needed.

2.3. Data extraction and assessment

We extracted information on the basic characteristics of the included reporting standards. For standards adapted from adult or general standards, we also extracted the original reporting items and the pediatric-specific reporting items and categorized them into broader themes. We assessed the robustness of the standards development process by their adherence to the Guidance for Developers of Health Research Reporting Guidelines (GDHRG) [13]. We assessed the uptake of each reporting standards by the number of Science Citation Index (SCI) indexed pediatric journals and major general medicine journals, referring to the reporting standard in their Instructions to Authors, number of citations of the reporting standard, and the number of publications reporting their research in accordance with the cited reporting standard. The details about data extraction and assessment are presented in Supplementary Material Table S2.

2.4 Statistical Analysis

We used descriptive statistics to summarize the variables according to their type, continuous or categorical. The concordance with respect to selection of standards between the investigators was calculated using Cohen's kappa with 95% confidence intervals. Kappa-value was interpreted as follows: poor (<0.00), slight (0.00 to 0.20), fair (0.21 to 0.40), moderate (0.41 to 0.60), substantial (0.61 to 0.80), or almost perfect (0.81 to 1.00) [14]. The analysis was carried out with IBM SPSS 26.0.

3. Results

A total of 811 records were identified in the initial search. After excluding duplicates, 803 records were screened by reading the titles and abstracts, and 36 full-text documents were retrieved for further evaluation. Six reporting standards meeting the specified criteria were included (Fig. 1) [15-20]. The level of concordance between the investigators was substantial (kappa-value 0.75, 95% confidence interval: 0.51 to 0.99).

3.1. Characteristics of the reporting standards

Among the six identified reporting standards, four standards were published. These include STROBE-NI [15] designed for observational studies on newborn infections, Checklist for Reporting Ecological Momentary Assessments Studies (CREMAS) [16] designed for diet and physical activity research in youth, Consolidated Advice for Reporting Early Childhood Development Implementation Research (C.A.R.E.) [17] for implementation research on nurturing care interventions during childhood, and Reporting stAndards for research in PedIatric Dentistry (RAPID) for research in pediatric dentistry [18]. These standards had 46, 16, 21, and 28 reporting items, respectively [15-18]. Two reporting standards, one for pediatric RCT protocols and reports [19] and one for systematic review protocols and reports [20] were still under development. Therefore, data could not be extracted for these. STROBE-NI [15], CREMAS [16], C.A.R.E.[17], RAPID [18], and Consolidated Standards of Reporting Trials in children (CONSORT-C) [19] have been indexed in EQUATOR. Three reporting standards declared no conflict of interests [16-18], one declared the interests of some participants, but did not declare whether these participants had conflicts of interest and how they were managed [15]. Further information is available in Table 1 and Table 2.

Table 1 Basic characteristics and dissemination of the reporting standards

Reporting standard	Development status	Version	Development duration (month)[#]	Number of participants	Country	Number of items	Indexed in EQUATOR	Protocol published	Funder	Conflicts of interest disclosure
STROBE-NI [15]	Completed	Extension	20	147	UK	46	Yes	No	Wellcome Trust, WHO, and the Bill & Melinda Gates Foundation	NR
CREMAS [16]	Completed	Extension	12	4	USA	16	Yes	No	NIH and ACS	None
C.A.R.E. [17]	Completed	De novo	10	17	USA	21	Yes	No	The New York Academy of Sciences, UNICEF and the New Venture Fund	None
RAPID [18]	Completed	De novo	28	69	USA	28[&]	Yes	Yes	None	None
CONSORT-C and SPIRIT-C [19]	Ongoing	Extension	NA	NA	Canada	NA	Partial[*]	Yes	Canadian Institute of Health Research Knowledge Synthesis Grant	NA
PRISMA-C and PRISMA-P-C [20]	Ongoing	Extension	NA	NA	Canada	NA	No	Yes	Hospital for Sick Children Investigator award, New Investigator Salary Award	NA

Reporting standard	Publication year	Published in multiple journals	Journal of checklist publication	Number of citations	Number of studies adhering to the standard	Journal endorsement
STROBE-NI [15]	2016	No	The Lancet Infectious Diseases	103	5	No
CREMAS [16]	2016	No	Journal of Medical Internet Research	111	17	No
C.A.R.E. [17]	2018	No	Annals of the New York Academy of Sciences	36	4	No
RAPID [18]	2021	No	BMC Oral Health	1	0	No
CONSORT-C and SPIRIT-C [19]	NA	NA	NA	NA	NA	NA
PRISMA-C and PRISMA-P-C [20]	NA	NA	NA	NA	NA	NA

Note: STROBE-NI: Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection; CREMAS: Checklist for Reporting Ecological Momentary Assessments (EMA) Studies; C.A.R.E.: consolidated advice for reporting Early Childhood Development (ECD) implementation research; RAPID: Reporting stAndards for research in PedIatric Dentistry; CONSORT-C: Consolidated Standards of Reporting Trials in children; SPIRIT-C: Standard Protocol Items: Recommendations for Interventional Trials in Children; PRISMA-C: Preferred Reporting Items in Systematic Review and Meta-Analysis in Children; PRISMA-P-C: Preferred Reporting Items in Systematic Review and Meta-Analysis Protocol in Children; WHO: World Health Organization; NIH: National Institutes of Health; ACS: American Cancer Society; UNICEF: United Nations International Children's Emergency Fund; RCT: randomized controlled trial; NA: not applicable, NR: not report; [#]: Development duration: the duration between commencement and publication; [&]: items in the "General" theme; [*]: CONSORT-C has been indexed in EQUATOR, but SPIRIT-C has not.

Table 2 Reporting standards for different types of pediatric studies

Study type	Reporting standards	
	Finished	Ongoing
Randomised trials	NA	CONSORT-C [19]
Observational studies	STROBE-NI [15] CREMAS [16]	NA
Systematic reviews	NA	PRISMA-C [20]
Study protocols	NA	SPIRIT-C [19] PRISMA-P-C [20]
Diagnostic/prognostic studies	NA	NA
Case reports	NA	NA
Clinical practice guidelines	NA	NA
Qualitative research	NA	NA
Animal pre-clinical studies	NA	NA
Quality improvement studies	NA	NA
Economic evaluations	NA	NA
Implementation studies	C.A.R.E. [17]	NA
Others	RAPID [18]	NA

Note: NA: Not available; STROBE-NI: Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection; CREMAS: Checklist for Reporting Ecological Momentary Assessments (EMA) Studies; C.A.R.E.: consolidated advice for reporting Early Childhood Development (ECD) implementation research; RAPID: Reporting stAndards for research in PedIatric Dentistry; CONSORT-C: Consolidated Standards of Reporting Trials in Children; PRISMA-C: Preferred Reporting Items in Systematic Review and Meta-Analysis in Children; SPIRIT-C: Standard Protocol Items for Randomized Trials in Children; PRISMA-P-C: Preferred Reporting Items in Systematic Review and Meta-Analysis Protocol in Children

186

187 *3.2. Reporting items and themes specific for child health research*

188 Original reporting items and new or revised reporting items specific for child health research are
189 presented in Supplementary Material Table S3. We identified five main reporting themes for
190 reporting in child health studies, including age of the study participants, pediatrics-specific
191 characteristics of study participants, interventions (dosage per unit body weight, form, strength of
192 formulation used, bioavailability, excipients, rationale for choice, modification of adult dose),
193 choice of appropriate outcomes, and research ethics. A detailed explanation and examples of these
194 themes are presented in Supplementary Material Table S4.

195

196 *3.3. Adherence of the reporting standards to the GDHRG*

197 The GDHRG recommended 18 steps for developing a reporting standard. STROBE-NI,
198 CREMAS, C.A.R.E., and RAPID applied only 12 (66.7%), 2 (27.8%), 9 (50.0%), and 15 (83.3%)
199 steps, respectively [15-18]. The data are summarized in Supplementary Material Table S5. During
200 the stage of preparing consensus meeting, none of the standards mentioned the meeting logistics,
201 only one (25%) of the four published standards mentioned the agenda of the meeting, including
202 details of the presentations on relevant background topics, sharing the results of the Delphi exercise,
203 invitation of session chairs, preparation of materials to be sent to participants prior to meeting, and
204 recording the meeting [18]. None of the four published standards discussed the strategy for
205 producing the documents, and only one (25%) of the four standards considered multiple and
206 simultaneous publications, discussed knowledge translation strategy and addressed the measures to
207 support adherence to the standard [18].

208

209 *3.4. Dissemination of the reporting standards*

210 The four published reporting standards, STROBE-NI (2016) [15], CREMAS (2016) [16],
211 C.A.R.E. (2018) [17] and RAPID (2021) [18] had been cited 103, 111, 36, and 1 times by March

15, 2022, respectively. Only five primary research studies declared explicitly to have reported according to STROBE-NI, 17 studies according to CREMAS and four studies according to C.A.R.E. None of the 129 pediatric SCI journals or the major general medical journals referred to any of the four reporting standards in their Instructions to Authors' section. Further information is available in Table 1.

4. Discussion

4.1. Summary of main findings

We identified only six standards for reporting child health research, which together covered a very narrow spectrum of study designs and types; two of these being under development. These comprised a very small fraction of the 497 guidelines listed in EQUATOR, confirming paucity of standards for reporting child health research. Further, the median adherence rate of four published standards to the GDHRG guidance was below 60%. The standards rarely addressed the preparation of consensus meetings, or the dissemination strategies. Although the four guidelines were published in prestigious journals, they were rarely cited in the same or other publications, and none of the pediatric journals endorsed their use.

4.2. The challenges from the past

It is intriguing that although the importance of reporting standards for child health research has been constantly emphasized [2,11,21,22], hardly any standards exist. In fact, for several types of study designs no reporting standard could be identified. In particular, we could not identify any reporting standards for case reports, clinical practice guidelines (CPGs) or other types such as economic evaluations or qualitative research on children.

The development process of the four published standards had several major gaps. This problem may not be unique to pediatric standards. Moher et al previously reported that among 45 reporting standards, only five disclosed the agenda of the consensus meeting, four reported sending materials

238 to participants, and four reported on recording the meeting [23].

239 We also found very few studies that declared having followed the identified standards. No
240 pediatric SCI journal nor any of the major general medicine journals referred to the four so far
241 published pediatric reporting standards in their Instructions to Authors section. One reason for the
242 poor adoption of these reporting standards by journals could be that they only address a few specific
243 medical issues and may not apply to general medicine journals or journals that fall outside the scope
244 of the reporting standards. Another reason could be that the developers of the reporting standards
245 did not use efficient methods to promote the reporting standards after they were published. As a
246 result, journal editors and researchers may be unaware of these reporting standards, let alone the
247 benefits of adopting them over the current ones [24,25].

248

249 *4.3. The future of reporting standards for child health research*

250 The need for developing standards for reporting child health research, or to develop pediatric-
251 specific extensions to existing reporting standards, such as those for the CAse REport (CARE)
252 standard [26] and Reporting Items for Practice Guidelines in Healthcare (RIGHT) guidelines [27],
253 is evident given the paucity of reporting standards that were expanded specifically for children and
254 contained items tailored to children.

255 Standards for pediatric case reports and series are especially important because many new clinical
256 findings, new therapeutic options, and extrapolations of adult research to children, are initially
257 published as case reports or series. Neonatal and pediatric case reports need to take into account
258 several unique considerations including parental consent, children's assent, drug dosage, adverse
259 reactions, and issues related to growth and development, that are not necessarily applicable for adult
260 patients [11]. However, CARE standard, offering reporting guidance for case reports, does not
261 include these pediatric-specific items [26].

262 CPGs for children also have special characteristics. Due to a lack of clinical research on children,
263 indirect evidence from adults is often used to support recommendations for children. Therefore,

CPGs should report clearly and transparently how the indirect evidence from adults has been used to make recommendations. Further, off-label prescribing of drugs is common in children [28]. However, the Reporting Items for Practice Guidelines in Healthcare (RIGHT) guidelines, designed for reporting of CPGs, did not cover these topics [27].

We encourage the reporting standard developers to strictly follow the guidance of GDHRG [13]. Efforts are particularly needed in improving the description of the consensus meeting preparation and the dissemination strategies. Although GDHRG provides a robust fundament for the methodology of developing reporting standards, it needs to be updated in the future. For example, the GDHRG working group could develop extensions of the guidance for different study types including child health research, or add pediatrics-specific items in the updated standard. In addition, a multidisciplinary expert group including methodologists should be involved in the development of any standard to increase the robustness of the development process [13,24].

Developers of reporting standards should be encouraged to promote their standards through multiple ways, such as publication in journals, conference presentations, creating dedicated websites, developing easy-to-use apps and checklists, and organizing training on the practical use of these reporting standards [13,25,29]. The developers may also consider writing a simplified version and an explanatory document of their reporting standard and translate the standard into multiple languages to increase its accessibility [13,25,29]. Journals should consider different ways to maximize the impact of reporting standards, such as by asking authors to submit completed reporting checklists and by asking peer reviewers to use these standards to guide their review [13,25,29]. Authors and peer reviewers are encouraged to use these reporting standards when they write and review the original studies [13,25,29].

In order to alleviate the problems of inadequate reporting of studies, global organizations for different study types such as CONSORT (http://www.consort-statement.org/) for randomized trials, STROBE (https://www.strobe-statement.org/index.php?id=strobe-home) for observational studies, PRISMA (http://www.prisma-statement.org/) for systematic reviews, CARE (http://www.care-

statement.org/) for case reports, and Appraisal of Guidelines, Research and Evaluation (AGREE) (https://www.agreetrust.org/) and RIGHT (http://www.right-statement.org/) for clinical practice guidelines have been established. After the establishment of these organizations, the reporting quality in the respective study types tended to improve massively [25, 29-34]. However, the reporting standards developed by these organizations are for clinical research among adults/general population, not specifically children. StaR Child Health (https://www.starchildhealth.org/) aim to develop standards for the design, conduct and reporting of clinical trials with children. However, they mainly focus on clinical trials. The pediatric-specific reporting standards for other study types, such as case reports, CPGs, economic evaluations, and qualitative research are also needed. Therefore, we call for an establishment of a global working group, RESCUE (REporting Standards strengthen Children's stUdies Explicitness), that could bring together researchers, medical journal editors, peer reviewers, developers of reporting standards, research funding bodies, and other stakeholders with a common interest in improving the reporting quality of all types of studies in children in the future. Such an organization could effectively facilitate the development and dissemination of reporting standards for child health research. Collaboration with organizations such as the United Nations International Children's Emergency Fund (UNICEF) (https://www.unicefusa.org/), EQUATOR (https://www.equator-network.org/), StaR Child Health, CONSORT, STROBE, PRISMA, AGREE, and RIGHT are encouraged.

4.4. Strengths and limitations

This is the first study to investigate the quantity, development process, and impact of reporting standards specifically developed for child health research. We included both standards that have been completed and those that are under development. We also analyzed the dissemination of the reporting standards, in a similar way to studies on standards in other fields [23,35,36]. We also investigated the items of the reporting standards for child health research and categorized them into themes, which may help to facilitate the development of reporting standards for child health studies

in the future.

Our study has also some limitations. First, we only extracted the reported information, and did not contact the authors of reporting standards still under development for further information [19,20]. Second, we did not list all reporting items but only summarized the frequently reported items into broad categories. Third, we only analyzed the endorsement of reporting standards by SCI indexed pediatric journals but did not assess their endorsement by other SCI indexed or non-SCI journals. Fourth, we did not search the gray literature to help identify the reporting standards. It is possible that we missed some reporting standards that might have been eligible for this review, and we encourage readers to notify us of any missed eligible standards.

5. Conclusions

There are very few reporting standards for child health research, and none that encompass all study designs. This limited quantity also lacks methodological quality, with considerable room for improvement in their dissemination and application. There is urgent need to develop pediatric specific standards for reporting research in children.

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Contribution

Qinyuan Li: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Visualization, Writing - original draft. Qi Zhou: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing - original draft. Ivan D. Florez, Joseph L. Mathew, Yasser Sami Amer, Janne Estill, Rosalind Louise Smyth, and Enmei Liu: Conceptualization, Methodology, Writing - review & editing. Yaolong Chen and Zhengxiu Luo: Conceptualization, Data curation, Methodology, Project administration, Resources, Supervision, Writing - review & editing.

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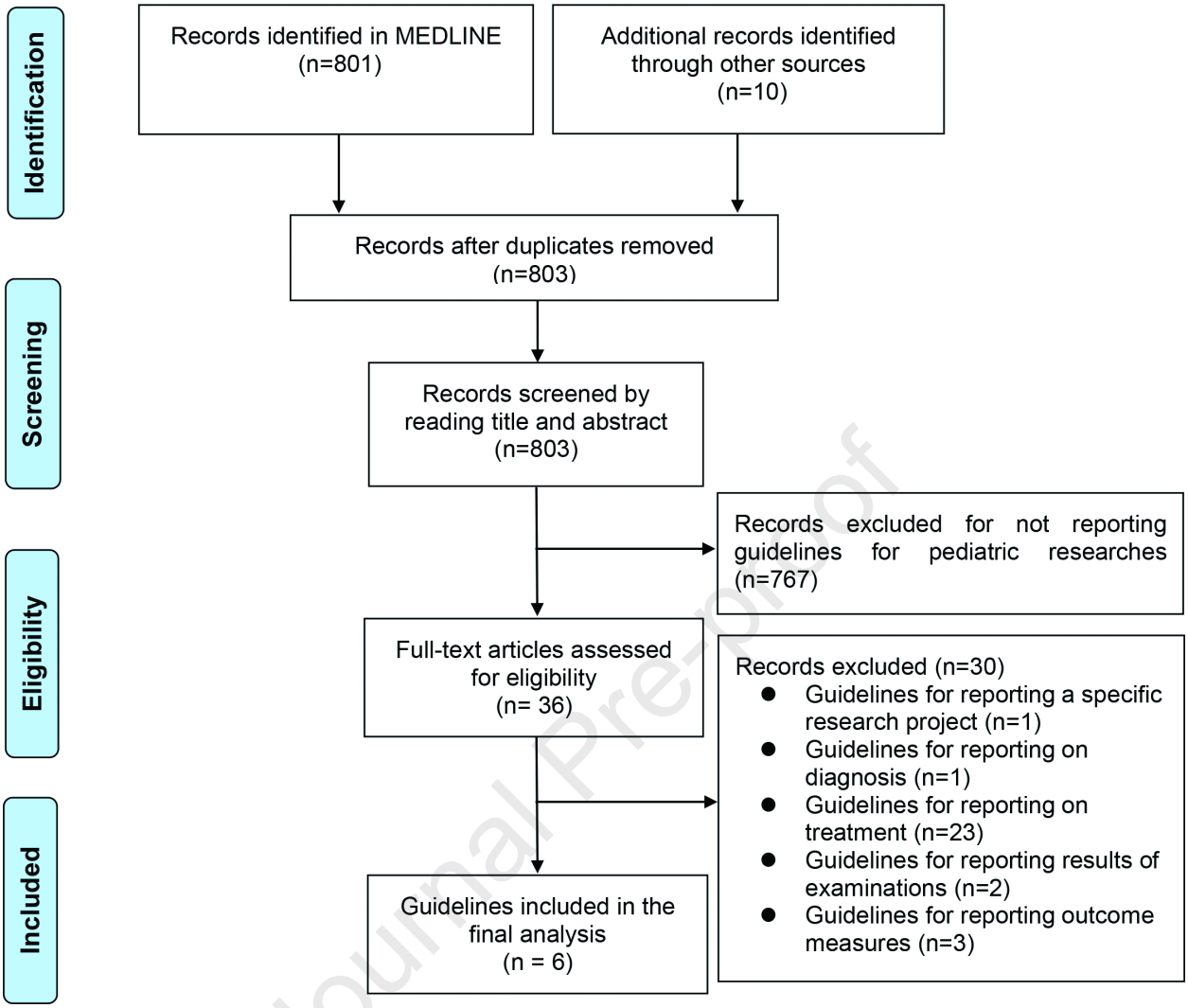
Table legends:

Table 1 Basic characteristics and dissemination of the reporting standards

Table 2 Reporting standards for different types of pediatric studies

Figure legends:

Fig. 1 Flow chart of the literature search of reporting standards for child health research



What is new?

Key findings

- There is a quantitative and qualitative paucity of well-developed reporting standards for child health research.
- The available reporting standards for child health research are poorly implemented.

What this adds to what was known?

- This is the first study to investigate the quantity, quality, and impact of reporting standards for child health research.

What is the implication and what should change now?

- Robust reporting standards for child health research should be developed and ensured implementation.

Declaration of interests

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

☐ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Author statement

Qinyuan Li: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Visualization, Writing - original draft. Qi Zhou: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing - original draft. Ivan D. Florez, Joseph L. Mathew, Yasser Sami Amer, Janne Estill, Rosalind Louise Smyth, and Enmei Liu: Conceptualization, Methodology, Writing - review & editing. Yaolong Chen and Zhengxiu Luo: Conceptualization, Data curation, Methodology, Project administration, Resources, Supervision, Writing - review & editing.